	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Iris neovascularisation A [2]*	0/114 (0%)	4/74 (5.41%)	0/110 (0%)	0/60 (0%)
Lacrimation increased A [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	4/60 (6.67%)
Macular oedema ^{A [2]} *	0/114 (0%)	0/74 (0%)	20/110 (18.18%)	0/60 (0%)
Maculopathy ^{A [2]} *	10/114 (8.77%)	0/74 (0%)	6/110 (5.45%)	0/60 (0%)
Optic disc vascular disorder A [2]*	8/114 (7.02%)	0/74 (0%)	6/110 (5.45%)	5/60 (8.33%)
Retinal exudates ^{A [2]} *	7/114 (6.14%)	0/74 (0%)	0/110 (0%)	5/60 (8.33%)
Retinal haemorrhage ^{A [1]} *	0/114 (0%)	0/74 (0%)	6/110 (5.45%)	4/60 (6.67%)
Retinal pigment epitheliopathy A [2]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	12/60 (20%)
Retinal vascular disorder ^A [2]*	6/114 (5.26%)	4/74 (5.41%)	8/110 (7.27%)	0/60 (0%)
Visual acuity reduced A [2]*	7/114 (6.14%)	12/74 (16.22%)	27/110 (24.55%)	8/60 (13.33%)
Vitreous detachment A [2]*	0/114 (0%)	5/74 (6.76%)	8/110 (7.27%)	0/60 (0%)
Vitreous floaters ^A [2]*	6/114 (5.26%)	0/74 (0%)	0/110 (0%)	0/60 (0%)
Infections and infestations				
Influenza ^A *	0/114 (0%)	0/74 (0%)	7/110 (6.36%)	0/60 (0%)
Nasopharyngitis ^A *	0/114 (0%)	4/74 (5.41%)	6/110 (5.45%)	0/60 (0%)
Upper respiratory tract infection A*	6/114 (5.26%)	0/74 (0%)	6/110 (5.45%)	0/60 (0%)
Investigations				<u> </u>
Blood pressure systolic increased A*	0/114 (0%)	0/74 (0%)	0/110 (0%)	4/60 (6.67%)

	Intravitreal Aflibercept Injection (IAI) (Baseline to Week 24)	Sham Treatment (Baseline to Week 24)	IAI to IAI (Week 24 to Week 100)	Sham Treatment to IAI (Week 24 to Week 100)
Blood urine present A*	0/114 (0%)	0/74 (0%)	0/110 (0%)	4/60 (6.67%)
Intraocular pressure increased A [1]*	0/114 (0%)	0/74 (0%)	0/110 (0%)	4/60 (6.67%)
Protein urine present A*	0/114 (0%)	0/74 (0%)	0/110 (0%)	5/60 (8.33%)
Vascular disorders				
Hypertension ^{A*}	10/114 (8.77%)	4/74 (5.41%)	13/110 (11.82%)	9/60 (15%)

^{*} Indicates events were collected by non-systematic methods.

- A Term from vocabulary, MedDRA Version 13.1
- [1] Ocular AE Fellow Eye
- [2] Ocular AE Study Eye

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Clinical Trials Administrator Organization: Regeneron Pharmaceuticals

Phone: 914 847 5385

Email: clinicaltrials@regeneron.com

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ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only
 applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in red.
- Study additions are displayed in green

Study Record Versions

Version	A	В	Submitted Date	Changes
1	0	0	·	None (earliest Version on record)
2	0	0	September 3, 2009	Contacts/Locations and Study Status

Version	Α	В	Submitted Date	Changes
3	0	0	October 7, 2009	Contacts/Locations and Study Status
4	0	0	<u>December 3, 2009</u>	Study Status
5	0	0	February 18, 2010	Contacts/Locations and Study Status
6	0	0	<u>July 2, 2010</u>	Recruitment Status, Study Status and Contacts/Locations
7	0	0	November 18, 2010	Study Status
8	0	0	February 11, 2011	Study Status and Study Design
9	0	0	<u> May 5, 2011</u>	Study Status
10	0	0	<u>May 9, 2011</u>	Study Status
11	0	0	March 28, 2012	Sponsor/Collaborators, Study Status and Contacts/Locations
12	0	®	<u>June 7, 2012</u>	Recruitment Status, Study Status
13	0	0	<u> April 16, 2013</u>	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow
Comp	270		Comparison Form	● Merged nat: ○ Side-by-Side

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Study NCT00943072

Submitted Date: June 7, 2012 (v12)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central

Retinal Vein Occlusion (CRVO)

Official Title: A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of

Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With

Macular Edema Secondary to Central Retinal Vein Occlusion

Secondary IDs:

Study Status

Record Verification: June 2012

Overall Status: Completed

Study Start: July 2009

Primary Completion: October 2010 [Actual]

Study Completion: April 2012 [Actual]

First Submitted: July 10, 2009

First Submitted that July 20, 2009

Met QC Criteria:

First Posted: July 21, 2009 [Estimate]

Certification/Extension May 9, 2011

First Submitted:

Certification/Extension May 9, 2011

First Submitted that

Met QC Criteria:

Certification/Extension May 16, 2011 [Estimate]

First Posted:

Last Update Submitted that June 7, 2012

Met QC Criteria:

Last Update Posted: June 11, 2012 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party: Sponsor

Collaborators: Bayer

Oversight --

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision

function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions --

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema

Retinal vein occlusion

CRVO

VEGF Trap-Eye

best-corrected visual acuity

Regeneron COPERNICUS

Study Design -

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 189 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures ---

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment. Week 24

Secondary Outcome Measures:

2. Visual acuity
Week 24

3. Retinal thickness by OCT Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
- Prior panretinal laser photocoagulation or macular laser photocoagulation in the study eye
- CRVO disease duration > 9 months from date of diagnosis
- Previous use of intraocular corticosteroids in the study eye or use of periocular corticosteroids in the study eye within the 3 months prior to Day 1
- Iris neovascularization, vitreous hemorrhage, traction retinal detachment, or preretinal fibrosis involving the macula in either the study eye or fellow eye

Contacts/Locations

Study Officials: Clinical Trial Management

Study Director

Regeneron Pharmaceuticals

Locations: United States, Arizona

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Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

United States, California

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Toronto, Ontario, Canada, M4N 3M5

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	Tel Aviv, Israel, 64239	j
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ClinicalTrials.gov archive

History of Changes for Study: NCT00943072

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

Latest version (submitted April 16, 2013) on ClinicalTrials.gov

- A study version is represented by a row in the table.
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Study Record Versions

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2	0	0		Contacts/Locations and Study Status

Version	A	В	Submitted Date	Changes
3	0	0	October 7, 2009	Contacts/Locations and Study Status
4	0	0	<u>December 3, 2009</u>	Study Status
5	0	0	February 18, 2010	Contacts/Locations and Study Status
6	0	0	<u>July 2, 2010</u>	Recruitment Status, Study Status and Contacts/Locations
7	0	0	November 18, 2010	Study Status
8	0	0	February 11, 2011	Study Status and Study Design
9	0	0	<u>May 5, 2011</u>	Study Status
10	0	0	<u>May 9, 2011</u>	Study Status
11	(8)	(1)	<u> March 28, 2012</u>	Sponsor/Collaborators, Study Status and Contacts/Locations
12	0	0	<u>June 7, 2012</u>	Recruitment Status, Study Status
13	0	0	<u> April 16, 2013</u>	Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics and Participant Flow
Comp	370		Comparison Form	® Merged nat: ○ Side-by-Side

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Study NCT00943072

Submitted Date: March 28, 2012 (v11)

Study Identification

Unique Protocol ID: VGFT-OD-0819

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Central

Retinal Vein Occlusion (CRVO)

Official Title: A Randomized, Double Masked, Controlled Phase 3 Study of the Efficacy, Safety, and Tolerability of

Repeated Intravitreal Administration of Vascular Endothelial Growth Factor Trap-Eye in Subjects With

Macular Edema Secondary to Central Retinal Vein Occlusion

Secondary IDs:

Study Status

Record Verification: March 2012

Overall Status: Active, not recruiting

Study Start: July 2009

Primary Completion: October 2010 [Actual]

Study Completion: April 2012 [Anticipated]

First Submitted: July 10, 2009

First Submitted that July 20, 2009

Met QC Criteria:

First Posted: July 21, 2009 [Estimate]

Certification/Extension May 9, 2011

First Submitted:

Certification/Extension May 9, 2011

First Submitted that

Met QC Criteria:

Certification/Extension May 16, 2011 [Estimate]

First Posted:

Last Update Submitted that March 28, 2012

Met QC Criteria:

Last Update Posted: March 30, 2012 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party: Sponsor

Collaborators: Bayer

Oversight -

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This is a phase 3 study to determine the efficacy of VEGF Trap-Eye injected into the eye on vision

function in subjects with macular edema as a consequence of central retinal vein occlusion.

Detailed Description:

Conditions --

Conditions: Macular Edema Secondary to Central Retinal Vein Occlusion

Keywords: Macular edema

Retinal vein occlusion

CRVO

VEGF Trap-Eye

best-corrected visual acuity

Regeneron COPERNICUS

Study Design -

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 189 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: VEGF Trap-Eye Monthly IVT injection of VEGF Trap-Eye 2.0 mg until Week 24 Primary Endpoint	Biological: VEGF Trap-Eye 2.0mg Monthly intravitreal injection out to the Week 24 Primary endpoint
Sham Comparator: Sham Monthly Sham IVT injection until Week 24 Primary Endpoint	Drug: Sham Monthly sham intravitreal injection out to Week 24 Primary Endpoint

Outcome Measures

Primary Outcome Measures:

1. The primary efficacy measure is improvement in visual acuity versus baseline after 6 months of treatment. Week 24

Secondary Outcome Measures:

2. Visual acuity
Week 24

3. Retinal thickness by OCT Week 24

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Subjects at least 18 years of age with center-involved macular edema secondary to CRVO with mean central retinal thickness ≥ 250 µm on OCT
- ETDRS best corrected visual acuity of 20/40 to 20/320 (73 to 24 letters) in the study eye

Exclusion Criteria:

- Previous treatment with anti-angiogenic drugs in the study eye (Pegaptanib sodium,anecortave acetate, bevacizumab, ranibizumab, etc.)
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Study Officials: Clinical Trial Management

Study Director

Regeneron Pharmaceuticals

Locations: United States, Arizona

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Phoenix, Arizona, United States, 85020

Tucson, Arizona, United States, 85704

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United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Ft Worth, Texas, United States, 76102

Houston, Texas, United States, 77030

San Antonio, Texas, United States, 78240

Canada, British Columbia

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Victoria, British Columbia, Canada, V8V 4X3

Canada, Nova Scotia

Halifax, Nova Scotia, Canada, B3H 2Y9

Canada, Ontario

London, Ontario, Canada, N6A 4V2

Mississauga, Ontario, Canada, L4W 1W9

Toronto, Ontario, Canada, M4N 3M5

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I	ndia, Karnataka	
	Bangalore, Karnataka, India, 560010	
I	ndia, West Bengal	
	Kolkata, West Bengal, India, 700073	
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	Petah Tikva, Israel, 49100	
	Rehovot, Israel, 76100	
	Tel Aviv, Israel, 64239	j
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ARVO Annual Meeting Abstract | April 2010

DA VINCI: DME and VEGF Trap-Eye: INvestigation of Clinical Impact: Phase 2 Study in Patients With Diabetic Macular Edema (DME)

J. C. Major, Jr.; D. M. Brown; DA VINCI Study Group

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science April 2010, Vol.51, 6426. doi:

Abstract

Purpose: : VEGF Trap-Eye (VTE) is a recombinant fusion protein consisting of VEGF binding domains of human VEGF receptors 1 and 2 fused to the Fc domain of human IgG1. This phase 2 study assesses the efficacy and safety of intravitreal VTE vs. laser photocoagulation in DME at the 24-week primary endpoint.

Methods: : DA VINCI is a multi-center, randomized, active-controlled Phase 2 clinical study, designed to assess safety and efficacy of 4 dose/dose intervals of VTE in comparison to laser photocoagulation. 221 patients were randomized (219 treated) to 1 of the following treatment arms: 0.5mg q4wks, 2mg q4wks, 2mg q8wks, 2mg prn or laser photocoagulation. The primary endpoint is the mean change from baseline in BCVA at week 24. Secondary endpoints include changes in retinal thickness (CRT) on OCT and central retinal sensitivity. Central retinal sensitivity was measured using the Nidek MP-1 microperimeter with values corresponding to the OCT central subfield.

Results: : At 6 months, the mean change in BCVA for each VTE arm ranged from +8.5 to +11.4 letters and was statistically significantly better than the mean change in BCVA in the laser arm (+2.5 letters; p<0.01). No significant difference was noted among the VTE arms. Anatomical effects (mean change in CRT) for each VTE arm ranged from -127µm to -195µm and were significantly greater than the mean change in CRT for the laser arm (-68µm; p<0.01). VTE arms had a mean gain in central retinal sensitivity ranging from 1.5 to 4.1dB, while the laser arm had a mean decrease of -0.4dB. VTE was generally well-tolerated, and APOTEX V: REGENERON IPR2022-01524

REGENERON EXHIBIT 2008 PAGE 398

adverse events (AEs) reported were those typically associated with intravitreal injections or underlying disease. There were two cases of endophthalmitis, one culture negative and one positive for Staphylococcus epidermidis. The most frequent AEs reported in the VTE arm include conjunctival hemorrhage, eye pain, floaters, ocular hyperemia, and increased IOP.

Conclusions: : In this patient population at the 24-week primary endpoint, intravitreal VTE was generally well tolerated and produced significant improvements from baseline in visual acuity and retinal thickness and a trend toward improvement in central retinal sensitivity as compared to laser photocoagulation.

Clinical Trial: : www.clinicaltrials.gov NCT00789477

Keywords: diabetic retinopathy • clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials • vascular endothelial growth factor

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Randomized, Double-masked, Activecontrolled Phase 3 Trial Of The Efficacy And Safety Of Intravitreal VEGF Trap-Eye In Wet AMD: One-year Results Of The View-1 Study

Quan D. Nguyen; Jeffery Heier; David Brown; Allen Ho; Peter Kaiser; Robert Vitti; VIEW 1 Study Group

+ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science April 2011, Vol.52, 3073. doi:

Abstract

Purpose: : To evaluate the efficacy and safety of VEGF Trap-Eye (VTE) vs ranibizumab in patients with choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD).

Methods: : In this non-inferiority study conducted in N. America, 1217 patients were randomized to VTE 0.5 mg every month (4 weeks; 0.5q4wk), 2 mg every month (2q4wk), 2 mg every 2 months (8 weeks; 2q8wk) following 3 monthly doses, or ranibizumab 0.5 mg every month (Rq4wk). The proportion of patients avoiding moderate vision loss (patients losing <15 ETDRS letters) from baseline to week 52 was the primary endpoint. Secondary endpoints included the mean change from baseline in best corrected visual acuity by an ETDRS letter score.

Results: : The proportions of patients maintaining vision at 52 weeks were 94.4%, 95.9%, 95.1%, and 95.1% for Rq4wk, 0.5q4wk, 2q4wk, and 2q8wk, respectively. All VTE groups were non-inferior (non-inferiority margin of 10%) to ranibizumab. Mean improvements from baseline in ETDRS letter score for Rq4wk, 0.5q4wk, 2q4wk and 2q8wk were 8.1, 6.9, 10.9, and 7.9 letters, respectively. 2q4wk was significantly better (P<0.01) than Rq4wk; differences between the other VTE groups and Rq4wk were non-significant. The incidences of ocular treatment emergent adverse events (AEs) were similar across all treatments, with

the most frequent AEs associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular AEs were conjunctival hemorrhage, macular degeneration, eye pain, vitreous detachment, and vitreous floaters.

Conclusions: : Dosing monthly or every two months with VEGF Trap-Eye was non-inferior to monthly ranibizumab. VEGF Trap-Eye was generally well tolerated and had a generally favorable safety profile. Based upon these results, VEGF Trap-Eye may provide convenient management of wet AMD with predictable, every two month dosing.

Clinical Trial: : http://www.clinicaltrials.gov NCT00509795

Keywords: age-related macular degeneration • vascular endothelial growth factor • clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials

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ARVO Annual Meeting Abstract | May 2006

Results of a Phase I, Dose–Escalation, Safety, Tolerability, and Bioactivity Study of Intravitreous VEGF Trap in Patients With Neovascular Age–Related Macular Degeneration

Q.D. Nguyen; S.M. Shah; D. Browning; P. Sonkin; H. Hudson; K. Chu; K. Rich; A. Lucas; J. Cedarbaum; P.A. Campochiaro

→ Author Affiliations & Notes

Investigative Ophthalmology & Visual Science May 2006, Vol.47, 2144. doi:

Abstract

Purpose: : To determine the safety, tolerability, maximum tolerated dose, and bioactivity of intravitreous injection of VEGF Trap in patients with neovascular age-related macular degeneration (AMD).

Methods: : Patients with neovascular AMD who had lesions ≤ 12 disc areas in size with at least 50% active choroidal neovascularization and best–corrected visual acuity (VA) of ≤ 20/40 (ETDRS protocol) received a single intravitreous injection of VEGF Trap at day 0. Safety assessments included eye examinations, vital signs, and laboratory tests (hematology, chemistry, urinalysis, levels of VEGF Trap and antibodies directed against VEGF Trap). Measures of bioactivity were changes from baseline in VA, excess foveal thickness and excess macular volume determined by optical coherence tomography, and lesion size and leakage determined by fluorescein angiography. Patients were monitored for 12 weeks following VEGF Trap administration.

Results: : Three patients at each of 4 dose levels, 0.05, 0.15, 0.5, and 1 mg, have been enrolled. There have been no serious adverse events and no identifiable intraocular inflammation. Excess foveal thickness and excess macular volume decreased rapidly after

injection of VEGF Trap. At day 29, excess foveal thickness was reduced by at least 70% in 75% of patients and VA was stable or improved in 75% of patients.

Conclusions: : Intravitreous injection of up to 1 mg of VEGF Trap has been well-tolerated. Although the number of patients in each cohort is small, preliminary evidence of bioactivity in patients with neovascular AMD has been seen. Higher doses are being investigated to identify the ideal dose of VEGF Trap for a phase II trial in patients with neovascular AMD.

Keywords: macula/fovea • choroid: neovascularization • clinical (human) or epidemiologic studies: treatment/prevention assessment/controlled clinical trials

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Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-K

Filing Date: 2/27/2008

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal year ended December 31, 2007

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 0-19034

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction of incorporation or organization)

13-3444607

(I.R.S. Employer Identification No)

777 Old Saw Mill River Road, Tarrytown, New York

(Address of principal executive offices)

10591-6707

(Zip code)

(914) 347-7000 (Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None Securities registered pursuant to Section 12(g) of the Act:

Title of each class

Common Stock — par value \$.001 per share

Name of each exchange on which registered

Nasdag Global Market

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 🗹 No 🗆

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes 🗆 No 🗹

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes \square No \square

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer \square

Accelerated filer

Non-accelerated filer

Smaller reporting company \square

 $\label{thm:company} \mbox{(Do not check if a smaller reporting company)} \mbox{ Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes \square No $\square$$

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$1,112,577,000 computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2007, the last trading day of the registrant's most recently completed second fiscal quarter.

The number of shares outstanding of each of the registrant's classes of common stock as of February 15, 2008:

Class of Common Stock

Class A Stock, \$.001 par value Common Stock, \$.001 par value Number of Shares

2,257,698 76.727.047

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2007 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 59 to 61 of this filing.

PART I

Item I. Business

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We currently have four clinical development programs, including three late-stage clinical programs: ARCALYSTTM(rilonacept; also known as IL-1Trap) in various inflammatory indications, aflibercept (VEGF Trap) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. Aflibercept is being developed in oncology in collaboration with the sanofi-aventis Group. The VEGF Trap-Eye is being developed in collaboration with Bayer HealthCare LLC. Our fourth clinical development program is REGN88, an antibody to the Interleukin-6 receptor (IL-6R) that is being developed with sanofi-aventis. REGN88 entered clinical development in patients with rheumatoid arthritis in the fourth quarter of 2007. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the VelocImmune platform which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we moved our first antibody product candidate (REGN88) into clinical trials in the fourth quarter of 2007. We plan to advance two new antibody product candidates into clinical development in 2008 and an additional two to three antibody product candidates each year thereafter beginning in 2009. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Late-Stage Clinical Programs:

1. ARCALYSTTM — Inflammatory Diseases

ARCALYSTTM(rilonacept; also known as IL-1Trap) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating ARCALYSTTM in a number of diseases and disorders where IL-1 may play an important role, including a group of

rare diseases called Cryopyrin-Associated Periodic Syndromes (CAPS) and other diseases associated with inflammation.

In November 2007, we announced that we received notification from the U.S. Food and Drug Administration (FDA) that the action date for the FDA's priority review of the Biologics License Application (BLA) for ARCALYSTTM in CAPS had been extended three months to February 29, 2008. In August 2007, the FDA granted priority review status to the BLA for ARCALYSTTM for the long-term treatment of CAPS. The FDA previously granted Orphan Drug status and Fast Track designation to ARCALYSTTM for the treatment of CAPS. In July 2007, ARCALYSTTM also received Orphan Drug designation in the European Union for the treatment of CAPS.

CAPS represents a group of rare inherited auto-inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). CAPS also includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYSTIM has not been studied, and is not expected to be indicated, for the treatment of NOMID. The syndromes included in CAPS are characterized by spontaneous, systemic inflammation and are termed auto-inflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as CIASI) which encodes a protein named cryopyrin. Currently, there are no medicines approved for the treatment of CAPS.

We have initiated a Phase 2 safety and efficacy trial of ARCALYSTTM in the prevention of gout flares induced by the initiation of uric acid-lowering drug therapy used to control the disease. We previously reported positive results from an exploratory proof of concept study of ARCALYSTTM in ten patients with chronic active gout. In those patients, treatment with ARCALYSTTM demonstrated a statistically significant reduction in patient pain scores in the single-blind, placebocontrolled study. Mean patients' pain scores, the key symptom measure in persistent gout, were reduced 41% (p=0.025) during the first two weeks of active treatment and reduced 56% (p<0.004) after six weeks of active treatment. In this study, in which safety was the primary endpoint measure, treatment with ARCALYSTTM was generally well-tolerated. We are also evaluating the potential use of ARCALYSTTM in other indications in which IL-1 may play a role.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

Under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our ARCALYSTTM product candidate currently in clinical development.

2. Aflibercept (VEGF Trap) — Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PIGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis began the first four trials of our global Phase 3 development program in the second half of 2007. One trial is evaluating aflibercept in combination with docetaxel/prednisone in patients with first line metastatic androgen

2

independent prostate cancer. A second trial is evaluating aflibercept in combination with docetaxel in patients with second line metastatic non-small cell lung cancer. The third Phase 3 trial is evaluating aflibercept in first-line metastatic pancreatic cancer in combination with gemcitabine. The fourth Phase 3 trial is evaluating aflibercept in second-line metastatic colorectal cancer in combination with FOLFIRI (Folinic Acid (leucovorin), 5-fluorouracil, and irinotecan). In all of these trials, aflibercept is being combined with the current standard of chemotherapy care for the stated development stage of the cancer type.

The collaboration is conducting a number of other trials in the global development program for affibercept. Five safety and tolerability studies of affibercept in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the Phase 3 clinical program. Sanofi-aventis has also expanded the development program to Japan, where they are conducting a Phase 1 safety and tolerability study in combination with another investigational agent in patients with advanced solid malignancies.

The collaboration is also conducting Phase 2 single-agent studies of affibercept in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). The AOC and NSCLA trials are fully enrolled and ongoing. The SMA trial is approximately 50% enrolled and continues to enroll patients. In 2004, the FDA granted Fast Track designation to affibercept for the treatment of SMA.

In addition, more than 10 studies are currently underway or scheduled to begin that are being conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

The first registration submission to a regulatory agency for aflibercept is possible as early as 2008, potentially as third line treatment as a single agent in advanced ovarian cancer (AOC) or in AOC patients with SMA. However, in order for our ongoing Phase 2 study in AOC to be sufficient to support such a submission, we believe that the final unblinded results of the study would have to demonstrate a more robust response rate than that reported in the interim analysis of blinded data from the study presented in June 2007 at the annual meeting of the American Society of Clinical Oncology (ASCO).

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). Vascular Endothelial Growth Factor (VEGF) is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth, and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin® (a trademark of Genentech, Inc.) is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

Aflibercept Collaboration with the sanofi-aventis Group

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaboration on the development of aflibercept to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share copromotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400.0 million in milestone

payments upon receipt of specified marketing approvals. This total includes up to \$360.0 million in milestone payments related to receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union. Another \$40.0 million of milestone payments relate to receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

3. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 3 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and has completed a small pilot study in patients with diabetic macular edema (DME).

In the clinical development program for the VEGF Trap-Eye, we and Bayer HealthCare have initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. This first trial, known as VIEW 1 (YEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), is comparing the VEGF Trap-Eye and Genentech, Inc.'s Lucentis® (ranibizumab), an anti-angiogenic agent approved for use in wet AMD. This Phase 3 trial is evaluating dosing intervals of four and eight weeks for the VEGF Trap-Eye compared with ranibizumab dosed according to its label every four weeks. We and Bayer HealthCare plan to initiate a second Phase 3 trial in wet AMD in 2008. This second trial will be conducted primarily in the European Union and other parts of the world outside the U.S.

In October 2007, we and Bayer HealthCare announced positive results from the full analysis of the primary 12-week endpoint of a Phase 2 study evaluating the VEGF Trap-Eye in wet AMD. The VEGF Trap-Eye met the primary study endpoint of a statistically significant reduction in retinal thickness, a measure of disease activity, after 12 weeks of treatment compared with baseline (all five dose groups combined, mean decrease of 119 microns, p<0.0001). The mean change from baseline in visual acuity, a key secondary endpoint of the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.7 letters, p<0.0001). Preliminary analyses at 16 weeks showed that the VEGF Trap-Eye, dosed monthly, achieved a mean gain in visual acuity of 9.3 to 10 letters (for the 0.5 and 2 mg dose groups, respectively). In additional exploratory analyses, the VEGF Trap-Eye, dosed monthly, reduced the proportion of patients with vision of 20/200 or worse (a generally accepted definition for legal blindness) from 14.3% at baseline to 1.6% at week 16; the proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) was likewise increased from 19.0% at baseline to 49.2% at 16 weeks. These findings were presented at the Retina Society Conference in September 2007.

We and Bayer HealthCare are also developing the VEGF Trap-Eye in DME. In May 2007, at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), the companies reported results from a small pilot study of the VEGF Trap-Eye in patients with DME. In the study, the VEGF Trap-Eye was well tolerated and demonstrated activity in five patients, with decreases in retinal thickness and improvement in visual acuity.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis® (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is

characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of the VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic eye diseases, and other diseases and disorders. Bayer HealthCare will market the VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of the VEGF Trap-Eye. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare. In 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in wet AMD, and can earn up to \$90.0 million in additional development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135.0 million in sales milestones if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

Antibody Research Technologies and Development Program:

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of secreted proteins can have clinical benefit.

Regeneron scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the "Trap" technology, was used to generate our current clinical pipeline, including aflibercept, the VEGF Trap-Eye, and ARCALYSTTM. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates.

Regeneron scientists also have discovered and developed a new technology for designing protein therapeutics that facilitates the discovery and production of fully human monoclonal antibodies. We call our technology *VelocImmune*® and, as described below, we believe that it is an improved way of generating a wide variety of high affinity, therapeutic, fully human monoclonal antibodies.

VelocImmune® (Human Monoclonal Antibodies)

We have developed a novel mouse technology platform, called *VelocImmune*, for producing fully human monoclonal antibodies. The *VelocImmune* mouse platform was generated by exploiting our *VelociGene* technology platform (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. The *VelocImmune* mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. *VelocImmune* and our related technologies offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the *VelocImmune* technology to produce our next generation of drug

candidates for preclinical development and are exploring possible additional licensing or collaborative arrangements with third parties related to VelocImmune and related technologies.

Antibody Collaboration with the sanofi-aventis Group

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The first therapeutic antibody to enter clinical development under the collaboration, REGN88, is an antibody to the Interleukin-6 receptor (IL-6R), which has started clinical trials in rheumatoid arthritis. The second is expected to be an antibody to Delta-like ligand-4 (Dll4) which is currently scheduled to commence clinical development in mid-2008. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis will fund up to \$475.0 million of our research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against these targets through December 31, 2012. Sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis funding drug candidate development costs up front. We are responsible for reimbursing sanofi-aventis for half of the total development costs it paid for all collaboration products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250.0 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

License Agreement with AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable, up-front payment to us. AstraZeneca is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a midsingle-digit royalty on any future sales of antibody products discovered by AstraZeneca using our VelocImmune technology.

License Agreement with Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable, up-front payment to us. Astellas is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

VelociGene® and VelociMouse™ (Target Validation)

Our VelociGene platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene and accelerates the production of knock-out and transgenic

expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker is substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body, during normal body functioning, as well as in disease processes. For the optimization of pre-clinical development and toxicology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

The *VelociMouse* technology also allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, Regeneron's *VelociMice* are suitable for direct phenotyping or other studies.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We use our VelociGene technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our VelociGene technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse ES cells which can be used to produce knockout mice. These materials will be made widely available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, we are entitled to receive a minimum of \$17.9 million over a five-year period. We will receive another \$1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Cell Line Expression Technologies

Many proteins that are of potential pharmaceutical value are proteins which are "secreted" from the cells into the bloodstream. Examples of secreted proteins include growth factors (such as insulin and growth hormone) and antibodies. Current technologies for the isolation of cells engineered to produce high levels of secreted proteins are both laborious and time consuming. We have developed enabling platforms for the high-throughput, rapid generation of high-producing cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

Research Programs:

Oncology and Angiogenesis

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In 1994, we discovered a second family of angiogenic growth factors, termed Angiopoietins, and we have received patents covering members of this family. Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. Angiopoietins are being evaluated in preclinical research by us and our academic collaborators. Our preclinical studies have revealed that VEGF and Angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Manipulation of both VEGF and Angiopoietins seems to be of value in blocking vessel growth. We have research programs focusing on several targets in the areas of oncology and angiogenesis.

Tumors depend on the growth of new blood vessels (a process called "angiogenesis") to support their continued growth. Therapies that block tumor angiogenesis, specifically those that block VEGF, the key initiator of

tumor angiogenesis, recently have been validated in human cancer patients. However, anti-VEGF approaches do not work in all patients, and many tumors can become resistant to such therapies

In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like Ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. We plan in mid-2008 to commence Phase 1 clinical development of a fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune* technology.

Metabolic and Related Diseases

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in integrating peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program in this area encompasses the study of peripheral (hormonal) regulators of food intake and metabolism in health and disease. We have identified several targets in these therapeutic areas and are evaluating potential antibodies to evaluate in preclinical studies.

Muscle Diseases and Disorders

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle research program is currently focused on conducting in vivo and in vitro experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. We have several molecules in late stage research and are evaluating them for possible further development.

Other Therapeutic Areas

We also have research programs focusing on ophthalmology, inflammatory and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Manufacturing

In 1993, we purchased our 104,000 square foot Rensselaer, New York manufacturing facility, and in 2003 completed a 19,500 square foot expansion of this facility. This facility is used to manufacture therapeutic candidates for our own preclinical and clinical studies. We also used the facility to manufacture a product for Merck & Co., Inc. under a contract that expired in October 2006. In July 2002, we leased 75,000 square feet in a building near our Rensselaer facility which we have used primarily for the manufacture of Traps and for warehouse space. In June 2007, we exercised a purchase option on this building, which totals 272,000 square feet (including the 75,000 square feet we already leased), and completed the purchase of this property in October 2007. At December 31, 2007, we employed 207 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2007.

Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the good manufacturing practice (GMP) regulations of the health authority. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies. If our manufacturing facilities fail

to comply with FDA and other regulatory requirements, we will be required to suspend manufacturing. This would likely have a material adverse effect on our financial condition, results of operations, and cash flow.

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies (see "Risk Factors — Even if our product candidates are approved for marketing their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability."). Our competitors include Genentech, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Abbott Laboratories, sanofi-aventis, Merck, Amgen Inc., Roche, and others. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also be significant if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, one or more of our competitors may achieve product commercialization earlier than we do or obtain patent protection that dominates or adversely affects our activities. Our ability to compete will depend on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

ARCALYSTTM. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex Corporation), Remicade® (Centocor, Inc.), and Humira® (Abbott) and the IL-1 receptor antagonist Kineret (Amgen), and other marketed therapies, makes it difficult to successfully develop and commercialize ARCALYSTTM. Even if ARCALYSTTM is ever approved for sale, it will be difficult for our drug to compete against these FDA approved drugs because doctors and patients will have significant experience using these effective medicines. Moreover, there are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company, Novartis, and Xoma Ltd. are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over ARCALYSTTM. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYSTTM.

Aflibercept and VEGF Trap-Eye. Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to our VEGF Trap in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate.

In particular, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and a number of pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Pfizer, and Imclone Systems Incorporated. Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that

modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The National Eye Institute plans to initiate a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. Avastin is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other areas.

REGN88. We are developing REGN88 for the treatment of rheumatoid arthritis as part of our global, strategic collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humita® (Abbott), and other marketed therapies makes it difficult to successfully develop and commercialize REGN88. REGN88 is a human monoclonal antibody targeting the interleukin-6 receptor. Roche is developing an antibody against the interleukin-6 (IL-6) receptor. Roche's antibody has completed Phase 3 clinical trials and is the subject of a filed Biologics License Application with the FDA for the treatment of rheumatoid arthritis. Roche's IL-6 receptor antibody, other clinical candidates in development, and the drugs on the market to treat rheumatoid arthritis could offer competitive advantages over REGN88. This could delay or impair our ability to successfully develop and commercialize REGN88.

Other Areas. Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics that are the focus of other research or development programs we are now conducting. These competitors include Amgen and Genentech, as well as many others. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

If a competitor announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, the announcement may have an adverse effect on our operations or future prospects or on the market price of our Common Stock.

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties or other consideration for use of their technology. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see "Risk Factors — We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights."). Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. We are the nonexclusive licensee of a number of additional U.S. patents and patent applications. We also rely upon trade secrets, know-how, and continuing technological innovation in an effort to develop and maintain our competitive position. We or our licensors or collaborators have filed patent applications on various products and processes relating to our product candidates as well as other technologies and inventions in the United States and in certain foreign countries. We intend to file additional patent applications, when appropriate, relating to improvements in

these technologies and other specific products and processes. We plan to aggressively prosecute, enforce, and defend our patents and other proprietary technology.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process patent applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of our product candidates (see "Risk Factors — If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them."). All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase 3, large-scale clinical trials are conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a Biologics License Application, or BLA, for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

Various federal, state, and foreign statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, and other aspects of pharmaceutical product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

In addition to the foregoing, our present and future business will be subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations.

Business Segments

Through 2006, our operations were managed in two business segments: research and development, and contract manufacturing. The research and development segment includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. It also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and our grant from the NIH, and (ii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology. The contract manufacturing segment included all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006 and 2005, the Company manufactured a product for Merck under a contract that expired in October 2006. For financial information about these segments, see Note 20, "Segment Information", beginning on page F-36 in our Financial Statements. Due to the expiration of our manufacturing agreement with Merck, beginning in 2007, we only have a research and development business segment.

Employees

As of December 31, 2007, we had 682 full-time employees, of whom 107 held a Ph.D. or M.D. degree or both. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the Securities and Exchange Commission, or SEC, under the Securities Exchange Act of 1934, or the Exchange Act. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, the SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding issuers, including Regeneron, that file electronically with the SEC. The public can obtain any documents that we file with the SEC at http://www.sec.gov.

We also make available free of charge on or through our Internet website (http://www.regn.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair

our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through December 31, 2007, we had a cumulative loss of \$793.2 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt that is scheduled to mature in 2008.

We have \$200.0 million of convertible debt that, unless converted to shares of our Common Stock, will mature in October 2008. Our debt obligations could require us to use a significant portion of our cash to pay principal and interest on our debt.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are studying our lead product candidates, affibercept, VEGF Trap-Eye, and ARCALYST TM , in a wide variety of indications. We are studying affibercept in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and ARCALYST TM in a variety of systemic inflammatory disorders.

Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are being, or are planned to be, studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of ARCALYSTTM in different diseases after a Phase 2 trial using lower doses of ARCALYSTTM in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

The data from the Phase 3 clinical program for ARCALYSTTM in CAPS (Cryopyrin-Associated Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of ARCALYSTTM.

We submitted a completed BLA to the FDA for ARCALYSTIM in CAPS in the second quarter of 2007. However, the efficacy and safety data from the Phase 3 clinical program included in the BLA may be inadequate to support approval for commercialization of ARCALYSTIM. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance.

Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for ARCALYSTTM, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize ARCALYSTTM profitably.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYSTIM in those countries.

Serious complications or side effects have occurred, and may continue to occur, in clinical trials of some of our product candidates which could lead to delay or discontinuation of development and severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These serious and potentially life-threatening risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, intestinal perforation, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These include side effects that we have not yet seen in our trials such as heart attack and stroke. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

It is possible that safety or tolerability concerns may arise as we continue to test ARCALYSTTM in patients with inflammatory diseases and disorders. Like cytokine antagonists such as Kineret® (Amgen), Enbrel® (Immunex), and Remicade® (Centocor), ARCALYSTTM affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYSTTM may interfere with the body's ability to fight infections. Treatment with Kineret® (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious infections have been reported in patients taking ARCALYSTTM. One subject with adult Still's diseases in a study of ARCALYSTTM developed an infection in his elbow with mycobacterium intracellulare. The patient was on chronic glucocorticoid treatment for Still's disease. The infection occurred after an intraarticular glucocorticoid injection into the elbow and subsequent local exposure to a suspected source of mycobacteria. One patient with polymayalgia rheumatica in another study developed bronchitis/sinusitis, which resulted in hospitalization. One patient in an open-label study of ARCALYSTTM in CAPS developed sinusitis and streptococcus pneumoniae meningitis and subsequently died. In addition, patients given infusions of ARCALYSTTM have developed hypersensitivity reactions or infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of ARCALYSTTM.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Of the clinical study subjects who

received ARCALYSTTM for rheumatoid arthritis and other indications, fewer than 5% of patients developed antibodies and no side effects related to antibodies were observed. Using a very sensitive test, approximately 40% of the patients in the CAPS pivotal study tested positive at least once for low levels of antibodies to ARCALYSTTM. Again, no side effects related to antibodies were observed and there were no observed effects on drug efficacy or drug levels. However, it is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, ARCALYSTTM, and REGN88, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune* technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that affibercept or the VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover affibercept or the VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell affibercept or the VEGF Trap-Eye, which

represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell aflibercept or the VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

In December 2003, we entered into a non-exclusive license agreement with Cellectis Inc. that granted us certain rights in a family of patents relating to homologous recombination. Cellectis now claims that agreements we entered into relating to our *VelocImmune* mice with AstraZeneca, Astellas, and sanofi-aventis are outside of the scope of our license from Cellectis. We disagree with Cellectis' position and are in discussions with Cellectis regarding this matter. If we are not able to resolve this dispute, Cellectis may commence a lawsuit against us and our *VelocImmune* licensees alleging infringement of Cellectis' patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending

application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated rules and listing standards covering a variety of subjects. Compliance with these rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2007, which report is included in this Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to \$475.0 million between 2008 and 2012 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. Sanofi-aventis may terminate the collaboration for our material breach or, in the case of the discovery agreement, if certain minimal criteria for the discovery program are not achieved by December 31, 2010. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activi

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business, operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for the VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, operations and financial condition, and our ability to develop and commercialize the VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of the VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional finding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of the VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the manufacture, development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may

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be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with commercial capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin® (Genentech), and their extensive, ongoing clinical development plan for Avastin® (Genentech) in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute recently has received funding for a Phase 3 trial to compare Lucentis® (Genentech) to Avastin® (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis® (Genentech) and the potential off-label use of Avastin® (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis® (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin® (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST™. This is one of the reasons we discontinued the development of ARCALYST™ in adult rheumatoid arthritis. In addition, even if ARCALYST™ is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST™, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has commenced advanced clinical testing of its IL-1 antibody in Muckle-Wells Syndrome, which is part of the group of rare genetic diseases called CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYSTTM. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYSTTM. For example, we may find it difficult to enroll patients in clinical trials for ARCALYSTTM if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications

We are developing ARCALYSTTM for the treatment of a group of rare diseases associated with mutations in the NLRP3 gene. These rare genetic disorders affect a small group of people, estimated to be in the hundreds. There may be too few patients with these genetic disorders to profitably commercialize ARCALYSTTM in this indication.

We are developing REGN88 for the treatment of rheumatoid arthritis. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott), and other marketed therapies makes it more difficult to successfully develop and commercialize REGN88. REGN88 is a human monoclonal antibody targeting the interleukin-6 receptor. Roche is developing an antibody against the interleukin-6 (IL-6) receptor. Roche's antibody has completed Phase 3 clinical trials and is the subject of a filed Biologics License Application with the FDA. Roche's IL-6 receptor antibody, other clinical candidates in development, and drugs now or in the future on the market to treat rheumatoid arthritis could offer competitive advantages over REGN88. This could delay or impair our ability to successfully develop and commercialize REGN88.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We are seeking approval to market ARCALYSTTM for the treatment of a group of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYSTTM. Physicians may not prescribe ARCALYSTTM and CAPS patients may not be able to afford ARCALYSTTM if third party payers do not agree to reimburse the cost of ARCALYSTTM therapy and this would adversely affect our ability to commercialize ARCALYSTTM profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including ARCALYSTTM, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- · progress, delays, or adverse results in clinical trials;
- · announcement of technological innovations or product candidates by us or competitors;
- · fluctuations in our operating results;
- · public concern as to the safety or effectiveness of our product candidates;
- · developments in our relationship with collaborative partners;
- · developments in the biotechnology industry or in government regulation of healthcare;
- · large sales of our common stock by our executive officers, directors, or significant shareholders;
- · arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of December 31, 2007, our seven largest shareholders beneficially owned 54.0% of our outstanding shares of Common

Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of December 31, 2007. As of December 31, 2007, sanofiaventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 19.3% of the shares of Common Stock then outstanding. Under our investor agreement with sanofiaventis, sanofiaventis may not sell these shares until December 20, 2012 except under limited circumstances and subject to earlier termination rights of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofiaventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofiaventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2007, holders of Class A Stock held 22.8% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of December 31, 2007:

- our current executive officers and directors beneficially owned 12.6% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2007, and 27.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2007; and
- our seven largest shareholders beneficially owned 54.0% of our outstanding shares of Common Stock, assuming, in the case of Leonard S.
 Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of December 31, 2007. In addition, these seven shareholders held 58.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of December 31, 2007.

Pursuant to an investor agreement, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take

other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- · a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of the Company's Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our chief executive officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. We currently lease approximately 232,000 square feet of laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, we entered into a new operating lease agreement for approximately 221,000 square feet of laboratory and office space at the Company's current Tarrytown location. The new lease includes approximately 27,000 square feet that we currently occupy (the "retained facilities") and approximately 194,000 square feet to be located in new facilities that are under construction and expected to be completed in mid-2009. In October 2007, we amended the December 2006 operating lease agreement to increase the amount of new space we will lease from approximately 194,000 square feet to approximately 230,000 square feet, for an amended total under the new lease of approximately 257,000 square feet. The term of the lease is expected to commence in mid-2008 and will expire approximately 16 years later. Under the new lease we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides

for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In November 2007 we entered into a new operating sublease for approximately 10,000 square feet of office space in Tarrytown, New York. The lease expires in September 2009 and we have the option to extend the term for two additional terms of three months each.

We own a facility in Rensselaer, New York, consisting of two buildings totaling approximately 123,500 square feet of research, manufacturing, office, and warehouse space. In June 2007, we exercised a purchase option on a 272,000 square foot building in Rensselaer, New York. Prior to the purchase, which was completed in October 2007, the Company leased approximately 75,000 square feet of manufacturing, office, and warehouse space in that building.

The following table summarizes the information regarding our current property leases:

			Current Monthly	
	Square		Base Rental	Renewal Option
Location	Footage	Expiration	Charges (1)	Available
Tarrytown (2)	205,000 Ju	ne, 2009 (3)	\$ 311,000	None
Tarrytown (2)		ne, 2024 (3)		Three 5-year terms
Tarrytown	27,000 Ju	ne, 2024 (3)	\$ 54,000	Three 5-year terms
Tarrytown (4)	10,000 Se	ptember, 2009	\$ 22,000	Two 3-month terms

- (1) Excludes additional rental charges for utilities, taxes, and operating expenses, as defined.
- (2) Upon completion of the new facilities, as described above, we will release the 205,000 square feet of space in our current facility and take over 230,000 square feet in the newly constructed buildings.
- (3) Estimated based upon expected completion of our new facilities, as described above.
- (4) Relates to sublease in Tarrytown, New York as described above.

We believe that our existing owned and leased facilities are adequate for ongoing, research, development, manufacturing, and administrative activities.

In the future, we may lease, operate, or purchase additional facilities in which to conduct expanded research and development activities and manufacturing and commercial operations.

Item 3. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of our security holders during the last quarter of the fiscal year ended December 31, 2007.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Our Common Stock is quoted on The NASDAQ Stock Market under the symbol "REGN." Our Class A Stock, par value \$.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The NASDAQ Stock Market:

	High	Low
2006		
First Quarter	\$ 18.00	\$ 14.35
Second Quarter	12.60	10.97
Third Quarter	17.00	10.88
Fourth Quarter	24,85	15,27
2007		
First Quarter		\$ 17.87
Second Quarter	28.74	17.55
Third Quarter	21.78	13,55
Fourth Quarter	24.90	16.77

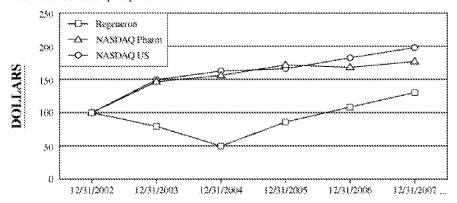
As of February 15, 2008, there were 515 shareholders of record of our Common Stock and 42 shareholders of record of our Class A Stock.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

The information under the heading "Equity Compensation Plan Information" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Report on Form 10-K.

STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) The Nasdaq Pharmaceuticals Stocks Index and (ii) The Nasdaq Stock Market (U.S.) Index for the period from December 31, 2002 through December 31, 2007. The comparison assumes that \$100 was invested on December 31, 2002 in our Common Stock and in each of the foregoing indices. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices. The historical stock price performance of our Common Stock shown in the graph below is not necessarily indicative of future stock price performance.



	12/31/2002	12/31/2003	12/31/2004	12/31/2005	12/31/2006	12/31/2007
Regeneron	\$100.00	\$ 79.47	\$ 49.76	\$ 85.90	\$108.43	\$130.47
Nasdaq Pharm	100,00	146.59	156,13	171.93	168,29	176.97
Nasdaq US	100.00	149.52	162.72	166.18	182.57	197.98

Item 6. Selected Financial Data

The selected financial data set forth below for the years ended December 31, 2007, 2006, and 2005 and at December 31, 2007 and 2006 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2004 and 2003 and at December 31, 2005, 2004, and 2003 are derived from our audited financial statements not included in this report.

		Year Ended December 31,				
	2007	2006	2005	2004	2003	
		(In thou	sands, except per sh	are data)		
Statement of Operations Data Revenues						
Contract research and development Research progress payments	\$ 96,603	\$ 51,136	\$ 52,447	\$ 113,157 42,770	\$ 47,366	
Contract manufacturing Technology licensing	28,421	12,311	13,746	18,090	10,131	
83 0	125,024	63,447	66,193	174,017	57,497	
Expenses						
Research and development	201,613	137,064	155,581	136,095	136,024	
Contract manufacturing General and administrative	37.865	8,146 25. 8 92	9,557 25.476	15,214 17,062	6,676 14,78 5	
Ceneral and administrative	239,478	171,102	190,614	168,371	157,485	
Income (loss) from operations	(114,454)	(107,655)	(124,421)	5,646	(99,988)	
	(114,424)	(101,020)	(124,441)	3,040	(22,200)	
Other income (expense) Other contract income			30,640	42,750		
Investment income	20,897	16,548	10,381	5,478	4,462	
Interest expense	(12,043)	(12,043)	(12,046)	(12,175)	(11,932)	
	8,854	4,505	28,975	36,053	(7,470)	
Net income (loss) before cumulative effect of a change in accounting principle	(105,600)	(103,150)	(95,446)	41,699	(107,458)	
Cumulative effect of adopting Statement of Accounting Standards No. 123R	NOTOKOTOK.		X			
("SFAS 123R") Net income (loss)	\$ (105,600)	<u>813</u> \$ (102,337)	\$ (95,446)	\$ 41,699	\$ (107,458)	
	<u>\$ (103,000)</u>	<u>\$ (192,337)</u>	<u> </u>	<u>5 41,099</u>	<u> </u>	
Net income (loss) per share, basic: Net income (loss) before cumulative effect of a change in accounting						
principle	\$ (1.59)	\$ (1.78)	\$ (1.71)	\$ 0.75	\$ (2.13)	
Cumulative effect of adopting SFAS 123R	ere and the second	0.01	and the second s			
Net income (loss)	\$ (1.59)	\$ (1.77)	\$ (1.71)	\$ 0.75	\$ (2.13)	
Net income (loss) per share, diluted	\$ (1.59)	\$ (1.77)	\$ (1.71)	\$ 0.74	\$ (2.13)	
			At December 31,			
	2007	2006	2005	2004	2003	
			(In thousands)			
Balance Sheet Data						
Cash, cash equivalents, restricted cash, marketable securities, and restricted	th 047 070	# 522.050	m 216.654	d 240.012	m 2//5//	
marketable securities (current and non-current) Total assets	\$ 846,279 936,258	\$ 522,859 5 8 5,090	\$ 316,654 423,501	\$ 348,912 473,108	\$ 366,566 479,555	
Notes payable — current portion	200,000	702,020	723,29I	T13,100	T18422	
Notes payable — long-term portion		200,000	200,000	200,000	200,000	
Stockholders' equity	460,267	216,624	114,002	182,543	137,643	

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

We are a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We currently have four clinical development programs, including three late-stage clinical programs: ARCALYST** (rilonacept; also known as IL-1 Trap) in various inflammatory indications, aflibercept (VEGF Trap) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. Aflibercept is being developed in oncology in collaboration with sanofi-aventis. The VEGF Trap-Eye is being developed in collaboration with Bayer HealthCare LLC. Our fourth clinical development program is REGN88, an antibody to the Interleukin-6 receptor (IL-6R) that entered clinical development in patients with rheumatoid arthritis in the fourth quarter of 2007. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and we may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through December 31, 2007, we had a cumulative loss of \$793.2 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and ARCALYSTTM; advance new product candidates into clinical development from our existing research programs utilizing our technology for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

As a company that does not expect to be profitable over the next several years, management of cash flow is extremely important. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. We are reimbursed for some of these research and development activities by our collaborators. Our principal sources of cash to-date have been from sales of common equity and convertible debt and from funding from our collaborators in the form of up-front payments, research progress payments, and payments for our research and development activities.

In 2007, our research and development expenses totaled \$201.6 million. In 2008, we expect these expenses to increase substantially as we (i) expand our research and preclinical and clinical development activities in connection with our new antibody collaboration with sanofi-aventis, (ii) expand our Phase 3 VEGF Trap-Eye clinical program and our ARCALYSTTM and aflibercept clinical programs, and (iii) increase our research and development headcount. Due to our new antibody collaboration with sanofi-aventis, we expect a greater proportion of our research and development expenses to be funded by our collaborators in 2008 than in 2007.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2007 was 627 compared with 573 in 2006 and 696 in 2005. In 2007 our average headcount increased primarily to support our expanded development programs for the VEGF Trap-Eye and ARCALYSTTM and our plans to move our first antibody candidate into clinical trials. In 2006, our average headcount decreased primarily as a result of reductions

made in the fourth quarter of 2005 and mid-year in 2006. These workforce reductions were associated with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in October 2006. In 2008, we expect our average headcount to increase to approximately 825-875 primarily to support the expansion of our research and development activities as described above, especially in connection with our new antibody collaboration with sanofi-aventis.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2007 and plans for 2008 are as follows:

Product Candidate	2007 Events	2008 Events/Plans
ARCALYST™ (rilonacept; also known as IL-1 Trap)	• Completed the 24-week open-label safety extension phase of the Phase 3 trial in CAPS	Receive FDA review decision on BLA submission for CAPS (expected at the end of February 2008)
	FDA accepted BLA submission for CAPS	- If marketing approval is obtained, launch ARCALYST $^{\mbox{\tiny TM}}$ commercially in CAPS
	 Granted Orphan Drug designation in CAPS in European Union 	Evaluate ARCALYST™ in certain other disease indications in which IL-1 may play an important role
	• Reported positive results in exploratory proof-of-concept study in patients with chronic active gout	in milet 12 1 may play an important total
	 Initiated Phase 2 trial evaluating safety and efficacy of ARCALYST™ in preventing gout-induced flares in patients initiating allopurinol therapy 	
Aflibercept (VEGF Trap — Oncology)	Sanofi-aventis initiated four Phase 3 trials of aflibercept in combination with standard chemotherapy regimens	• Sanofi-aventis to initiate a fifth Phase 3 study of aflibercept in combination with standard chemotherapy regimen
	NCI/CTEP initiated 10 studies of aflibercept	 Report final data from Phase 2 single-agent trials in advanced ovarian cancer and in non-small cell lung
	 Reported interim results from Phase 2 single-agent trials in advanced ovarian cancer and in non-small cell lung 	adenocarcinoma
	adenocarcinoma	Complete enrollment of Phase 2 single-agent study in symptomatic malignant ascites (SMA)
	 Initiated Japanese Phase 1 trial of affibercept in combination with another investigational agent in patients with solid malignancies 	Report interim data from the SMA Phase 2 trial
	with some manghancies	NCI/CTEP to begin to report data from trials
		NCI/CTEP to initiate additional exploratory safety and efficacy studies
VEGF Trap-Eye (intravitreal injection)	• Initiated first Phase 3 trial in wet AMD in patients in the U.S. and Canada	• Initiate second Phase 3 trial in wet AMD in the European Union and certain other countries around the world
	 Reported positive primary endpoint results and preliminary extended treatment results of Phase 2 trial in wet AMD 	Explore additional eye disease indications
	• Reported positive results in Phase 1 trial in DME	

Product Candidat
Antibodies

2007 Events

Entered global, strategic collaboration agreement with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies

· Initiated Phase 1 trial for REGN88 in rheumatoid arthritis

2008 Events/Plans

- · Initiate Phase 1 trial for the Dll4 antibody in oncology
- Report data for Phase 1 trial of REGN88 in rheumatoid arthritis
- Advance a third antibody candidate into clinical development

Collaborations

Our current collaboration agreements with sanofi-aventis and Bayer HealthCare, and our expired agreement with The Procter & Gamble Company, are summarized below.

The sanofi-aventis Group

Aflibercept

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. Sanofi-aventis made a non-refundable, up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for \$45.0 million

In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In connection with this amendment, sanofi-aventis made a \$25.0 million non-refundable payment to us.

In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a \$25.0 million non-refundable, up-front payment to us, which was received in January 2006. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept. We may also receive up to \$400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union. Another \$40.0 million of milestone payments relate to receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

We have agreed to manufacture clinical supplies of aflibercept at our plant in Rensselaer, New York. Sanofi-aventis has agreed to be responsible for providing commercial scale manufacturing capacity for aflibercept.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. Since inception of the collaboration through December 31, 2007, we and sanofi-aventis have incurred \$306.8 million in agreed upon development expenses related to the aflibercept program. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of aflibercept development expenses will terminate and we will retain all rights to aflibercept.

Antibodies

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The first therapeutic antibody to enter clinical development under the collaboration, REGN88, is an antibody to the Interleukin-6 receptor (IL-6R), which has started clinical trials in rheumatoid arthritis. The second is expected to be an antibody to Delta-like ligand-4 (Dll4), which is currently slated to enter clinical development in mid-2008

The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis will fund up to \$475.0 million of our research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against such targets through December 31, 2012, subject to specified funding limits of \$75.0 million for the period from the collaboration's inception through December 31, 2008, and \$100.0 million annually in each the next four years. The discovery agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate (called Shared Phase 3 Trial Costs) will be shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of \$0.7 million as of December 31, 2007) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the license agreement, we will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250.0 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, optout of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party and, in the case of the discovery agreement, a

termination right for sanofi-aventis under certain circumstances, including if certain minimal criteria for the discovery program are not achieved. Prior to December 31, 2012, sanofi-aventis has the right to terminate the discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

In December 2007, we sold sanofi-aventis 12 million newly issued, unregistered shares of Common Stock at an aggregate cash price of \$312.0 million, or \$26.00 per share of Common Stock. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with us. Under the investor agreement, sanofi-aventis has three demand rights to require us to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the license and collaboration agreement and the existing collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept, sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Sanofi-aventis has also agreed not to dispose of any shares of Common Stock that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2012, subject to certain limited exceptions. Following December 20, 2012, sanofi-aventis will be permitted to sell shares of Common Stock (i) in a registered underwritten public offering undertaken pursuant to the demand registration rights granted to sanofi- aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or more of the outstanding shares of Common Stock and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by our Board of Directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of our voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by our Board of Directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Shares, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

Bayer HealthCare LLC

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, the VEGF Trap-Eye. Under the terms of the agreement, Bayer HealthCare made a non-refundable, up-front payment to us of \$75.0 million. In August 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of the VEGF Trap-Eye in wet AMD, and are eligible to receive up to \$90.0 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. We are also eligible to receive up to an additional \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$25.4 million at December 31, 2007) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. Within the United States, we are responsible for any future commercialization of the VEGF Trap-Eye and retain exclusive rights to any future profits from commercialization.

Agreed upon development expenses incurred by both companies in 2007 under a global development plan were shared as follows: The first \$50.0 million was shared equally and we were solely responsible for up to the next \$40.0 million. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

In 2008, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$70.0 million will be shared equally, we are solely responsible for up to the next \$30.0 million, and over \$100.0 million will be shared equally. In 2009 and thereafter, all development expenses will be shared equally. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

Bayer HealthCare has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue for financial statement purposes. In the fourth quarter of 2007, we and Bayer HealthCare approved a global development plan for the VEGF Trap-Eye in wet AMD. The plan includes estimated development steps, timelines, and costs, as well as the projected responsibilities of each of the companies. In addition, in the fourth quarter of 2007, we and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for the VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, we determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's VEGF Trap-Eye development expenses, and the financial statement classifications and periods in which past and future payments from Bayer HealthCare (including the \$75.0 million up-front payment and development and regulatory milestone payments) and cost-sharing of VEGF Trap-Eye development expenses will be recognized in our Statement of Operations.

The Procter & Gamble Company

In May 1997, we entered into a long-term collaboration with Procter & Gamble to discover, develop, and commercialize pharmaceutical products, and Procter & Gamble agreed to provide funding in support of our research efforts related to the collaboration. In accordance with the companies' collaboration agreement, Procter & Gamble was obligated to fund our research on therapeutic areas that were of particular interest to Procter & Gamble through December 2005, with no further research obligations by either party thereafter. Under the collaboration agreement, research support from Procter & Gamble was \$2.5 million per quarter, plus annual adjustments for inflation, through December 2005.

In June 2005, we and Procter & Gamble amended our collaboration agreement. Under the terms of the modified agreement, the two companies agreed that the research activities being pursued under the collaboration agreement were completed on June 30, 2005, six months prior to the December 31, 2005 expiration date in the collaboration agreement. Procter & Gamble agreed to make a one-time \$5.6 million payment to Regeneron, which was received in July 2005, and to fund our research under the agreement through the second quarter of 2005. We agreed to pay Procter & Gamble approximately \$1.0 million to acquire certain capital equipment owned by Procter & Gamble and located at our facilities. We and Procter & Gamble divided rights to research programs and preclinical product candidates that were developed during the research term of the collaboration. Neither party has the right to participate in the development or commercialization of the other party's product candidates. We are entitled to receive royalties based on any future product sales of a Procter & Gamble preclinical candidate arising from the collaboration, and Procter & Gamble is entitled to receive a small royalty on any sales of a single Regeneron candidate that is not currently being developed. Neither party is entitled to receive either royalties or other payments based on any other products arising from the collaboration.

Other Agreements

AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable, up-front payment to us. AstraZeneca is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a midsingle-digit royalty on any future sales of antibody products discovered by AstraZeneca using our Velocimmune technology.

Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable, up-front payment to us. Astellas is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

National Institutes of Health

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We use our VelociGene® technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our VelociGene technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse embryonic stem cells (ES cells) which can be used to produce knockout mice. These materials will be made widely available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, we are entitled to receive a minimum of \$17.9 million over a five-year period. We will receive another \$1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. (SFAS) 123, Accounting for Stock-Based Compensation, using the modified prospective method as described in SFAS 148, Accounting for Stock-Based Compensation — Transition and Disclosure. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date. Prior to the adoption of the fair value method, we accounted for stock-based compensation to employees under the intrinsic value method of accounting set forth in Accounting Principles Board Opinion No. (APB) 25, Accounting for Stock Issued to Employees, and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period operating results were not restated.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, Share-Based Payment, which is a revision of SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005, and prior to our adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that were not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by \$0.8 million and is included in our operating results for the year ended December 31, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on our loss from operations, net loss, and net loss per share for the year ended December 31, 2006 was not significant, and there was no impact to our cash flows for the year ended December 31, 2006.

Non-cash stock-based employee compensation expense related to stock option awards (Stock Option Expense) recognized in operating expenses totaled \$28.0 million, \$18.4 million, and \$19.9 million for the years ended December 31, 2007, 2006, and 2005, respectively. In addition, for the year ended December 31, 2005, \$0.1 million of Stock Option Expense was capitalized into inventory. As of December 31, 2007, there was \$60.6 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.8 years. In addition, there are 723,092 options which are unvested as of December 31, 2007 and would become vested upon our products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2.7 million and will begin to be recognized only if, and when, these options' performance condition is considered to be probable of attainment.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average values of the assumptions we used in computing the fair value of option grants during 2007, 2006, and 2005:

	2007	2006	2005
Expected volatility	53%	67%	71%
Expected lives from grant date	5.6 years	6.5 years	5.9 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	3.60%	4.51%	4.16%

Changes in any of these assumptions may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

Results of Operations

Years Ended December 31, 2007 and 2006

Net Loss:

Regeneron reported a net loss of \$105.6 million, or \$1.59 per share (basic and diluted), for the year ended December 31, 2007, compared to a net loss of \$102.3 million, or \$1.77 per share (basic and diluted) for 2006.

Revenues:

Revenues for the years ended December 31, 2007 and 2006 consist of the following:

	2007	2006
	(In mil	lions)
Contract research & development revenue		
Sanofi-aventis	\$ 51./	\$ 47.8
Bayer HealthCare	35.9	
Other	9.0	3.3
Total contract research & development revenue	96.6	51.1
Contract manufacturing revenue		12.3
Technology licensing revenue		
Total revenue	\$ 125.0	<u>\$ 63.4</u>

We recognize revenue from sanofi-aventis, in connection with our aflibercept and antibody collaborations, in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104) and FASB Emerging Issue Task Force Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21) (see "Critical Accounting Policies and Significant Judgments and Estimates"). We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable, up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration. Non-refundable, up-front payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance periods based on the specific terms of the collaboration agreements, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

	Decem	ber 31,
Sanofi-aventis Contract Research & Development Revenue	2007	2006
	(In mi	llions)
Affibercept:		
Regeneron expense reimbursement	\$ 38.3	\$ 36.4
Regeneron expense reimbursement Recognition of deferred revenue related to up-front payments	8.8	11.4
Total aflibercept	47.1	47.8
Antibody		
Regeneron expense reimbursement	3.7	
Regeneron expense reimbursement Recognition of deferred revenue related to up-front payments	0,9	
Total antibody	4.6	
Total sanofi-aventis contract research & development revenue	<u>\$ 51.7</u>	<u>\$ 47.8</u>

Sanofi-aventis' reimbursement of Regeneron's affibercept expenses increased in 2007 compared to 2006, primarily due to higher preclinical and clinical development costs. Recognition of deferred revenue related to sanofi-aventis' up-front affibercept payments decreased in 2007 from 2006 due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of December 31, 2007, \$61.2 million

of the original \$105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2007, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of \$3.0 million under the collaboration's discovery agreement and \$0.7 million of REGN88 development costs under the license agreement. Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' \$85.0 million up-front payment. As of December 31, 2007, \$84.1 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. The \$75.0 million up-front licensing payment and the \$20.0 million milestone payment (which was received in August 2007 and not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue over the related estimated performance period in accordance with SAB 104 and EITF 00-21. In periods when we recognize VEGF Trap-Eye development expenses that we incur under the collaboration, we also recognize, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expenses, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, when we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, we recognized, as a cumulative catch-up, contract research and development revenue of \$35.9 million, consisting of (i) \$15.9 million related to the \$75.0 million up-front licensing payment and the \$20.0 million milestone payment, and (ii) \$20.0 million related to the portion of our 2007 VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. As of December 31, 2007, \$79.1 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$5.5 million and \$0.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue in 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in 2006 was \$1.2 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the \$20.0 million non-refundable, up-front payment, which we received in February 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the \$20.0 million non-refundable, up-front payment, which we received in April 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. For the year ended December 31, 2007, we recognized \$28.4 million of technology licensing revenue related to these agreements.

Expenses:

Total operating expenses increased to \$239.5 million in 2007 from \$171.1 million in 2006. Our average employee headcount in 2007 increased to 627 from 573 in 2006, primarily to support our expanded development programs for the VEGF Trap-Eye and ARCALYSTM and our activities to move our first antibody candidate (REGN88) into clinical trials. Operating expenses in 2007 and 2006 include a total of \$28.0 million and \$18.4 million of Stock Option Expense, respectively, as detailed below:

	For the Year Ended December 31, 2007			
	Expenses Before			
	Inclusion of Stock	Stock Option	Expenses as	
Expenses	Option Expense	Expense	Reported	
		(In millions)		
Research and development	\$ 185.5	\$ 16.1	\$ 201.6	
General and administrative	26.0	11.9	37.9	
Total operating expenses	\$ 211.5	\$ 28.0	\$ 239.5	

	For the Year Ended December 31, 2006			
	Expenses Before			
	Inclusion of Stock	Stock Option	Expenses as	
Expenses	Option Expense	Expense	Reported	
		(In millions)		
Research and development	\$ 126.9	\$ 10.2	\$ 137.1	
Contract manufacturing	7.8	0.3	8.1	
General and administrative	18.0	7.9	25.9	
Total operating expenses	\$ 152.7	\$ 18.4	\$ 171.1	

The increase in total Stock Option Expense in 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

$Research\ and\ Development\ Expenses:$

Research and development expenses increased to \$201.6 million for the year ended December 31, 2007 from \$137.1 million for 2006. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2007 and 2006:

	Year !	Ended Decembe	er 31,
Research and Development Expenses	2007	2006 (In millions)	Increase (Decrease)
Payroll and benefits (1)	\$ 60.6	\$ 44.8	\$ 15.8
Clinical trial expenses	37.6	14.9	22.7
Clinical manufacturing costs (2)	47.0	39.2	7.8
Research and preclinical development costs	23.2	17.5	5.7
Occupancy and other operating costs	22.6	20.7	1.9
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	10.6		10.6
Total research and development	\$ 201.6	<u>\$ 137.1</u>	<u>\$ 64.5</u>

- (1) Includes \$13.1 million and \$8.4 million of Stock Option Expense for the years ended December 31, 2007 and 2006, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies,

- depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$3.0 million and \$1.8 million of Stock Option Expense for the years ended December 31, 2007 and 2006, respectively.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of their VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, when we commenced recognizing cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, we recognized as additional research and development expense a cumulative catch-up of \$10.6 million of VEGF Trap-Eye development expenses that we were obligated to reimburse to Bayer HealthCare.

Payroll and benefits increased primarily due to the increase in employee headcount, as described above, annual compensation increases effective in 2007, and higher Stock Option Expense, as described above. Clinical trial expenses increased due primarily to higher costs related to our Phase 3 study of the VEGF Trap-Eye in wet AMD, which we initiated in the third quarter of 2007, and our ongoing Phase 1 and 2 studies of the VEGF Trap-Eye in wet AMD. Clinical manufacturing costs increased due primarily to higher costs related to manufacturing ARCALYSTTM and preclinical and clinical supplies of REGN88, which were partly offset by lower costs related to manufacturing aflibercept and the VEGF Trap-Eye. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs, including REGN88, and utilization of our proprietary technology platforms. Occupancy and other operating costs primarily increased in connection with higher Company headcount and to support our expanded research and development activities.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Stock Option Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Aflibercept 33.7 30.7 3.0		Y	ear Ended Dec	ember 31,
ARCALYST 38.1 \$ 29.6 \$ 8.5 Aflibercept 33.7 30.7 3.0				Increase
ARCALYST ¹⁵⁴ \$ 38.1 \$ 29.6 \$ 8.5 Aflibercept 33.7 30.7 3.0	Project Costs	2007	2006	(Decrease)
ARCALYSTM			(In millio	ens)
	ARCALYST ¹⁶	\$ 38,1	\$ 29.6	\$ 8.5
	Aflibercept	33.7	30.7	3.0
VEGF Trap-Eye 33.7 21.9 31.8	VEGF Trap-Eye	53.7	21.9	31.8
REGN88 13.6 13.6	REGN88	13.6		13.6
Other research programs & unallocated costs 62.5 54.9 7.6	Other research programs & unallocated costs	62.5	54.9	7.6
Total research and development expenses \$ 201.6 \$ 137.1 \$ 64.5	Total research and development expenses	\$ 201.6	\$ 137.1	\$ 64.5

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in

which we will be developing a product. For example, we, and our collaborators, where applicable, continue to explore further development of ARCALYST TM , aflibercept, and the VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows. In the second quarter of 2007, we submitted a BLA for ARCALYSTTM for the treatment of CAPS, a group of rare genetic disorders. We cannot predict whether or when the commercialization of ARCALYSTTM in CAPS will result in a material net cash inflow to us.

Contract Manufacturing Expenses:

We had no contract manufacturing expenses in 2007 compared to \$8.1 million in 2006, due to the expiration of our manufacturing agreement with Merck in October 2006.

General and Administrative Expenses:

General and administrative expenses increased to \$37.9 million in 2007 from \$25.9 million in the same period of 2006 primarily due to (i) higher Stock Option Expense, as described above, (ii) higher compensation expense principally due to annual increases effective in 2007 and higher administrative headcount to support our expanded research and development activities, (iii) recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) market research and related expenses incurred in 2007 in connection with our ARCALYSTTM and VEGF Trap-Eye programs.

Other Income and Expense:

Investment income increased to \$20.9 million in 2007 from \$16.5 million in 2006, resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). This increase was partly offset by a \$5.9 million charge in 2007 related to marketable securities which we considered to be other than temporarily impaired in value. In the second half of 2007, deterioration in the credit quality of marketable securities from two issuers has subjected us to the risk of being unable to recover their full principal value, which totals \$14.0 million. Interest expense was \$12.0 million in 2007 and 2006. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

Years Ended December 31, 2006 and 2005

Net Loss:

Regeneron reported a net loss of \$102.3 million, or \$1.77 per share (basic and diluted), for the year ended December 31, 2006, compared to a net loss of \$95.4 million, or \$1.71 per (basic and diluted) for 2005.

Revenues:

Revenues for the years ended December 31, 2006 and 2005 consist of the following:

	2006	2005
	(In mi	llions)
Contract research & development revenue		
Sanofi-aventis	\$ 47.8	\$ 43.4
Procter & Gamble		6.0
Other	3.3	3.1
Total contract research & development revenue	51.1	52.5
Contract manufacturing revenue	12.3	13.7
Total revenue	\$ 63.4	\$ 66.2

We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

	December	r 31,
Sanofi-aventis Contract Research & Development Revenue	2006	2005
	(In milli	ons)
Regeneron expense reimbursement	\$ 36.4	\$ 33.9
Recognition of deferred revenue related to up-front payments	11.4	9.5
Total	<u>\$ 47.8</u>	\$ 43.4

Sanofi-aventis' reimbursement of Regeneron aflibercept expenses increased in 2006 compared to 2005, primarily due to higher costs related to our manufacture of aflibercept clinical supplies during the first half of 2006. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in 2006 from the same period in 2005, due to our receipt in January 2006 of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' aflibercept collaboration to include Japan. As of December 31, 2006, \$70.0 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract research and development revenue earned from Procter & Gamble decreased in 2006 compared to 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005, as described above under "Collaborations — The Procter & Gamble Company." Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

In October 2006 we entered into our VEGF Trap-Eye collaboration with Bayer HealthCare. In the fourth quarter of 2007, we determined the appropriate accounting policy for payments from Bayer HealthCare and, in 2007, commenced recognizing previously deferred payments in our Statement of Operations through a cumulative catch-up, as described above. Accordingly, there was no contract research and development revenue earned from Bayer HealthCare in 2006. As of December 31, 2006, the \$75.0 million up-front payment received from Bayer HealthCare in October 2006 was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$0.5 million recognized in connection with our NIH Grant, as described above.

Contract manufacturing revenue relates to our long-term agreement with Merck, which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer facility. Contract manufacturing revenue decreased in 2006 compared to 2005 due to a decrease in product shipments to Merck in 2006. Revenue and the related

manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in 2006 and 2005 were \$1.2 million and \$1.4 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck and there was no Merck deferred revenue as of the end of 2006.

Expenses:

Total operating expenses decreased to \$171.1 million in 2006 from \$190.6 million in 2005 due, in part, to our lower headcount, as described above. (Also see "Severance Costs" below.)

Operating expenses in 2006 and 2005 include a total of \$18.4 million and \$19.9 million of Stock Option Expense, respectively, as detailed below:

	For the Year Ended December 31, 2006			2006		
Expenses	Inclusio	es Before n of Stock		Option	Expe	enses as
- 1	Ортіоп	Expense	Ex	pense	Ke	portea
Research and development	\$	126.9	\$	10.2	\$	137.1
Contract manufacturing		7.8		0.3		8.1
General and administrative		18,0		7,9		2 5 .9
Total operating expenses	\$	152.7	\$	18.4	\$	171.1
		For the Year	Ended De	cember 31, 2	:005	

	For the Year	r Ended December 31, 2	005
	Expenses Before		
	Inclusion of Stock	Stock Option	Expenses as
Expenses	Option Expense	Expense	Reported
Research and development	\$ 143.7	\$ 11.9	\$ 155.6
Contract manufacturing	9.2	0.4	9.6
General and administrative	17.8	7.6	25.4
Total operating expenses	\$ 170.7	\$ 19.9	\$ 190.6

Research and Development Expenses:

Research and development expenses decreased to \$137.1 million for the year ended December 31, 2006 from \$155.6 million for 2005. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2006 and 2005:

	Year	Ended Decemb	oer 31,
			Increase
Research and Development Expenses	2006	2005	(Decrease)
Payroll and benefits (1)	\$ 44.8	\$ 53,6	\$ (8,8)
Clinical trial expenses	14.9	18.2	(3.3)
Clinical manufacturing costs (2)	39,2	41.6	(2.4)
Research and preclinical development costs	17.5	19.2	(1.7)
Occupancy and other operating costs	20,7	23.0	(2.3)
Total research and development	\$ 137.1	\$ 155.6	<u>\$ (18.5)</u>

⁽¹⁾ Includes \$8.4 million and \$10.5 million of Stock Option Expense for the years ended December 31, 2006 and 2005, respectively.

⁽²⁾ Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$1.8 million and \$1.4 million of Stock Option Expense for the years ended December 31, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in 2006. In addition, payroll and benefits in 2006 and 2005 included \$0.4 million and \$2.2 million, respectively, of severance costs associated with our workforce reduction plan that we initiated in October 2005. Clinical trial expenses decreased primarily due to lower ARCALYST™ costs in 2006 as we discontinued clinical development of ARCALYST™ in adult rheumatoid arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased because of lower costs in 2006 related to manufacturing ARCALYST™ clinical supplies, which were partially offset by higher costs related to manufacturing aflibercept clinical supplies. Research and preclinical development costs decreased principally because of lower costs for general research supplies in 2006 as we narrowed the focus of our research and development efforts due, in part, to the expiration of our collaboration with Procter & Gamble in June 2005, as described above. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount and lower costs for utilities associated with our leased research facilities in Tarrytown, New York.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, non-cash stock-based employee compensation expense related to stock option awards, and manufacturing and other costs related to activities that benefit multiple projects. Our estimates of research and development costs for clinical development programs are shown below:

	Yea	r Ended Decembe	r 31,
			Increase
Project Costs	2006	2005	(Decrease)
		(In millions)	
ARCALYSTIM	\$ 29.6	\$ 57.2	\$ (27.6)
Aflibercept	30.7	27.8	2.9
VEGF Trap-Eye	21.9	9,3	12,6
Other research programs & unallocated costs	54.9	61.3	(6.4)
Total research and development expenses	<u>\$ 137.1</u>	<u>\$ 155.6</u>	\$ (18.5)

For the reasons described above under "Research and Development Expenses" for the years ended December 31, 2007 and 2006, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased to \$8.1 million in 2006, compared to \$9.6 million in 2005, primarily because we shipped less product to Merck in 2006.

$General\ and\ Administrative\ Expenses:$

General and administrative expenses increased to \$25.9 million in 2006 from \$25.4 million in the same period of 2005 as higher legal expenses related to general corporate matters and higher patent-and trademark-related costs were partly offset by lower professional fees for internal audit and other administrative advisory services and lower administrative facility costs.

Other Income and Expense:

In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble made a one-time \$5.6 million payment to us, which we recognized as other contract income in 2005. In January 2005, we and sanofi-aventis amended our collaboration agreement to exclude rights to

develop and commercialize affibercept for intraocular delivery to the eye. In connection with the amendment, sanofi-aventis made a one-time \$25.0 million payment to us, which we recognized as other contract income in 2005.

Investment income increased to \$16.5 million in 2006 from \$10.4 million in 2005, due primarily to higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock), as well as higher effective interest rates on investment securities in 2006. Interest expense was \$12.0 million in 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, payments earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Bayer HealthCare, and Merck, and investment income.

Years Ended December 31, 2007 and 2006

At December 31, 2007, we had \$846.3 million in cash, cash equivalents, restricted cash and marketable securities compared with \$522.9 million at December 31, 2006. In connection with our non-exclusive license agreements with AstraZeneca and Astellas, as described above, AstraZeneca and Astellas each made an up-front payment to us of \$20.0 million in February and April 2007, respectively. In August 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in our Phase 3 study of the VEGF Trap-Eye in wet AMD. In December 2007, we received an \$85.0 million upfront payment in connection with our new collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. Sanofi-aventis also purchased 12 million newly issued, unregistered shares of our Common Stock in December 2007 for gross proceeds to us of \$312.0 million.

Cash Provided by Operations:

Net cash provided by operations was \$27.4 million in 2007 and \$23.1 million in 2006, and net cash used in operations was \$30.3 million in 2005. Our net losses of \$105.6 million in 2007, \$102.3 million in 2006, and \$95.4 million in 2005 included \$28.1 million, \$18.7 million, and \$21.9 million, respectively, of non-cash stock-based employee compensation costs, consisting primarily of Stock Option Expense. Our net losses also included depreciation and amortization of \$11.5 million, \$14.6 million, and \$15.5 million in 2007, 2006, and 2005, respectively, and a \$5.9 million non-cash charge in 2007 related to marketable securities which we considered to be other than temporarily impaired in value.

In 2007, end-of-year accounts receivable increased by \$10.8 million compared to 2006 due to higher receivable balances related to our collaborations with sanofiaventis and Bayer HealthCare. Also, prepaid expenses and other assets increased \$9.6 million at December 31, 2007 compared to end-of-year 2006 due primarily to higher prepaid clinical trial costs. At December 31, 2007, our deferred revenue balances increased by \$89.8 million, compared to end-of-year 2006, due primarily to (i) the \$85.0 million up-front payment received from sanofi-aventis, (ii) the \$20.0 million milestone payment from Bayer HealthCare which was deemed to be non-substantive and fully deferred, and (iii) the two \$20.0 million up-front payments received from each of AstraZeneca and Astellas, all as described above, partly offset by 2007 revenue recognition, principally from these deferred payments and prior year deferred payments from sanofi-aventis and Bayer HealthCare, in our Statement of Operations. Accounts payable, accrued expenses, and other liabilities increased \$18.2 million at December 31, 2007 compared to end-of-year 2006 primarily due to a \$4.9 million cost-sharing payment due to Bayer Healthcare in connection with the companies' VEGF Trap-Eye collaboration and higher accruals in 2007 for payroll costs and clinical-related expenses.

In 2006, end-of-year accounts receivable balances decreased by \$29.0 million compared to 2005, due to the January 2006 receipt of a \$25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, in connection with an amendment to our affibercept collaboration to include Japan, and lower amounts due from sanofi aventis for reimbursement of affibercept development expenses. Also, our deferred revenue balances at December 31, 2006 increased by \$60.8 million compared to end-of-year 2005, due primarily to the October 2006 \$75.0 million up-front payment from Bayer, as described above, partly offset by 2006 revenue

recognition from deferred sanofi-aventis up-front payments. In 2005, our deferred revenue balances increased by \$14.5 million compared to 2004, due primarily to the January 2006 \$25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, partly offset by 2005 revenue recognition from deferred sanofi-aventis up-front payments.

The majority of our cash expenditures in 2007, 2006, and 2005 were to fund research and development, primarily related to our clinical programs and, in 2007, our preclinical human monoclonal antibody programs. In 2007, 2006, and 2005, we made two semi-annual interest payments totaling \$11.0 million per year on our convertible senior subordinated notes.

Cash Provided by Investing Activities:

Net cash used in investing activities was \$85.7 million in 2007 and \$155.1 million in 2006, and net cash provided by investing activities was \$115.5 million in 2005. In 2007 and 2006, purchases of marketable securities exceeded sales or maturities by \$67.3 million and \$150.7 million, respectively, whereas in 2005, sales or maturities of marketable securities exceeded purchases by \$120.5 million. In addition, capital expenditures in 2007 included the purchase of land and a building in Rensselaer, NY for \$9.0 million.

Cash Provided by Financing Activities:

Cash provided by financing activities was \$319.4 million in 2007, \$185.4 million in 2006, and \$4.1 million in 2005. In 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of our Common Stock for gross proceeds to us of \$312.0 million. In 2006, we completed a public offering of 7.6 million shares of our Common Stock and received proceeds, after expenses, of \$174.6 million. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were \$7.6 million in 2007, \$10.4 million in 2006, and \$4.1 million in 2005.

Collaborations with the sanofi-aventis Group:

Aflibercept

Under our aflibercept collaboration agreement with sanofi-aventis, as described under "Collaborations" above, agreed upon worldwide aflibercept development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs. Since inception of the collaboration agreement through December 31, 2007, we and sanofi-aventis have incurred \$306.8 million in agreed upon development expenses related to aflibercept. Currently, multiple clinical studies to evaluate aflibercept as both a single agent and in combination with other therapies in various cancer indications are ongoing, and we and sanofi-aventis plan to initiate additional aflibercept clinical studies in 2008.

Sanofi-aventis funded \$38.3 million, \$36.4 million, and \$33.9 million, respectively, of our aflibercept development costs in 2007, 2006, and 2005, of which \$10.5 million, \$6.8 million, and \$10.5 million, respectively, were included in accounts receivable as of December 31, 2007, 2006, and 2005. In addition, we received up-front payments of \$80.0 million in September 2003 and \$25.0 million in January 2006 from sanofi-aventis in connection with our collaboration. Both up-front payments were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2007, 2006, and 2005, we recognized \$8.8 million, \$11.4 million, and \$9.5 million of revenue, respectively, related to these up-front payments.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of aflibercept development expenses will terminate and we will retain all rights to aflibercept.

Antibodies

As part of the discovery agreement under our collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies, as described under "Collaborations" above, sanofi-aventis will fund up to \$475.0 million for ur research through December 31, 2012, subject to specified funding limits of \$75.0 million for the period from the collaboration's inception through December 31, 2008, and \$100.0 million annually in each of the next four years. The discovery agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

As part of the license agreement under the collaboration, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs (called Shared Phase 3 Trial Costs) for that drug candidate will be shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of \$0.7 million as of December 31, 2007) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. The first therapeutic antibody to enter clinical development under the collaboration is REGN88, which has started clinical trials in rheumatoid arthritis. The second is expected to be a Dll4 antibody, which is currently slated to enter clinical development in mid-2008.

In 2007, sanofi-aventis funded \$3.0 million of our expenses under the collaboration's discovery agreement and \$0.7 million of our REGN88 development costs under the license agreement. These amounts were included in accounts receivable as of December 31, 2007. In addition, the \$85.0 million up-front payment received from sanofi-aventis in December 2007 was recorded to deferred revenue and is being recognized as contract research and development revenue over the period during which we expect to perform services. In 2007, we recognized \$0.9 million related to this up-front payment.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, optout of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party and, in the case of the discovery agreement, a termination right for sanofi-aventis under certain circumstances, including if certain minimal criteria for the discovery program are not achieved. Prior to December 31, 2012, sanofi-aventis has the right to terminate the discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

Collaboration with Bayer Health Care:

Under our collaboration agreement with Bayer HealthCare, as described under "Collaborations" above, agreed upon VEGF Trap-Eye development expenses incurred by both companies in 2007 under a global development plan, were shared as follows: The first \$50.0 million was shared equally and we were solely responsible for up to the next \$40.0 million. In 2007, cost-sharing between Bayer HealthCare and us of VEGF Trap-Eye development expenses resulted in (i) reimbursement of \$14.3 million of our VEGF Trap-Eye development expenses by Bayer HealthCare,

of which \$2.8 million was included in accounts receivable at December 31, 2007, and (ii) payment of \$4.9 million of Bayer HealthCare VEGF Trap-Eye development expenses by us, which was included in accrued expenses at December 31, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

In 2008, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$70.0 million will be shared equally, we are solely responsible for up to the next \$30.0 million, and over \$100.0 million will be shared equally. In 2009 and thereafter, all development expenses will be shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$25.4 million as of December 31, 2007) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. In 2007, we and Bayer HealthCare initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. A second Phase 3 study of the VEGF Trap-Eye in wet AMD is planned for 2008.

We received a \$75.0 million up-front payment in October 2006 and a \$20.0 non-substantive milestone payment in August 2007 from Bayer HealthCare in connection with our collaboration. Both payments were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2007, we recognized \$15.9 million of revenue related to these deferred payments. We did not recognize revenue in connection with our collaboration with Bayer HealthCare in 2006.

Bayer HealthCare has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

National Institutes of Health Grant:

Under our five-year grant from the NIH, as described under "Other Agreements" above, we are entitled to receive a minimum of \$17.9 million over a five-year period, subject to compliance with the grant's terms and annual funding approvals, and another \$1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2007 and 2006, we recognized \$5.5 million and \$0.5 million, respectively, of revenue related to the NIH Grant, of which \$1.0 million and \$0.5 million, respectively, was receivable at the end of 2007 and 2006. In 2008, we expect to receive funding of approximately \$5 million for reimbursement of Regeneron expenses related to the NIH Grant.

License Agreement with AstraZeneca and Astellas:

Under these non-exclusive license agreements, AstraZeneca and Astellas each made a \$20.0 million non-refundable, up-front payment to us in February and April 2007, respectively. AstraZeneca and Astellas are each required to make up to five additional annual payments of \$20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the first three additional payments or earlier if the technology does not meet minimum performance criteria.

Severance Costs:

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the September 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions occurred in 2006 as we completed activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction were comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included \$0.2 million of non-cash expenses. Estimated

termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities. Total costs associated with the 2005 and 2006 workforce reductions were \$2.6 million, of which \$2.2 million was charged to expense in the fourth quarter of 2005 and \$0.4 million was charged to expense in 2006.

Convertible Debt:

In 2001, we issued \$200.0 million aggregate principal amount of convertible senior subordinated notes in a private placement and received proceeds, after deducting the initial purchasers' discount and out-of pocket expenses, of \$192.7 million. The notes bear interest at 5.5% per annum, payable semi-annually, and mature in 2008. The notes are convertible into shares of our Common Stock at a conversion price of approximately \$30.25 per share, subject to adjustment in certain circumstances. If the price per share of our Common Stock is above \$30.25 at maturity, we would expect the notes would be converted into shares of Common Stock. Otherwise, we will be required to repay the \$200.0 million aggregate principal amount of the notes or refinance the notes prior to maturity; however, we can provide no assurance that we will be able to successfully arrange such refinancing.

New Operating Lease — Tarrytown, New York Facilities:

We currently lease approximately 232,000 square feet of laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, we entered into a new operating lease agreement for approximately 221,000 square feet of laboratory and office space at our current Tarrytown location. The new lease includes approximately 27,000 square feet that we currently occupy (our retained facilities) and approximately 194,000 square feet to be located in new facilities that are under construction and expected to be completed in mid-2009. In 2007, we amended the December 2006 operating lease agreement to increase the amount of new space we will lease from approximately 194,000 square feet to approximately 230,000 square feet, for an amended total under the new lease of approximately 257,000 square feet. The term of the lease is now expected to commence in mid-2008 and will expire approximately 16 years later. Under the new lease we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, we issued a letter of credit in the amount of \$1.6 million to our landlord, which is collateralized by a \$1.6 million bank certificate of deposit.

Capital Expenditures:

Our additions to property, plant, and equipment totaled \$19.6 million in 2007, \$3.3 million in 2006, and \$4.7 million in 2005. In 2008, we expect to incur approximately \$55 to \$65 million in capital expenditures primarily in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our new Tarrytown operating lease, as described above. We expect that approximately \$30 million of projected 2008 Tarrytown tenant improvement costs will be reimbursed by our landlord in connection with our new operating lease.

Funding Requirements:

Our total expenses for research and development from inception through December 31, 2007 have been approximately \$1,352 million. We have entered into various agreements related to our activities to develop and commercialize product candidates and utilize our technology platforms, including collaboration agreements, such as those with sanofi-aventis and Bayer HealthCare, and agreements to use our *Velocigene* technology platform. We incurred expenses associated with these agreements, which include an allocable portion of general and administrative costs, of \$108.2 million, \$43.4 million, and \$42.2 million in 2007, 2006, and 2005, respectively.

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55-65% of our expenditures for 2008 will be directed toward the preclinical and clinical development of product candidates, including ARCALYSTTM, affibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88 and the Dll4 antibody); approximately 15-20% of our expenditures for 2008 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2008 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2007. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

			Payments	Due by Period	l
	Total	Less than one year	1 to 3 <u>years</u> (In millions	3 to 5 years	Greater than 5 years
Convertible senior subordinated notes payable (1)					
Operating leases (2)	253.0	5.1	\$ 24.6	\$ 29.7	\$ 193.6
Purchase obligations (3)		60.4	65.5		<u></u>
Total contractual obligations	\$ 589.9	\$ 276.5	\$ 90.1	\$ 29.7	\$ 193.6

- (1) Includes amounts representing interest.
- (2) Includes projected obligations based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities under construction in Tarrytown, New York, as described above. Excludes future contingent rental costs for utilities, real estate taxes, and operating expenses. In 2007, these costs were \$8.8 million.
- (3) Purchase obligations primarily relate to (i) research and development commitments, including those related to clinical trials, (ii) capital expenditures for equipment acquisitions, and (iii) license payments. Our obligation to pay certain of these amounts may increase or be reduced based on certain future events. Open purchase orders for the acquisition of goods and services in the ordinary course of business are excluded from the table above.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare will share agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as described above. In addition, under our collaboration agreements with sanofi-aventis and Bayer HealthCare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by sanofi-aventis and Bayer HealthCare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for our affibercept collaboration with sanofi-aventis, royalties on product sales in Japan) otherwise payable to us unless we agree to reimburse these expenses at a faster rate at our option. Given the uncertainties related to drug development (including the development of affibercept and co-developed antibody candidates in collaboration with sanofi-aventis and the VEGF Trap-Eye in collaboration with Bayer HealthCare) such as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer HealthCare will become profitable.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third

parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. Other than the \$1.6 million letter of credit issued to our landlord in connection with our new operating lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of December 31, 2007, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

Revenue Recognition:

We recognize contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104) and Emerging Issues Task Force 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21). We earn contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize our technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development lifecycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing p

We enter into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. We may share the costs of research and development activities with our collaborator, such as in our VEGF Trap-Eye collaboration with Bayer HealthCare, or we may be reimbursed for all or a significant portion of the costs of our research and development activities, such as in our aflibercept and antibody collaborations with sanofi-aventis. We record our internal and third-party development costs associated with these collaborations as research and development expenses. When we are entitled to reimbursement of all or a portion of the research and development expenses that we incur under a collaboration, we record those reimbursable amounts as contract research and development revenue proportionately as we recognize our expenses. If the collaboration is a cost-sharing arrangement in which both we and our collaborator perform development work and share costs, in periods when our collaborator incurs development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expenses, the portion of the collaborator's development expenses that we are obligated to reimburse. In addition, we record revenue in connection with a government research grant using a proportional performance model as we incur expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are possible, and could result in material changes to the amount of revenue recognized each year in the future. In addition, performance periods may be extended if development programs encounter delays or we and our collaborators decide to expand our clinical plans for a drug candidate into additional disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an upfront or previously deferred payment at the time of the termination. For the year ended December 31, 2006, changes in estimates of our performance periods, including an extension of our estimated performance period for our aflibercept collaboration with sanofi-aventis, did not have a material impact on contract research and development revenue that we recognized. For the year ended December 31, 2007, we recognized \$2.6 million less in contract research and development revenue, compared to amounts recognized in 2006, in connection with \$105.0 million of non-refundable up-front payments previously received from sanofi-aventis pursuant to the companies' aflibercept collaboration, due to an extension of our estimated performance period.

Clinical Trial Expenses:

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations (CROs). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 15% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts with CROs are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and ssumptions for clinical expense of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the years ended December 31, 2007 or 2006.

Depreciation of Property, Plant, and Equipment:

Property, plant, and equipment are stated at cost. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	7-30 years
Laboratory and computer equipment	3-5 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

In some situations, the life of the asset may be extended or shortened if circumstances arise that would lead us to believe that the estimated life of the asset has changed. The life of leasehold improvements may change based on the extension of lease contracts with our landlords. Changes in the estimated lives of assets will result in an increase or decrease in the amount of depreciation recognized in future periods.

Stock-based Employee Compensation:

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS 123, Accounting for Stock-Based Compensation, using the modified prospective method as described in SFAS 148, Accounting for Stock-Based Compensation — Transition and Disclosure. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date. Prior to the adoption of the fair value method, we accounted for stock-based compensation to employees under the intrinsic value method of accounting set forth in APB 25, Accounting for Stock Issued to Employees, and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period operating results have not been restated.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, Share-Based Payment, which is a revision of SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the

time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005, and prior to our adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that were not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by \$0.8 million and is included in our operating results for the year ended December 31, 2006 as a cumulative-effect adjustment of a change in accounting principle.

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

Future Impact of Recently Issued Accounting Standards

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS 157, Fair Value Measurements, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles (GAAP), and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, however on December 14, 2007, the FASB issued a proposed staff position (FSP FAS 157-b) which would delay the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. We are required to adopt SFAS 157 as it relates to our financial assets and financial liabilities effective for the fiscal year beginning January 1, 2008, and as it relates to our nonfinancial assets and nonfinancial liabilities for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of SFAS 157 will have a material impact on our financial statements.

In February 2007, the FASB issued SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Our management does not anticipate that the adoption of SFAS 159 will have a material impact on our financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities (EITF 07-3). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We are required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Our management does not anticipate that the adoption of EITF 07-3 will have a material impact on our financial statements.

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate, asset-backed, and U.S. government securities.

We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in approximately a \$1.9 million and \$1.7 million decrease in the fair value of our investment portfolio at December 31, 2007 and 2006, respectively. The increase in the potential impact of an interest rate change at December 31, 2007, compared to December 31, 2006, is due primarily to slight increases in our investment portfolio's duration to maturity at the end of 2007 versus the end of 2006.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. In 2007, we recognized a \$5.9 million charge related to marketable securities which we considered to be other than temporarily impaired in value.

Item 8. Financial Statements and Supplementary Data

The financial statements required by this Item are included on pages F-1 through F-38 of this report. The supplementary financial information required by this Item is included at pages F-37 and F-38 of this report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the framework in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation our management has concluded that our internal control over financial reporting was effective as of December 31, 2007. The effectiveness of our internal control over financial reporting as of December 31, 2007 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers and Corporate Governance

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included under the captions "Election of Directors," "Board Committees and Meetings," "Executive Officers of the Company," and "Section 16(a) Beneficial Ownership Reporting Compliance," in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our officers, directors and employees. The full text of our code of business conduct and ethics can be found on the Company's website (http://www.regn.com) under the Investor Relations heading.

Item 11. Executive Compensation

The information called for by this item will be included under the captions "Compensation Committee Report," "Compensation Committee Interlocks and Insider Participation," "Executive Compensation" and "Compensation of Directors" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information called for by this item will be included under the captions "Equity Compensation Plan Information", "Security Ownership of Management" and "Stock Ownership of Certain Beneficial Owners" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be included under the captions "Elections of Directors" and "Review of Transactions with Related Persons" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information called for by this item will be included under the caption "Information about Fees Paid to Independent Registered Public Accounting Firm" in our definitive proxy statement with respect to our 2008 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and therefore have been omitted.

3. Exhibits

Exhibit Number		Description
		- ·
3.1		 Restated Certificate of Incorporation, filed February 11, 2008 with the New York Secretary of State.
3.2	(a)	 By-Laws of the Company, currently in effect (amended through November 9, 2007).
10.1	(b)	 1990 Amended and Restated Long-Term Incentive Plan.
10.2	(c)	— 2000 Long-Term Incentive Plan.
10.3.1	(d)	 Amendment No. 1 to 2000 Long-Term Incentive Plan, effective as of June 14, 2002.
10.3.2	(d)	 Amendment No. 2 to 2000 Long-Term Incentive Plan, effective as of December 20, 2002.
10.3.3	(e)	 Amendment No. 3 to 2000 Long-term Incentive Plan, effective as of June 14, 2004.
10,3,4	(f)	 Amendment No. 4 to 2000 Long-term Incentive Plan, effective as of November 15, 2004.
10,3.5	(g)	 Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10,3.6	(g)	 Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10,3,7	(h)	 Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.4	(d)	 Employment Agreement, dated as of December 20, 2002, between the Company and Leonard S. Schleifer, M.D., Ph.D.
10.5*	(i)	 Employment Agreement, dated as of December 31, 1998, between the Company and P. Roy Vagelos, M.D.
10.6	(j)	 Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, effective as of February 1, 2006.
10.7	(k)	 Indenture, dated as of October 17, 2001, between Regeneron Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, as trustee.
10.8	(k)	 Registration Rights Agreement, dated as of October 17, 2001, among Regeneron Pharmaceuticals, Inc., Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Robertson Stephens, Inc.
10.9*	(1)	 IL-1 License Agreement, dated June 26, 2002, by and among the Company, Immunex Corporation, and Amgen Inc.
10.10*	(m)	 Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
10.11*	(n)	 Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10,11,1*	(i)	 Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 31, 2004.
10.11.2	(0)	 Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of January 7, 2005.
10,11,3*	(p)	 Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 21, 2005.
10.11.4*	(p)	 Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals, Inc.) and Regeneron Pharmaceuticals, Inc., effective as of January 31, 2006.

Exhibit			
Number			<u>D</u> escription
10.12	(n)	_	Stock Purchase Agreement, dates as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.13*	(p)	_	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
10.14*	(r)	_	Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007 by and between AstraZeneca UK Limited and Regeneron Pharmaceuticals, Inc.
10.15	(s)	_	Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc.
10.16*	(t)	_	Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
10.17*	(u)	_	First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
10.18*		_	Discovery and Preclinical Development Agreement, dated as of November 28, 2007, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.19*		_	License and Collaboration Agreement, dated as of November 28, 2007, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique Du Nord and Regeneron Pharmaceuticals, Inc.
10,20		_	Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique Du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.
10,21		_	Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and Regeneron Pharmaceuticals, Inc.
12.1		_	Statement re: computation of ratio of earnings to combined fixed charges of Regeneron Pharmaceuticals, Inc.
23.1		_	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1		_	Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2		_	Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32		_	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

- (a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.
- (b) Incorporated by reference from the Company's registration statement on Form S-1 (file number 33-39043).
- (c) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2001, filed March 22, 2002.
- (d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2002, filed March 31, 2003.
- (e) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2004, filed August 5, 2004.
- (f) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 17, 2004.
- (g) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.
- (h) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.
- (i) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2004, filed March 11, 2005.
- (j) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 25, 2006.
- (k) Incorporated by reference from the Company's registration statement on Form S-3 (file number 333-74464).

- (l) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.
- (m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.
- (n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 11, 2003.
- (o) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.
- (p) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2005, filed February 28, 2006.
- (q) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed October 18, 2006.
- (r) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2006, filed March 12, 2007.
- (s) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
- (t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended March 31, 2007, filed May 4, 2007.
- (u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended September 31, 2007, filed November 7, 2007.
- * Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

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SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

Dated: New York, New York February 27, 2008

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Murray A. Goldberg, Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, and each of them, his true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	<u>T</u> itle
/s/ LEONARD S. SCHLEIFER Leonard S. Schleifer, M.D., Ph.D.	President, Chief Executive Officer, and Director (Principal Executive Officer)
/s/ Murray A. Goldberg Muttay A. Goldberg	Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer)
/s/ DOUGLAS S. McCorkle Douglas S. McCorkle	Vice President, Controller and Assistant Treasurer (Principal Accounting Officer)
/s/ GEORGE D. YANCOPOULOS George D. Yancopoulos, M.D., Ph.D	Executive Vice President, Chief Scientific Officer, President, Regeneron Research Laboratories, and Director
/s/ P. Roy Vagelos P. Roy Vagelos, M.D.	Chairman of the Board
/s/ Charles A. Baker Charles A. Baker	Director
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<u>S</u> ignature	Title	
/s/ Michael S. Brown	Director	
Michael S. Brown, M.D.		
/s/ Alfred G. Gilman	Director	
Alfred G. Gilman, M.D., Ph.D.		
/s/ Joseph L. Goldstein	Director	
Joseph L. Goldstein, M.D.		
/s/ Arthur F. Ryan	Director	
Arthur F. Ryan		
/s/ George L. Sing	Director	
George L. Sing	-	

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REGENERON PHARMACEUTICALS, INC. INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Regeneron Pharmaceuticals, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. at December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control — Integrated* Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting, assessing the risk

As discussed in note 2 to the financial statements, effective January 1, 2006, the Company changed its method of accounting for share-based payment, to conform with FASB Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-based Payment."

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP

New York, New York February 27, 2008

BALANCE SHEETS December 31, 2007 and 2006

		2006 nds, except share data)	
ASSETS			
Current assets Cash and cash equivalents	\$ 498.925	\$ 237,876	
Marketable securities	267.532	221.400	
Accounts receivable from the sanofi-aventis Group	14.244	6.900	
Accounts receivable — other	4,076	593	
Prepaid expenses and other current assets	13,052	3,215	
Total current assets	797,829	469,984	
Restricted cash	1,600	1,600	
Marketable securities	78,222	61,983	
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	58,304	49,353	
Other assets	303	2,170	
Total assets	<u>\$ 936,258</u>	\$ 585,090	
LIABILITIES and STOCKHOLDERS' EQUITY			
Current liabilities			
Accounts payable and accrued expenses	\$ 39,232	\$ 21,471	
Deferred revenue from sanofi-aventis, current portion	18,855	8,937	
Deferred revenue — other, current portion	25,577	14,606	
Notes payable	200,000		
Total current liabilities	283,664	45,014	
Deferred revenue from sanofi-aventis Deferred revenue — other	126,431	61,013 62,439	
Notes payable	65,896	200,000	
Total liabilities	475.991	368,466	
Commitments and contingencies			
Stockholders' equity			
Preferred stock, \$.01 par value, 30,000,000 shares authorized; issued and outstanding — none			
Class A Stock, convertible, \$.001 par value: 40,000,000 shares authorized;			
shares issued and outstanding — 2,260,266 in 2007 and 2,270,353 in 2006	2	2	
Common Stock, \$ 001 par value; 160,000,000 shares authorized;			
shares issued and outstanding — 76,592,218 in 2007 and 63,130,962 in 2006	77	63	
Additional paid-in capital Accumulated deficit	1,253,235 (793,217)	904,407 (687,617)	
Accumulated other comprehensive income (loss)	(/93,21/) 170	(087,017)	
Total stockholders' equity	460.267	216,624	
Total liabilities and stockholders' equity	\$ 936.258	\$ 585.090	
rotat naotines and stockholders equity	<u>3</u> 930,238	D 35,090	

The accompanying notes are an integral part of the financial statements.

${\bf REGENERON\,PHARMACEUTICALS,INC.}$

STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2007, 2006, and 2005

	2007	2006	2005	
	(In thousa	nds, except per sha	re data)	
Revenues				
Contract research and development from sanofi-aventis	\$ 51,687	\$ 47,763	\$ 43,445	
Other contract research and development	44,916	3,373	9,002	
Contract manufacturing Technology licensing	28,421	12,311	13,746	
A Community in Community	125,024	63,447	66,193	
Expenses				
Research and development	201,613	137,064	155,581	
Contract manufacturing		8,146	9,557	
General and administrative	37,865	25,892	25,476	
	239,478	171,102	190,614	
Loss from operations	(114,454)	(107,655)	(124,421)	
Other income (expense)				
Other contract income (includes \$25.0 million from sanofi-aventis)			30,640	
Investment income	20,897	16,548	10,381	
Interest expense	(12,043)	(12,043)	(12,046)	
	8,854	4,505	28,975	
Net loss before cumulative effect of a change in accounting principle	(105,600)	(103,150)	(95,446)	
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")		813		
Net loss	\$ (105,600)	\$ (102,337)	\$ (95,446)	
Net loss per share, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	\$ (1.59)	\$ (1.78)	\$ (1.71)	
Cumulative effect of adopting SFAS 123R		0.01		
Net loss	\$ (1.59)	\$ (1.77)	\$ (1.71)	
Weighted average shares outstanding, basic and diluted	66,334	57,970	55,950	

STATEMENTS OF STOCKHOLDERS' EQUITY For the Years Ended December 31, 2007, 2006, and 2005

								Accumulated		
			_		Additional			Other	Tetal	
		A Stock	Commo		Paid-in	Unearned	Accumulated	Comprehensive	Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Compensation (In thousan	Deficit	Income (Loss)	Equity	Income (Loss)
	000000000000000000	50000000000000000000	************		00000000000000000				52-22-04-04-04-04-04-04-04-04-04-04-04-04-04-	000000000000000000000
Balance, December 31, 2004	2,358	\$ 2	53,502	\$ 54	\$675,389	\$ (2,299)	\$ (489,834)	\$ (769)	\$ 182,543	
Issuance of Common Stock in connection with exercise of stock options, net of shares										
tendered			494	.00000000000000000	4,081				4,081	000000000000000000000
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			90		632				632	
Conversion of Class A Stock to Common Stock	(11)		11							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(5)		(54)	54				
Stock-based compensation expense					19,963	1,930			21,893	
Net loss, 2005							(95,446)		(95,446)	
Change in net unrealized gain (loss) on marketable securities								299	299	299
Balance, December 31, 2005	2,347	2	54,092	54	700,011	(315)	(585,280)	(470)	114,002	\$ (95,147)
Issuance of Common Stock in a public offering at \$23.03 per share			7,600	8	175,020				175,028	
Cost associated with issuance of equity securities					(412)				(412)	
Issuance of Common Stock in connection with exercise of stock options, net of shares										
tendered			1,243	1	10,391				10,392	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution			121		1,884				1,884	
Conversion of Class A Stock to Common Stock	(77)		77							
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(2)							
Stock-based compensation expense					18,641				18,641	
Adjustment to reduce unearned compensation upon adoption of SFAS 123R					(315)	315				
Cumulative effect of adopting SFAS 123R					(813)				(813)	
Net loss, 2006							(102,337)		(102,337)	\$ (102,337)
Change in net unrealized gain (loss) on marketable securities								239	239	239
Balance, December 31, 2006	2,270	2	63,131	63	904,407		(687,617)	(231)	216,624	\$ (102,098)
		(Contin	ued)							

STATEMENTS OF STOCKHOLDERS' EQUITY — (Continued) For the Years Ended December 31, 2007, 2006, and 2005

					Additional			Accumulated Other	Total	
	Class	A Stock	Commo	n Stock	Paid-in	Unearned	Accumulated	Comprehensive	Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Compensation	Deficit	Income (Loss)	Equity	Income (Loss)
						(In thousand	s)			
Issuance of Common Stock in connection with exercise of stock options, net of shares										
tendered			886	1	7,618				7,619	
Issuance of Common Stock to sanofi-aventis			12,000	12	311,988				312,000	
Cost associated with issuance of equity securities to sanofi-aventis					(219)				(219)	
Issuance of Common Stock in connection with Company 401(k) Savings Plan										
contribution			65		1,367				1,367	
Issuance of restricted Common Stock under Long- Term Incentive Plan			500	1	(1)					
Conversion of Class A Stock to Common Stock	(10)		10							
Stock-based compensation expense					28,075				28,075	
Net loss, 2007							(105,600)		(105,600)	\$ (105,600)
Change in net unrealized gain (loss) on marketable securities								401	401	401
Balance, December 31, 2007	2,260	\$ 2	76,592	\$ 77	\$1,253,235		\$ (793,217)	\$ 170	\$ 460,267	\$ (105,199)

The accompanying notes are an integral part of the financial statements.

STATEMENTS OF CASH FLOWS For the Years Ended December 31, 2007, 2006, and 2005

2007

319,400

319,400

261,049

237,876

498,925

11,000

\$

2006

185,008

185,398

53,368

184,508

237,876

11,000

390

2005

4,081

4,081

89,279 95,229

184,508

11,002

\$

(In thousands) Cash flows from operating activities (95,446) (105,600) Net loss (102,337) Adjustments to reconcile net loss to net cash provided by (used in) operating activities Depreciation and amortization 11,487 14,592 15,504 28,075 Non-cash compensation expense 18,675 21,859 5,943 Impairment charge on marketable securities Cumulative effect of a change in accounting principle (813)Changes in assets and liabilities (Increase) decrease in accounts receivable (10,827)29,028 6,581 74 (Increase) decrease in prepaid expenses and other assets (9,649) 155 3,594 1.250 Decrease in inventory Increase in deferred revenue 89,764 60,833 14,469 Increase (decrease) in accounts payable, accrued expenses, 5,413 18,179 (652)and other liabilities 132,972 125,412 65,150 Total adjustments Net cash provided by (used in) operating activities 27,372 23,075 (30,296)Cash flows from investing activities (102,990) Purchases of marketable securities (594,446) (456,893) 527.169 306.199 223.448 Sales or maturities of marketable securities (2,811) (4,964) (18,446)Capital expenditures Increase in restricted cash (1,600)Net cash (used in) provided by investing activities (85,723) (155,105)115,494 Cash flows from financing activities

The accompanying notes are an integral part of the financial statements.

Net proceeds from the issuance of Common Stock

Net cash provided by financing activities

Net increase in cash and cash equivalents

Cash and cash equivalents at end of period

Cash paid for interest

Cash and cash equivalents at beginning of period

Supplemental disclosure of cash flow information

Other

NOTES TO FINANCIAL STATEMENTS

For the years ended December 31, 2007, 2006, and 2005 (Unless otherwise noted, dollars in thousands, except per share data)

1. Organization and Business

Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") was incorporated in January 1988 in the State of New York. The Company is engaged in research and development programs to discover and commercialize therapeutics to treat human disorders and conditions. The Company's facilities are located in New York. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, obtaining regulatory approvals, commercializing products, and obtaining and enforcing patents.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

For purposes of the statement of cash flows and the balance sheet, the Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements 7-30 years
Laboratory and computer equipment 3-5 years
Furniture and fixtures 5 years

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful lives of the assets. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

Accounting for the Impairment of Long-Lived Assets

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount in accordance with Statement of Financial Accounting Standards No. ("SFAS") 144, Accounting for the Impairment or Disposal of Long-Lived Assets. For all periods presented, no impairment losses were recorded.

Patents

As a result of the Company's research and development efforts, the Company has obtained, applied for, or is applying for, a number of patents to protect proprietary technology and inventions. All costs associated with patents are expensed as incurred.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Revenue Recognition

a. Contract Research and Development and Research Progress Payments

The Company recognizes contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition ("SAB 104") and Emerging Issues Task Force 00-21, Accounting for Revenue Arrangements with Multiple Deliverables ("EITF 00-21"). The Company earns contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advan

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, such as in the Company's VEGF Trap-Eye collaboration with Bayer HealthCare LLC, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities, such as in the Company's affibercept and antibody collaborations with sanofi-aventis. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as contract research and development revenue proportionately as the Company recognizes its expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, in periods when the Company's collaborator incurs development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expenses, the portion of the collaborator's development expenses that the Company is obligated to reimburse. In addition, the Company records revenue in connection with a government research grant using a proportional performance model as it incurs expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are possible, and could result in material changes to the amount of revenue recognized each year in the future. In addition, performance periods may be extended if the Company and its collaborators decide to expand the clinical plans for a drug candidate into

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

additional disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, the Company would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

b. Contract Manufacturing

The Company manufactured product and performed services for a third party under a contract manufacturing agreement which expired in October 2006. Contract manufacturing revenue was recognized as product was shipped and as services were performed (see Note 13).

c. Technology Licensing

The Company enters into non-exclusive license agreements with third parties that allow the third party to utilize the Company's *VelocImmune®* technology in its internal research programs. The terms of these agreements include annual, non-refundable, up-front payments and entitle the Company to receive royalties on any future sales of products discovered by the third party using the Company's *VelocImmune* technology (see Note 12). Annual, non-refundable, up-front payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective annual license periods.

Investment Income

Interest income, which is included in investment income, is recognized as earned.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements (see Note 10), the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur (see Note 11), expenses related to the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by contract research organizations ("CROs"). CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 15% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of the Company's contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates and assumptions for clinical expense recognition could differ significantly from its actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

Per Share Data

Net income (loss) per share, basic and diluted, is computed on the basis of the net income (loss) for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock outstanding, and of common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the treasury stock method when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's outstanding convertible senior subordinated notes, which are included under the if-converted method when dilutive. The computation of diluted net loss per share for the years ended December 31, 2007, 2006, and 2005 does not include common stock equivalents, since such inclusion would be antidilutive. Disclosures required by SFAS 128, Earnings per Share, have been included in Note 19.

Income Taxes

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain. See Note 17.

Comprehensive Income (Loss)

The Company presents comprehensive income (loss) in accordance with SFAS 130, Reporting Comprehensive Income. Comprehensive income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive income (loss) is immaterial. Comprehensive losses for the years ended December 31, 2007, 2006, and 2005 have been included in the Statements of Stockholders' Equity.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities, and receivables from sanofi-aventis and Bayer HealthCare. The Company generally invests its excess cash in obligations of the U.S. government and its agencies, investment grade debt securities issued by corporations, governments, and financial institutions, bank deposits, asset-backed securities, commercial paper, and money market funds that invest in these instruments. The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject the Company to the risk of not being able to recover the full principal value of the security. The Company recognizes a charge to earnings in a period when the Company considers a marketable security to be other than temporarily impaired in value.

Risks and Uncertainties

Regeneron has had no sales of its products and there is no assurance that the Company's research and development efforts will be successful, that the Company will ever have commercially approved products, or that the Company will achieve significant sales of any such products. The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) payments from the Company's collaborators and other entities for the Company's development activities with respect to product candidates and to utilize the Company's technology platforms, (ii) payments for past contract manufacturing activities, and (iii) investment income. The Company operates in an environment of rapid change in technology and is dependent upon the services of its employees, consultants, collaborators, and certain third-party suppliers, including single-source unaffiliated third-party suppliers of certain raw materials and equipment. Regeneron, as licenses certain technologies that are important to the Company's business which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate the Company's licenses.

Contract research and development revenue in 2007 was primarily earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 11 for the terms of these agreements). The Company recognizes revenue from its collaborations with sanofi-aventis and Bayer HealthCare in accordance with SAB 104 and EITF 00-21, as described above. These collaboration agreements contain early termination provisions, as defined, by sanofi-aventis or Bayer HealthCare, as applicable.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Significant estimates include (i) useful lives of property, plant, and equipment, (ii) the periods over which certain revenues and expenses will be recognized, including contract research and development revenue recognized from non-refundable licensing payments and expense recognition of certain clinical trial costs which are included in research and development expenses, (iii) the extent to which deferred tax assets and liabilities are offset by a valuation allowance, and (iv) the fair value of stock options on their date of grant using the Black-Scholes option-pricing model, based on assumptions with respect to (a) expected volatility of our Common Stock price, (b) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (c) expected dividend yield on the Company's Common Stock, and (d) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. In addition, in connection with the recognition of compensation expense in accordance with the provisions of SFAS 123R, Share-

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Based Payment, as described below, the Company is required to estimate, at the time of grant, the number of stock option awards that are expected to be forfeited.

Stock-based Employee Compensation

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS 123, Accounting for Stock-Based Compensation, using the modified prospective method as described in SFAS 148, Accounting for Stock-Based Compensation — Transition and Disclosure. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 (including replacement options granted under the Company's stock option exchange program which concluded on January 5, 2005 (see Note 14)) and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, Share-Based Payment, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate, at the time of grant, the number of awards that are expected to be forfeited and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005 and prior to the Company's adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that were not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by \$0.8 million and is included in the Company's operating results in 2006 as a cumulative-effect adjustment of a change in accounting principle.

For the years ended December 31, 2007, 2006, and 2005, \$28.0 million, \$18.4 million, and \$19.9 million, respectively, of non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") was recognized in operating expenses. In addition, for the year ended December 31, 2005, \$0.1 million of Stock Option Expense was capitalized in inventory.

Other disclosures required by SFAS 123 and SFAS 123R have been included in Note 14.

Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

In 2007, 2006, and 2005, the Company recognized \$0.1 million, \$0.3 million, and \$1.9 million, respectively, of compensation expense related to Restricted Stock awards, the fair value of which is expensed, on a pro rata basis, over the period that the restrictions on the shares lapse (see Note 14).

Included in accounts payable and accrued expenses at December 31, 2007, 2006, and 2005 were \$1.7 million, \$0.8 million, and \$0.2 million of capital expenditures, respectively.

Included in accounts payable and accrued expenses at December 31, 2006, 2005, and 2004 were \$1.4 million, \$1.9 million, and \$0.6 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2007, 2006, and 2005, the Company contributed 64,532, 120,960, and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Included in marketable securities at December 31, 2007, 2006, and 2005 were \$2.2 million, \$1.5 million, and \$1.2 million of accrued interest income, respectively.

Future Impact of Recently Issued Accounting Standards

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS 157, Fair Value Measurements, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles ("GAAP"), and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, however on December 14, 2007, the FASB issued a proposed staff position ("FSP FAS 157-b") which would delay the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The Company is required to adopt SFAS 157 as it relates to the Company's financial assets and financial liabilities effective for the fiscal year beginning January 1, 2008, and as it relates to the Company's nonfinancial assets and nonfinancial liabilities for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of SFAS 157 will have a material impact on the Company's financial statements.

In February 2007, the FASB issued SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company is required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Management does not anticipate that the adoption of SFAS 159 will have a material impact on the Company's financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities ("EITF 07-3"). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company is required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Management does not anticipate that the adoption of EITF 07-3 will have a material impact on the Company's financial statements.

3. Severance Costs

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions occurred during 2006 as the Company completed activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction were comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included non-cash expenses due to the accelerated vesting of certain stock options and restricted stock held by affected employees. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and were expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, Accounting for

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NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Costs Associated with Exit or Disposal Activities. The total costs associated with the 2005 and 2006 workforce reductions were \$2.6 million, including \$0.2 million of non-cash expenses.

Severance costs associated with the workforce reduction plan that were charged to expense in 2005, 2006, and 2007 consist of the following:

	Costs charged to expense in 2005	Costs paid or settled in 2005	Accrued liability at December 31, 2005
Employee severance, payroll taxes, and benefits Other severance costs Non-cash expenses	\$ 1,786 206 221	\$ 879 30 221	\$ 907 176
Total	\$ 2,213	\$ 1,130	\$ 1,083
	Costs charged to expense 2006	Costs paid or settled in 2006	Accrued liability at December 31, 2006
Employee severance, payroll taxes, and benefits Other severance costs	\$ 315 33	\$ (1,159) (209)	\$ 63
Total	<u>\$ 348</u>	<u>\$ (1,368)</u>	<u>\$ 63</u>
	Costs charged to expense in 2007	Costs paid or settled in 2007	Accrued liability at December 31,
Employee severance, payroll taxes, and benefits	\$ 43	\$ (106)	\$ —

These severance costs are included in the Company's Statement of Operations for the years ended December 31, 2007, 2006, and 2005 as follows:

	2007	2006		2005	
	R&D	R&D	G&A	R&D	G&A
Employee severance, payroll taxes, and benefits	\$ 43	\$317	\$ (2)	\$ 1,734	\$ 52
Other severance costs		33		206	
Non-cash expenses				215	6
Total	<u>\$ 43</u>	\$ 350	<u>\$ (2)</u>	\$ 2,155	\$ 58

For segment reporting purposes (see Note 20), all severance-related expenses are included in the Research & Development segment.

4. Marketable Securities

The Company considers its unrestricted marketable securities to be "available-for-sale," as defined by SFAS 115, Accounting for Certain Investments in Debt and Equity Securities. Gross unrealized holding gains and losses are reported as a net amount in a separate component of stockholders' equity entitled Accumulated Other Comprehensive Income (Loss). The net change in unrealized holding gains and losses is excluded from operations and included in stockholders' equity as a separate component of comprehensive loss.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

The following tables summarize the amortized cost basis of marketable securities, the aggregate fair value of marketable securities, and gross unrealized holding gains and losses at December 31, 2007 and 2006:

	Amortized			nortized Fair _		Amortized Fair Unrealiz		nrealized Holdi		
	Cost Basis	Value	Gains	(Losses)	Net_					
At December 31, 2007										
Maturities within one year					*******					
Corporate and municipal bonds	\$ 69,213	\$ 69,263	\$ 74	\$ (24)	\$ 50					
Asset-backed securities	73,939 64.846	73,706 64.87 0	99 25	(332)	(233)					
Commercial paper U.S. government obligations	50.386	50.475	23 89	(1)	24 89					
Certificates of deposit	9,220	9.218	37	(2)	(2)					
CARLITORING OF INSPOSI	267,604	267,532	287	(359)	(72)					
Maturities between one and two years	207,004	201,332	207	(337)	(12)					
Corporate and municipal bonds	49.724	49.947	289	(66)	223					
Asset-backed securities	20.295	20.323	173	(145)	28					
Commercial paper	7,952	7,952								
* * *	77,971	78,222	462	(211)	251					
	\$ 345,575	\$ 345,754	\$ 749	\$ (570)	\$ 179					
At December 31, 2006										
Maturities within one year					000000000000000000000000000000000000000					
Corporate and municipal bonds	\$ 25,254	\$ 25,221		\$ (33)	\$ (33)					
Asset-backed securities	94,159	94,075	\$ 6	(90)	(84)					
Commercial paper	69,547	69,535	9	(21)	(12)					
U.S. government obligations	22,267	22,243	1	(25)	(24)					
Certificates of deposit	10,327	10,326	2	(3)	(1)					
	221,554	221,400	18	(172)	(154)					
Maturities between one and two years										
Corporate and municipal bonds	6,047	6,032		(15)	(15)					
Asset-backed securities	32,835	32,762	3	(76)	(73)					
U.S. government obligations	23,190	23,189	<u> </u>	(7)	(1)					
	62,072	61,983	9	(98)	(89)					
	\$ 283,626	\$ 283,383	\$ 27	<u>\$ (270)</u>	\$ (243)					

In addition, cash equivalents at December 31, 2007 and 2006 included an unrealized holding loss of \$9 thousand and an unrealized holding gain of \$12 thousand, respectively.

Realized gains and losses are included as a component of investment income. For the years ended December 31, 2007, 2006, and 2005, gross realized gains and losses on sales of marketable securities was not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the securities, adjusted for the amortization of any discount or premium. In 2007, deterioration in the credit quality of marketable securities from two issuers

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

has subjected the Company to the risk of not being able to recover the full principal value of these securities, which totals \$14.0 million. Since market activity for these securities is very limited, their fair values at December 31, 2007 were developed based on information provided by the Company's investment advisors, including but not limited to estimated value of the assets underlying each security and quoted bid prices, as applicable. As a result, the Company recognized a \$5.9 million charge related to these marketable securities, which the Company considered to be other than temporarily impaired. Excluding these other than temporarily impaired securities, are value of marketable securities has been estimated based on inputs that are observable for each security, either directly or indirectly, through corroboration with observable market data

The following table shows the unrealized losses and fair value of the Company's marketable securities with unrealized losses that are deemed to be only temporarily impaired, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at December 31, 2007 and 2006. The securities listed at December 31, 2007 mature at various dates through December 2009.

					Tot	al
	Less that	n 12 Months	12 Mon	ths or Greater		Unrealized
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Loss
At December 31, 2007						
Corporate and municipal						
bonds	\$ 36,979	\$ (89)	\$ 3,056	\$ (1)	\$ 40,035	\$ (90)
Asset-backed securities	18,674	(360)	12,390	(116)	31,064	(476)
Commercial paper	14,950	(2)			14,950	(2)
Certificates of deposit	9,218	(2)			9,218	(2)
	\$ 79,821	\$ (453)	\$ 15,446	\$ (117)	\$ 95,267	\$ (570)
At December 31, 2006				*****		
Corporate and municipal						
bonds	\$ 12.113	\$ (31)	\$ 12.191	\$ (18)	\$ 24,304	\$ (49)
Asset-backed securities	92 544	(161)	891	(5)	93,435	(166)
Commercial paper	12.949	(20)			12.949	(20)
U.S. government obligations	23,273	(25)	2.023	(7)	25.296	(32)
Certificates of deposit	3,034	(3)		X.7	3,034	(3)
	\$ 143,913	\$ (240)	\$ 15,105	§ (30)	\$ 159.018	\$ (270)
	<u>a 143,313</u>	<u>a (240)</u>	<u> </u>	<u>w</u> (39)	<u>p 192,010</u>	φ (Δ/Ω)

At December 31, 2007, the unrealized losses in the Company's marketable securities were primarily caused by general instability in the credit markets at the end of 2007. At December 31, 2006, the unrealized losses in the Company's marketable securities were primarily caused by interest rate increases, which generally resulted in a decrease in the market value of the Company's portfolio. Based upon the Company's currently projected sources and uses of cash, the Company intends to hold these securities until a recovery of fair value, which may be maturity. Therefore, the Company does not consider these marketable securities at December 31, 2007 and 2006 to be other than temporarily impaired. However, further deterioration in the credit markets may subject the Company to the risk of not being able to recover the full principal value of certain of its marketable securities, which could have a material impact on the Company's financial statements.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

5. Accounts Receivable

Accounts receivable as of December 31, 2007 and 2006 consist of the following:

	2007	2006
Receivable from sanofi-aventis (see Note 11)	\$ 14,244	\$ 6,900
Receivable from Bayer HealthCare (see Note 11)	2,797	
Other	1,279	593
	\$ 18,320	\$ 7,493

6. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2007 and 2006 consist of the following:

_	2007	2006
Land	3 2,117	\$ 475
Building and improvements	66,208	57,045
Leasehold improvements	13,982	14,662
Construction-in-progress	4,677	203
Laboratory and other equipment	61,717	59,164
Furniture, fixtures, software and computer equipment	6,080	5,413
	154,781	136,962
Less, accumulated depreciation and amortization	(96,477)	(87,609)
	5 58,304	<u>\$ 49,353</u>

In October 2007, the Company purchased land and a building in Rensselaer, New York for \$9.0 million. The Company previously leased manufacturing, office, and warehouse space in a portion of the purchased building (see Note 10).

Depreciation and amortization expense on property, plant, and equipment amounted to \$10.4 million, \$14.3 million, and \$15.4 million for the years ended December 31, 2007, 2006, and 2005, respectively. Included in these amounts was \$0.7 million and \$0.9 million of depreciation and amortization expense related to contract manufacturing that was capitalized into inventory for the years ended December 31, 2006 and 2005, respectively.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2007 and 2006 consist of the following:

	2007	2006
Accounts payable	\$ 8,128	\$ 4,349
Payable due to Bayer HealthCare (see Note 11)	4,892	
Accrued payroll and related costs	14,514	9,932
Accrued clinical trial expense	5,609	2,606
Accrued expenses, other	3,797	2,292
Interest payable on convertible notes	2,292	2,292
	\$ 39,232	\$ 21,471

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

8. Deferred Revenue

Deferred revenue as of December 31, 2007 and 2006 consists of the following:

	2007	2006
Current portion:		
Received from sanofi-aventis (see Note 11)	\$ 18,855	\$ 8,937
Received from Bayer HealthCare (see Note 11)	13,179	12,561
Received for technology license agreements (see Note 12)	11,579	
Other	819	2,045
	\$ 44,432	\$ 23,543
Long-term portion:		
Received from sanofi-aventis	\$ 126,431	\$ 61,013
Received from Bayer HealthCare	65,896	62,439
	\$ 192,327	\$ 123,452

9. Stockholders Equity

The Company's Restated Certificate of Incorporation provides for the issuance of up to 40 million shares of Class A Stock, par value \$0.001 per share, and 160 million shares of Common Stock, par value \$0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that Class A Stockholders are entitled to ten votes per share, while Common Stockholders are entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's Board of Directors (the "Board") is authorized to issue up to 30 million shares of preferred stock, in series, with rights, privileges, and qualifications of each series determined by the Board.

In October 2001, the Company completed a private placement of \$200.0 million aggregate principal amount of senior subordinated notes, which are convertible into shares of the Company's Common Stock. See Note 10.

In November 2006, the Company completed a public offering of 7.6 million shares of Common Stock at a price of \$23.03 per share and received proceeds, after expenses, of \$174.6 million.

In September 2003, sanofi-aventis purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for \$45.0 million. See Note 11.

In December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for an aggregate cash price of \$312.0 million. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with the Company. Under the investor agreement, sanofi-aventis has three demand rights to require the Company to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Company's Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the License and Collaboration Agreement under the Company's antibody collaboration with sanofi-aventis (see Note 11) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of affiliercept (see Note 11), sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of the Company's Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Sanofi-aventis has also agreed not to dispose of any shares of the Company's Common Stock

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2012, subject to certain limited exceptions. Following December 20, 2012, sanofi-aventis will be permitted to sell shares of the Company's Common Stock (i) in a registered underwritten public offering imdertaken pursuant to the demand registration rights granted to sanofi-aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of the Company's Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or more of the outstanding shares of the Company's Common Stock and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by the Company's Board of Directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of the Company's voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by the Company's Board of Directors or proportionally with the votes cast by the Company's other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of the Company's Class A Stock and Common Stock, and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

10. Commitments and Contingencies

a. Operating Leases

The Company currently leases laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, the Company entered into a new operating lease agreement to lease laboratory and office space that is now under construction and expected to be completed in mid-2009 at the Company's current Tarrytown location, plus retain a portion of the Company's existing space. In October 2007, the Company amended the December 2006 operating lease agreement to increase the amount of new space to be leased. The term of the lease is expected to commence in mid-2008 and will expire approximately 16 years later. Under the new lease the Company also has various options and rights on additional space at the Tarrytown site, and will continue to lease its present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for the Company's retained facilities only. The lease provides for monthly payments over the term of the lease related to the Company's retained facilities, the costs of construction and tenant improvements for the Company's new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, the Company issued a letter of credit in the amount of \$1.6 million to its landlord, which is collateralized by a \$1.6 million bank certificate of deposit. The certificate of deposit has been classified as restricted cash at December 31, 2007 and 2006 in the accompanying financial statements.

In November 2007, the Company entered into a new operating sublease for additional office space in Tarrytown, New York. The lease expires in September 2009 and contains two renewal options to extend the term of the sublease by three months each.

The Company formerly leased manufacturing, office, and warehouse facilities in Rensselaer, New York under an operating lease agreement. The lease provided for base rent plus additional rental charges for utilities, taxes, and operating expenses, as defined. In June 2007, the Company exercised a purchase option under the lease and, in October 2007, purchased the land and building (see Note 6).

The Company leases certain laboratory and office equipment under operating leases which expire at various times through 2011.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities to be constructed in Tarrytown, New York, as described above, at December 31, 2007, the estimated future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2008	\$ 4,686	\$ 429	\$ 5,115
2009	9,573	339	9,912
2010	14.453	185	14.638
2011	14,713	13	14,726
2012			
Thereafter	193,643		193,643
	3 Z3Z,U44	\$ 966	\$ 253,013

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
2007	\$ 4,632	\$ 363	\$ 4,995
2006	4,492	307	4,799
2005	4,606	319	4,925

In addition to its rent expense for various facilities, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of \$8.8 million, \$8.7 million, and \$9.5 million for the years ended December 31, 2007, 2006, and 2005, respectively.

b. Convertible Debt

In October 2001, the Company issued \$200.0 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company of \$192.7 million, after deducting the initial purchasers' discount and out-of-pocket expenses (collectively, "Deferred Financing Costs"). The Notes bear interest at 5.5% per annum, payable semi-annually, and mature on October 17, 2008. Deferred Financing Costs, which are included in other assets, are amortized as interest expense over the period from the Notes' issuance to stated maturity. The Notes are convertible, at the option of the holder at any time, into shares of the Company's Common Stock at a conversion price of approximately \$30.25 per share, subject to adjustment in certain circumstances. Regeneron may also redeem some or all of the Notes at any time if the closing price of the Company's Common Stock has exceeded 140% of the conversion price then in effect for a specified period of time. The fair market value of the Notes fluctuates over time. The estimated fair value of the Notes at December 31, 2007 was approximately \$206.1 million.

c. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with related and unrelated companies, scientific collaborators, universities, and consultants. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company, services to be provided, and ownership rights to certain proprietary technology developed under the agreements. Some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.25% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

Certain agreements under which the Company is required to pay fees permit the Company, upon 30 to 90-day written notice, to terminate such agreements. With respect to payments associated with these agreements, the

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Company incurred expenses of \$1.0 million, \$1.1 million, and \$1.0 million for the years ended December 31, 2007, 2006, and 2005, respectively.

In July 2002, Amgen Inc. and Immunex Corporation (now part of Amgen) granted the Company a non-exclusive license to certain patents and patent applications which may be used in the development and commercialization of ARCALYSTIM(rilonacept; also known as IL-1 Trap). The license followed two other licensing arrangements under which Regeneron obtained a non-exclusive license to patents owned by ZymoGenetics, Inc. and Tularik Inc. for use in connection with the ARCALYSTIM program. These license agreements would require the Company to pay royalties based on the net sales of ARCALYSTIM if and when it is approved for sale. In total, the royalty rate under these three agreements would be in the mid-single digits.

In December 2003, the Company entered into a non-exclusive license agreement with Cellectis Inc. that granted the Company certain rights in a family of patents relating to homologous recombination. Cellectis now claims that agreements the Company entered into relating to its *VelocImmune* mice with AstraZeneca UK Limited, Astellas Pharma Inc., and sanofi-aventis are outside of the scope of the Company's license from Cellectis. The Company disagrees with Cellectis' position and is in discussions with Cellectis regarding this matter. If the Company is not able to resolve this dispute, Cellectis may commence a lawsuit against the Company and its *VelocImmune* licensees alleging infringement of Cellectis' patents. The Company is unable to estimate the losses or expenses, if any, that may result from the resolution of this matter; however, such losses or expenses could be material.

11. Research and Development Agreements

The Company has entered into various agreements related to its activities to develop and commercialize product candidates and utilize its technology platforms. Amounts earned by the Company in connection with these agreements, which were recognized as contract research and development revenue or other contract income, as applicable, totaled \$96.6 million, \$51.1 million, and \$83.1 million in 2007, 2006, and 2005, respectively. Total Company incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost-sharing of a collaborator's development expenses, where applicable (see Bayer HealthCare below), were \$108.2 million, \$43.4 million and \$42.2 million in 2007, 2006, and 2005, respectively. Significant agreements of this kind are described below.

a. The sanofi-aventis Group

Aflibercept

In September 2003, the Company entered into a collaboration agreement (the "Aventis Agreement") with Aventis Pharmaceuticals Inc. (predecessor to sanofiaventis U.S.), to jointly develop and commercialize aflibercept. In connection with this agreement, sanofiaventis made a non-refundable, up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for \$45.0 million.

In January 2005, the Company and sanofi-aventis amended the Aventis Agreement to exclude intraocular delivery of aflibercept to the eye ("Intraocular Delivery") from joint development under the agreement, and product rights to aflibercept in Intraocular Delivery reverted to Regeneron. In connection with this amendment, sanofi-aventis made a \$25.0 million non-refundable payment to Regeneron (the "Intraocular Termination Payment") in January 2005.

In December 2005, the Company and sanofi-aventis amended the Aventis Agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a \$25.0 million non-refundable, up-front payment to the Company, which was received in January 2006. Under the Aventis Agreement, as amended, the Company and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan, for disease indications

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

included in the companies' collaboration. The Company is entitled to a royalty of approximately 35% on annual sales of affibercept in Japan, subject to certain potential adjustments. The Company may also receive up to \$400.0 million in additional milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 million in milestone payments related to the receipt of marketing approvals for up to eight affibercept oncology and other indications in the United States or the European Union. Another \$40.0 million of milestone payments relate to receipt of marketing approvals for up to five affibercept oncology indications in Japan.

Under the Aventis Agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of these development expenses, or half of \$306.8 million as of December 31, 2007, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits and Japan royalties, or at a faster rate at Regeneron's option. Regeneron has the option to conduct additional pre-Phase III studies at its own expense. In connection with the January 2005 amendment to the Aventis Agreement, the Intraocular Termination Payment of \$25.0 million will be considered an aflibercept development expense and will be subject to 50% reimbursement by Regeneron to sanofi-aventis, as described above, if the collaboration becomes profitable. In addition, if the first commercial sale of an aflibercept product in Intraocular Delivery predates the first commercial sale of an aflibercept product under the collaboration by two years, Regeneron will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, Regeneron's obligation to reimburse sanofi-aventis, for 50% of aflibercept development expenses will terminate, and the Company will retain all rights to aflibercept.

Revenue related to payments from sanofi-aventis under the Aventis Agreement, as amended, is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The up-front payments received in September 2003 and January 2006, of \$80.0 million and \$25.0 million, respectively, and reimbursement of Regeneron-incurred development expenses, are being recognized as contract research and development revenue over the related performance period. The Company recognized \$47.1 million, \$47.8 million, and \$43.4 million of contract research and development revenue in 2007, 2006, and 2005, respectively, in connection with the Aventis Agreement, as amended. The Company also recognized the \$25.0 million Intraocular Termination Payment as other contract income in 2005. At December 31, 2007 and 2006, amounts receivable from sanofi-aventis totaled \$10.5 million and \$6.9 million, respectively, and deferred revenue was \$61.2 million and \$70.0 million, respectively, in connection with the Aventis Agreement.

Antibodies

In November 2007, the Company entered into a global, strategic collaboration (the "Antibody Collaboration") with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. In connection with the collaboration, in December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for \$312.0 million (see Note 9).

The Antibody Collaboration is governed by a Discovery and Preclinical Development Agreement (the "Discovery Agreement") and a License and Collaboration Agreement (the "License Agreement"). The Company received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the Discovery Agreement. In addition, sanofi-aventis will fund up to \$475.0 million of the Company's research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against such targets through December 31, 2012, subject to specified funding limits of \$75.0 million for the period from the collaboration's inception through December 31, 2008, and \$100.0 million annually in each of the next four years. The Discovery

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the Discovery Agreement, sanofi-aventis has the option to license rights to the candidate under the License Agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with the Company through product approval. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the License Agreement, the Company will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. Upon inception of the Antibody Collaboration, the Company and sanofi-aventis began co-developing the first therapeutic antibody, REGN88, under the License Agreement.

Under the License Agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") will be shared 80% by sanofi-aventis and 20% by Regeneron. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of \$0.7 million as of December 31, 2007) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products.

Sanofi-aventis will lead commercialization activities for products developed under the License Agreement, subject to the Company's right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (Regeneron) and ending at 55% (sanofi-aventis)/45% (Regeneron), and losses outside the United States at 55% (sanofi-aventis)/45% (Regeneron). In addition to profit sharing, the Company is entitled to receive up to \$250.0 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured.

With respect to each antibody product which enters development under the License Agreement, sanofi-aventis or the Company may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. The Company may also opt-out of the further development of an antibody product if it gives notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the License Agreement. Each of the Discovery Agreement and the License Agreement contains other termination provisions, including for material breach by the other party and, in the case of the Discovery Agreement, a termination right for sanofi-aventis under certain circumstances, including if certain minimal criteria for the discovery program are not achieved. Prior to December 31, 2012, sanofi-aventis has the right to terminate the Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to the Company the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate. Upon expiration of the Discovery Agreement, sanofi-aventis has an option to license the Company's VelocImmune technology for agreed upon consideration.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Revenue related to payments from sanofi-aventis under the Antibody Collaboration is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The \$85.0 million up-front payment received in December 2007 and reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements are being recognized as contract research and development revenue over the related performance period. In connection with the Antibody Collaboration, the Company recognized \$4.6 million of contract research and development revenue in 2007. In addition, at December 31, 2007, amounts receivable from sanofi-aventis totaled \$3.7 million and deferred revenue was \$84.1 million.

b. Bayer HealthCare LLC

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer HealthCare made a non-refundable, up-front payment to the Company of \$75.0 million. In addition, the Company is eligible to receive up to \$110.0 million in development and regulatory milestones related to the VEGF Trap-Eye program, of which the Company received a \$20.0 million milestone payment in August 2007 in connection with the initiation of a Phase 3 trial of the VEGF Trap-Eye in the neovascular form of age-related macular degeneration ("wet AMD"). The Company is also eligible to receive up to an additional \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer HealthCare out of its share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$25.4 million as of December 31, 2007) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. Within the United States, the Company is responsible for any future commercialization of the VEGF Trap-Eye and retains exclusive rights to any future profits from commercialization.

Agreed upon development expenses incurred by both companies in 2007 under a global development plan were shared as follows: The first \$50.0 million were shared equally and the Company was solely responsible for up to the next \$40.0 million. Neither party was reimbursed for any development expenses that it incurred prior to 2007

In 2008, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$70.0 million will be shared equally, the Company is solely responsible for up to the next \$30.0 million; and over \$100.0 million will be shared equally. In 2009 and thereafter, all development expenses will be shared equally. Regeneron is also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

Bayer HealthCare has the right to terminate the Bayer Agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to the VEGF Trap-Eye.

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue for financial statement purposes. In the fourth quarter of 2007, Regeneron and Bayer HealthCare approved a global development plan for the VEGF Trap-Eye in wet AMD. The plan includes estimated development steps, timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. In addition, in the fourth quarter of 2007, Regeneron and Bayer

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for the VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's VEGF Trap-Eye development expenses, and the financial statement classifications and periods in which past and future payments from Bayer HealthCare (including the \$75.0 million up-front payment and development and regulatory milestone payments) and cost-sharing of VEGF Trap-Eye development expenses will be recognized in the Company's Statement of Operations.

The \$75.0 million up-front licensing payment and \$20.0 million milestone payment (which was not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue over the related estimated performance period in accordance with SAB 104 and EITF 00-21 (see Note 2). In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse. In the fourth quarter of 2007, when the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, the Company recognized, as a cumulative catch-up, contract research and development revenue of \$35.9 million, consisting of (i) \$15.9 million related to the \$75.0 million up-front licensing payment and the \$20.0 million milestone payment, and (ii) \$20.0 million related to the portion of the Company's 2007 VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In addition, in the fourth quarter of 2007, the Company recognized as additional research and development expenses that the Company was obligated to reimburse to Bayer HealthCare.

At December 31, 2007, in connection with cost-sharing of VEGF Trap-Eye development expenses under the collaboration, \$4.9 million was payable to Bayer HealthCare and \$2.8 million was receivable from Bayer HealthCare. In addition, at December 31, 2007 and 2006, deferred revenue from the Company's collaboration with Bayer HealthCare was \$79.1 million and \$75.0 million, respectively.

c. The Procter & Gamble Company

In May 1997, the Company entered into a long-term collaboration with The Procter & Gamble Company to discover, develop, and commercialize pharmaceutical products, and Procter & Gamble agreed to provide funding for Regeneron's research efforts related to the collaboration. In accordance with the companies' collaboration agreement (the "P&G Agreement"), Procter & Gamble was obligated to fund Regeneron research on therapeutic areas that were of particular interest to Procter & Gamble through December 2005, with no further research obligations by either party thereafter. Under the P&G Agreement, research support from Procter & Gamble was \$2.5 million per quarter, plus adjustments for inflation, through December 2005.

In June 2005, the Company and Procter & Gamble amended the P&G Agreement. Pursuant to the terms of the modified agreement, the Company and Procter & Gamble agreed that the research activities of the parties under the P&G Agreement were completed on June 30, 2005, six months prior to the December 31, 2005 expiration date in the P&G Agreement. In connection with the amendment, Procter & Gamble made a one-time \$5.6 million payment to Regeneron and the Company paid approximately \$1.0 million to Procter & Gamble to acquire certain capital equipment owned by Procter & Gamble and located at the Company's facilities. Procter & Gamble and the Company divided rights to research programs and pre-clinical product candidates that were developed during the research term of the P&G Agreement. Neither party has the right to participate in the development or commercialization of the other party's product candidates. The Company is entitled to receive royalties based on any future

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

product sales of a Procter & Gamble pre-clinical candidate arising from the collaboration, and Procter & Gamble is entitled to receive a small royalty on any sales of a single Regeneron candidate that is currently not being developed. Neither party is entitled to receive royalties or other payments based on any other products arising from the collaboration.

Contract research and development revenue related to the Company's collaboration with Procter & Gamble was \$6.0 million in 2005. In addition, the one-time \$5.6 million payment made by Procter & Gamble to the Company in connection with the amendment to the P&G Agreement was recognized as other contract income in 2005.

d. Serono, S.A. (now part of Merck KGaA)

In December 2002, the Company entered into an agreement (the "Serono Agreement") with Serono S.A. to use Regeneron's proprietary *VelociGene®* technology platform to provide Serono with knock-out and transgenic mammalian models of gene function ("Materials"). The Serono Agreement contains provisions for minimum yearly order quantities. In connection with its orders for Materials, Serono makes advance payments to Regeneron, which are accounted for as deferred revenue. Regeneron recognizes revenue and reduces the deferred revenue balance as Materials are shipped to and accepted by Serono. In 2007, 2006, and 2005, the Company recognized \$2.4 million, \$1.8 million, and \$2.2 million, respectively, of contract research and development revenue in connection with the Serono Agreement.

e. National Institutes of Health

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. The NIH grant provides a minimum of \$17.9 million in funding over a five-year period, subject to compliance with its terms and annual funding approvals, for the Company's use of its *VelociGene* technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells which can be used to produce knockout mice. The Company will also receive another \$1.0 million in funding to optimize certain existing technology for use in the Knockout Mouse Project. In 2007 and 2006, the Company recognized contract research and development revenue of \$5.5 million and \$0.5 million, respectively, from the NIH Grant.

12. Technology Licensing Agreements

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize the Company's *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable, up-front payment to the Company which was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. AstraZeneca is required to make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's *VelocImmune* technology. In connection with the AstraZeneca license agreement, for the year ended December 31, 2007, the Company recognized \$17.1 million of revenue and, at December 31, 2007, deferred revenue was \$2.9 million.

In March 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable, up-front payment to the Company, which was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. Astellas is required to make up to five additional annual payments of

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

\$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's VelocImmune technology. In connection with the Astellas license agreement, for the year ended December 31, 2007, the Company recognized \$11.3 million of revenue and, at December 31, 2007, deferred revenue was \$8.7 million.

13. Manufacturing Agreement

During 1995, the Company entered into a long-term manufacturing agreement with Merck & Co., Inc., as amended, (the "Merck Agreement") to produce an intermediate (the "Intermediate") for a Merck pediatric vaccine at the Company's Rensselaer, New York facility. The Company modified portions of its facility for manufacture of the Intermediate and assisted Merck in securing regulatory approval for such manufacture in the Company's facility. The Merck Agreement called for the Company to manufacture Intermediate for Merck for a specified period of time (the "Production Period"), with certain minimum order quantities each year. The Production Period commenced in November of 1999 and originally extended for six years. In February 2005, the Company and Merck amended the Merck Agreement to extend the Production Period through October 2006, at which time the Merck Agreement terminated.

Merck agreed to reimburse the Company for the capital costs to modify the facility ("Capital Costs"). Merck also agreed to pay an annual facility fee (the "Facility Fee") of \$1.0 million beginning March 1995, subject to annual adjustment for inflation. During the Production Period, Merck agreed to reimburse the Company for certain manufacturing costs, pay the Company a variable fee based on the quantity of Intermediate supplied to Merck, and make additional bi-annual payments ("Additional Payments"), as defined. In addition, Merck agreed to reimburse the Company for the cost of Company activities performed on behalf of Merck prior to the Production Period and for miscellaneous costs during the Production Period ("Internal Costs"). These payments were recognized as contract manufacturing revenue as follows: (i) payments for Internal Costs were recognized as the activities were performed, (ii) the Facility Fee and Additional Payments were recognized over the period to which they related, (iii) payments for Capital Costs were deferred and recognized as Intermediate was shipped to Merck, and (iv) payments related to the manufacture of Intermediate during the Production Period ("Manufacturing Payments") were recognized after the Intermediate was tested and approved by, and shipped (FOB Shipping Point) to, Merck.

In 2006 and 2005, Merck contract manufacturing revenue totaled \$12.3 million and \$13.7 million, respectively. Such amounts include \$1.2 million and \$1.4 million of previously deferred Capital Costs, respectively.

14. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan") which, as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant. The maximum term of options that have been awarded under the 2000 Incentive Plan is ten years.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the Restricted Stock, which has not vested, will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts, if any, paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

Phantom Stock awards provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of the Company's Common Stock as determined by the Committee, equal to the sum of the fair market value of a share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests. Stock Bonus awards are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Company's Common Stock. Subject to the provisions of the 2000 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

During 1990, the Company established the 1990 Incentive Plan which, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, received awards as determined by a committee of independent directors. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. Awards under the 1990 Incentive Plan consisted of Incentive Stock Options and Nonqualified Stock Options which generally vested on a pro rata basis over a three or five year period and have a term of ten years.

The 1990 and 2000 Incentive Plans contain provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined.

As of December 31, 2007, there were 744,879 shares available for future grants under the 2000 Incentive Plan.

a. Stock Options

Transactions involving stock option awards during 2005, 2006, and 2007 under the 1990 and 2000 Incentive Plans are summarized in the table below.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Stock Options:	Number of Shares	Weighte Averag Exercise F	e	Weighted- Average Remaining Contractual Term (in years)		ntrinsic Value housands)
Outstanding at December 31, 2004	15,140,568	S	18.68			
2005:						
Granted	4,551,360	\$	10.08			
Forfeited	(1,975,108)	\$	20.83		00000000000000	
Expired	(2,399,410)	\$	30,18			
Exercised	(597,918)	\$	9.50	500000000000000000000000000000000000000	200000000000000	000000000000000000
Outstanding at December 31, 2005	14,719,492	\$	14,23			
2006: Granted	2.742.260	e e	19.59			
Forfeited	(338.122)	\$ \$	10.51			
Expired	(172.218)	S	24.23			
Exercised	(1,408,907)	\$	9.84			
Outstanding at December 31, 2006	15.542.505	\$	15.54			500000000000000000000000000000000000000
2007:	13,372,303					200000000000000000000000000000000000000
Granted	3.415.743	\$	21.78			
Forfeited	(220,342)	\$	14.43		*************	
Expired	(50,759)	\$	13,73			
Exercised	(1,014,791)	\$	10.58			
Outstanding at December 31, 2007	17,672,356	\$	17.05	6,68	\$	146,827
Vested and expected to vest at December 31, 2007	16,945,428	\$	17.09	6.62	\$	140,881
Exercisable at December 31, 2005	7,321,256	\$	17.79			
Exercisable at December 31, 2006	7,890,856	\$	17.41			
Exercisable at December 31, 2007	9,369,665	\$	17.02	5.27	\$	86,252

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2007, 2006, and 2005 was \$12.6 million, \$13.2 million, and \$1.6 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The Company grants stock options with exercise prices that are equal to or greater than the market price of the Company's Common Stock on the date of grant. The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2005, 2006, and 2007.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

	Number of Options Granted	Weighted- Average Exercise Price	Weighted- Average Fair Value
2005;	4 551 260	e 10.00	¢ ((0
Exercise price equal to market price 2006:	4,331,360		
Exercise price equal to market price 2007:			
Exercise price equal to market price	3,415,743	\$ 21.78	\$ 11.13

The following table summarizes stock option information as of December 31, 2007:

		Options Outstanding					e
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life	Weigh Avera Exercise	ige	Number Exercisable	A	eighted- verage cise Price
\$ 4.83 to \$ 8.50	2,075,472	3,35	\$	8.19	840,272	\$	7.80
\$ 8.52 to \$ 9.49	2,539,210	5.76	\$	9.30	1,973,719	\$	9.26
\$ 9.50 to \$11.64	2,122,728	7.79	\$	11.61	1,028,792	\$	11,59
\$11.70 to \$17.89	2,300,442	6.28	\$	13.47	2,018,882	\$	13.25
\$18.17 to \$20.32	3,481,247	7.91	\$	19.96	1,496,971	S	19.73
\$20.79 to \$27.07	3,221,553	9.72	\$	22.05	79,325	\$	23.50
\$27.53 to \$37.94	1,871,704	3,45	\$	32.85	1,871,704	\$	32.85
\$51.56 to \$51.56	60,000	2.16	\$	51.56	60,000	\$	51.56
\$ 4.83 to \$51.56	17,672,356	5.68	\$	17.05	9,369,665	\$	17.02

Non-cash stock-based employee compensation expense recognized in operating expenses is provided in Note 2. As of December 31, 2007, there was \$60.6 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years. In addition, there are 723,092 options which are unvested as of December 31, 2007 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2.7 million and will begin to be recognized only if, and when, these options' performance condition is considered to be probable of attainment.

Fair value Assumptions:

The fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Incentive Plan during 2007, 2006, and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The following table summarizes

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

the weighted average values of the assumptions used in computing the fair value of option grants during 2007, 2006, and 2005.

	2007	2006	2005
Expected volatility	53%	67%	71%
Expected lives from grant date	5.6 years	6.5 years	5.9 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	3,60%	4.51%	4.16%

2005 Stock Option Exchange:

In December 2004, the Company's shareholders approved a stock option exchange program. Under the program, Company regular employees who work an average of 20 hours per week, other than the Company's chairman and the Company's president and chief executive officer, were provided the opportunity to make a one-time election to surrender options granted under the 1990 and 2000 Incentive Plans that had an exercise price of at least \$18.00 and exchange them for replacement options granted under the 2000 Incentive Plan in accordance with the following exchange ratios:

	Exchange Katio
	(Number of Eligible
	Options to be
	Surrendered and
	Cancelled for Each
Exercise Price of Eligible Options	Replacement Option)
\$18.00 to \$28.00	1.50
\$28.01 to \$37.00	2.00
\$37.01 and up	3.00

Participation in the stock option exchange program was voluntary, and non-employee directors, consultants, former employees, and retirees were not eligible to participate. The participation deadline was January 5, 2005 and 329 eligible employees participated in the program. These employees elected to exchange options with a total of 3,665,819 underlying shares of Common Stock, and the Company issued 1,977,840 replacement options with an exercise price of \$8.50 per share on January 5, 2005

Each replacement option was completely unvested upon grant. Each replacement option granted to an employee other than our executive vice president and senior vice presidents will ordinarily become vested and exercisable with respect to one-fourth of the shares initially underlying such option on each of the first, second, third and fourth anniversaries of the grant date so that such replacement option will be fully vested and exercisable four years after it was granted. Each replacement option granted to the Company's executive vice president and senior vice presidents will ordinarily vest with respect to all shares underlying such option if both (i) the Company's products have achieved gross sales of at least \$100 million during any consecutive twelve month period (either directly by the Company or through its licenses) and (ii) the specific executive or senior vice president has remained employed by the Company for at least three years from the date of grant. For all replacement options, the recipient's vesting and exercise rights are contingent upon the recipients continued employment through the applicable vesting date and subject to the other terms of the 2000 Incentive Plan and the applicable option award agreement. As is generally the case with respect to the option award agreements for replacement options include provisions whereby the replacement options may be fully vested in connection with a "Change in Control" of the Company, as defined in the 2000 Incentive Plan.

Under the stock option exchange program, each replacement option has a term equal to the greater of (i) the remaining term of the surrendered option it replaces and (ii) six years from the date of grant of the replacement

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NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

option. This was intended to ensure that the employees who participated in the stock option exchange program would not derive any additional benefit from an extended option term unless the surrendered option had a remaining term of less than six years. In connection with the replacement options issued under the stock option exchange program, the Company will recognize total incremental compensation cost of \$2.0 million over the vesting periods of these options.

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the years ended December 31, 2005 and 2006 is summarized below:

		Ave	hted- rage
	Number of	Gran	t Date
Restricted Stock:	Shares	Fair	Value
Outstanding at December 31, 2004	286,417	\$	12.40
2005: Forfeited	(4,601)	\$	11.70
Released	(186,628)	\$	13.05
Outstanding at December 31, 2005	95,188	\$	11.16
2006: Forfeited	(1,703)	\$	9.74
Released	(93,485)	\$	11.18
Outstanding at December 31, 2006			
2007: Granted	500,000	\$	21.92
Outstanding at December 31, 2007	500,000	\$	21.92

In December 2007, the Company awarded a grant of Restricted Stock to the Company's executive vice president. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to grants of Restricted Stock awards. This amount is based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restriction on these shares lapse, which is five years for the grant made in 2007, approximately two years for grants made in 2003, and 18 months for grants made in 2004. In addition, unearned compensation in Stockholders' Equity is reduced due to forfeitures of Restricted Stock resulting from employee terminations. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation is combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

In connection with the 2007 grant of Restricted Stock, the Company recorded unearned compensation in Stockholder's Equity of \$11.0 nillion, which was combined with additional paid-in capital. In connection with forfeitures of past Restricted Stock awards, the Company reduced unearned compensation by \$17 thousand and \$0.1 million in 2006 and 2005, respectively. The Company recognized non-cash compensation expense from Restricted Stock awards of \$0.1 million, \$0.3 million, and \$1.9 million in 2007, 2006, and 2005, respectively. As of December 31, 2007, there were 500,000 unvested shares of Restricted Stock outstanding and \$10.9 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses.

15. Executive Stock Purchase Plan

In 1989, the Company adopted an Executive Stock Purchase Plan (the "Plan") under which 1,027,500 shares of Class A Stock were reserved for restricted stock awards. The Plan provides for the compensation committee of the board of directors to award employees, directors, consultants, and other individuals ("Plan participants") who render service to the Company the right to purchase Class A Stock at a price set by the compensation committee. The Plan provides for the vesting of shares as determined by the compensation committee and, should the

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Company's relationship with a Plan participant terminate before all shares are vested, unvested shares will be repurchased by the Company at a price per share equal to the original amount paid by the Plan participant. During 1989 and 1990, a total of 983,254 shares were issued, all of which vested as of December 31, 1999. As of December 31, 2007, there were 44,246 shares available for future grants under the Plan.

16. Employee Savings Plan

In 1993, the Company adopted the provisions of the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan provide for employees who have met defined service requirements to participate in the Savings Plan by electing to contribute to the Savings Plan a percentage of their compensation to be set aside to pay their future retirement benefits, as defined. The Savings Plan, as amended and restated, provides for the Company to make discretionary contributions ("Contribution"), as defined. The Company recorded Contribution expense of \$1.4 million in 2007, \$1.3 million in 2006, and \$2.0 million in 2005; such amounts were accrued as liabilities at December 31, 2007, 2006, and 2005, respectively. During the first quarter of 2008, 2007, and 2006, the Company contributed 58,575, 64,532, and 120,960 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

17. Income Taxes

In 2007, 2006, and 2005, the Company incurred net losses for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes has been recorded in the accompanying financial statements.

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2007 and 2006 was as follows:

	2007	2006
Deferred tax assets:		
Net operating loss carry-forward	5 166,714	\$ 177,034
Fixed assets	17,245	15,640
Deferred revenue	96,148	58,739
Deferred compensation	15,159	14,213
Research and experimental tax credit carry-forward	25,446	23,248
Capitalized research and development costs	15,236	19,555
Other	7,036	3,897
Valuation allowance	(342,984)	(312,326)
	_	_

The Company's valuation allowance increased by \$30.7 million in 2007, due primarily to the temporary difference related to deferred revenue, principally resulting from the non-refundable up-front payment received from sanofi-aventis in December 2007 (see Note 11). In 2006, the Company's valuation allowance increased by \$41.6 million, due primarily to increases in the Company's net operating loss carry-forward and the temporary difference related to deferred revenue, principally resulting from the non-refundable up-front payment received from Bayer HealthCare in 2006 (see Note 11).

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 ("FIN 48"), Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109. The implementation of FIN 48 had no impact on the Company's financial statements as the Company has not recognized any uncertain income tax positions.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

The Company is primarily subject to U.S. federal and New York State income tax. For all years presented, the Company's effective income tax rate is zero. The difference between the Company's effective income tax rate and the Federal statutory rate of 35% is attributable to state tax benefits and tax credit carry-forwards offset by an increase in the deferred tax valuation allowance. The Company's 1992 and subsequent tax years remain open to examination by U.S. federal and state tax authorities.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of January 1 and December 31, 2007, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2007, the Company had available for tax purposes unused net operating loss carry-forwards of \$423.2 million which will expire in various years from 2008 to 2027 and included \$12.7 million of net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of Incentive Stock Options, the tax benefit from which, if realized, will be credited to additional paid-in capital. The Company's research and experimental tax credit carry-forwards expire in various years from 2008 to 2027. Under the Internal Revenue Code and similar state provisions, substantial changes in the Company's ownership have resulted in an annual limitation on the amount of net operating loss and tax credit carry-forwards that can be utilized in future years to offset future taxable income. This annual limitation may result in the expiration of net operating losses and tax credit carry-forwards before utilization.

18. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition. Costs associated with the Company's resolution of legal proceedings are expensed as incurred.

19. Net Loss Per Share Data

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. In 2007, 2006, and 2005, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	December 31,		
	2007	2006	2005
Net loss (Numerator)	\$ (105,600)	\$ (102,337)	\$ (95,446)
Weighted-average shares, in thousands (Denominator)	66,334	57,970	55,950
Basic and diluted net loss per share	\$ (1.59)	\$ (1,77)	\$ (1.71)

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Shares issuable upon the exercise of options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the diluted per share amounts because their effect would have been antidilutive, include the following:

		December 31,	
	2007	2006	2005
Options:			
Weighted average number, in thousands	15,385	14,139	13,299
Weighted average exercise price	\$ 15,97	\$ 14.41	\$ 14.59
Restricted Stock:			
Weighted average number, in thousands	21	23	165
Convertible Debt:			
Weighted average number, in thousands	6,611	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25	\$ 30.25

In connection with the Company's stock option exchange program (see Note 14), on January 5, 2005, eligible employees elected to exchange options with a total of 3,665,819 underlying shares of Common Stock, and the Company issued 1,997,840 replacement options with an exercise price of \$8.50 per share.

20. Segment Information

Through 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. This segment includes revenues and expenses related to activities conducted under research and development agreements (see Note 11) and technology licensing agreements (see Note 12).

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006 and 2005, the Company produced a vaccine intermediate for Merck & Co., Inc. under a manufacturing agreement, which expired in October 2006 (see Note 13).

The accounting policies for the segments are the same as those described in Note 2, Summary of Significant Accounting Policies. Due to the expiration of the Company's manufacturing agreement with Merck in October 2006, beginning in 2007, the Company only has a research and development business segment. Therefore, segment information has not been provided for 2007 in the table below.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

The following table presents information about reported segments for the years ended December 31, 2006 and 2005.

	Research & Development	Contract Manufacturing	Reconciling Items	Total
2006	<u></u>			
Revenues	\$ 51,136	\$ 12,311		\$ 63,447
Depreciation and amortization	13,549	(1)	\$ 1,043	14,592
Non-cash compensation expense	18,357	318	(813)(2)	17,862
Interest expense			12,043	12,043
Net income (loss)	(111,820)	4,165	5,318(3)	(102,337)
Capital expenditures	3,339		<u></u>	3,339
Total assets	56,843	3	528,244(4)	585,090
2005				
Revenues	\$ 52,447	\$ 13,746	_	\$ 66,193
Depreciation and amortization	14,461	—(I)	\$ 1,043	15,504
Non-cash compensation expense	21,492	367		21,859
Interest expense			12,046	12,046
Other contract income	30,640		····	30,640
Net income (loss)	(97,970)	4,189	(1,665)(3)	(95,446)
Capital expenditures	4,667			4,667
Total assets	95,645	4,315	323,541(4)	423,501

⁽¹⁾ Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

21. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2007 and 2006 are set forth in the following tables.

	First Quarter Ended March 31, 2007	Second Quarter Ended June 30, 2007	Third Quarter Ended September 30, 2007	Fourth Quarter Ended December 31, 2007 (1)
			ıdited)	
Revenues	\$ 15,788	\$ 22,195	\$ 22,311	\$ 64,730
Net loss Net lose per chare basic and diluted	(29,917)	(26,774)	(35,838)	(13,071)

⁽²⁾ Represents the cumulative effect of adopting SFAS 123R (see Note 2).

⁽³⁾ Represents investment income net of interest expense related to convertible notes issued in October 2001 (see Note 10). For the year ended December 31, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 2).

⁽⁴⁾ Includes cash and cash equivalents, marketable securities, restricted cash (where applicable), prepaid expenses and other current assets, and other assets.

NOTES TO FINANCIAL STATEMENTS — (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

	First Quarter Ended March 31, 2006	Second Quart Ended June 30, 2006		nird Quarter Ended ptember 30, 2006	Fourth Quarter Ended December 31, 2006
			(Unaudited)		
Revenues	\$ 18,219	\$ 19),258 \$	15,624	\$ 10,346
Net loss before cumulative effect of a change in accounting principle	(21,193)	(23	3,576)	(27,410)	(30,971)
Net loss	(20,380	(2:	1,576)	(27,410)	(30,971)
Net loss per share, basic and diluted:					
Net loss before cumulative effect of a change in accounting principle	\$ (0.37)	\$	(0.41) \$	(0.48)	\$ (0.51)
Net loss	\$ (0.36)	\$	(0.41) \$	(0.48)	\$ (0.51)

⁽¹⁾ As described in Note 11, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. As a result, in the fourth quarter of 2007, when the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, the Company recognized contract research and development revenue from Bayer HealthCare of \$35.9 million and additional research and development expense of \$10.6 million.

EXHIBIT INDEX

Exhibit Number	Deceri	ntio	n.
	_ Descri	-	
3.1	(-)		Restated Certificate of Incorporation, filed February 11, 2008 with the New York Secretary of State.
	(a)		By-Laws of the Company, currently in effect (amended through November 9, 2007).
	(b)		1990 Amended and Restated Long-Term Incentive Plan.
	(c)		2000 Long-Term Incentive Plan.
	(d)		Amendment No. 1 to 2000 Long-Term Incentive Plan, effective as of June 14, 2002. Amendment No. 2 to 2000 Long-Term Incentive Plan, effective as of December 20, 2002.
	(d)		
	(e)		Amendment No. 3 to 2000 Long-term Incentive Plan, effective as of June 14, 2004.
	(f)		Amendment No. 4 to 2000 Long-term Incentive Plan, effective as of November 15, 2004.
	(g)		Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers.
10.3.6	(g)	_	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.3.7	(h)	_	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers.
10.4	(d)	_	Employment Agreement, dated as of December 20, 2002, between the Company and Leonard S. Schleifer, M.D., Ph.D.
	(i)		Employment Agreement, dated as of December 31, 1998, between the Company and P. Roy Vagelos, M.D.
10.6	(j)	_	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, effective as of February 1, 2006.
	(k)	_	Indenture, dated as of October 17, 2001, between Regeneron Pharmaceuticals, Inc. and American Stock Transfer & Trust Company, as
			trustee.
10.8	(k)	_	Registration Rights Agreement, dated as of October 17, 2001, among Regeneron Pharmaceuticals, Inc., Merrill Lynch & Co., Merrill Lynch, Pierce, Fenner & Smith Incorporated, and Robertson Stephens, Inc.
10.9*	(1)	_	IL-1 License Agreement, dated June 26, 2002, by and among the Company, Immunex Corporation, and Amgen Inc.
	(m)		Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals
	()		Corporation, and the Company.
10.11*	(n)	_	Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.11.1*	(i)	_	Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 31, 2004.
10,11,2	(o)		Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.,
10,11,2	(0)	_	effective as of January 7, 2005.
10,11,3*	(p)	_	Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.,
	47		effective as of December 21, 2005.
10.11.4*	(p)	_	Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals,
10.12			Inc.) and Regeneron Pharmaceuticals, Inc., effective as of January 31, 2006.
10.12	(n)	_	Stock Purchase Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
10.13*	(q)		License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron
10.15	(q)	_	Pharmaceuticals, Inc.
10.14*	(r)	_	Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007 by and between AstraZeneca UK Limited and
	. /		Regeneron Pharmaceuticals, Inc.

E.	Knibit			
	Number	Descri	ption	1
	10.15	(s)	_	Lease, dated as of December 21, 2006, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc.
	10.16*	(t)	_	Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
	10.17*	(u)	_	First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
	10.18*		_	Discovery and Preclinical Development Agreement, dated as of November 28, 2007, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc.
	10.19*		_	License and Collaboration Agreement, dated as of November 28, 2007, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord and Regeneron Pharmaceuticals, Inc.
	10.20		_	Stock Purchase Agreement, dated as of November 28, 2007, by and among sanofi-aventis Amerique du Nord, sanofi-aventis US LLC and Regeneron Pharmaceuticals, Inc.
	10.21		_	Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and Regeneron Pharmaceuticals, Inc.
	12.1		_	Statement re: computation of ratio of earnings to combined fixed charges of Regeneron Pharmaceuticals, Inc.
	23.1		_	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
	31.1		_	Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
	31.2		_	Certification of CFO pursuant to Rule 13a-14 (a) under the Securities and Exchange Act of 1934.
	32		_	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

Evhibit

- (a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.
- (b) Incorporated by reference from the Company's registration statement on Form S-1 (file number 33-39043).
- (c) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2001, filed March 22, 2002.
- (d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2002, filed March 31, 2003.
- (e) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2004, filed August 5, 2004.
- (f) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 17, 2004.
- (g) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.
- (h) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.
- (i) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2004, filed March 11, 2005.
- (j) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 25, 2006.
- (k) Incorporated by reference from the Company's registration statement on Form S-3 (file number 333-74464).
- (l) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.
- (m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.
- (n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 11, 2003.
- (o) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.
- (p) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2005, filed February 28, 2006.

- (q) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed October 18, 2006.
- (r) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2006, filed March 12, 2007.
- (s) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
- (t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended March 31, 2007, filed May 4, 2007.
- (u) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended September 31, 2007, filed November 7, 2007.
- * Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

RESTATED CERTIFICATE OF INCORPORATION OF REGENERON PHARMACEUTICALS, INC.

UNDER SECTION 807 THE BUSINESS CORPORATION LAW

The undersigned hereby certify that:

- 1. The name of the Corporation is Regeneron Pharmaceuticals, Inc. (the "Corporation").
- 2. The Certificate of Incorporation of the Corporation was filed with the Department of State of the State of New York on January 11, 1988.
- 3. This Restated Certificate of Incorporation restates the Certificate of Incorporation, as heretofore amended, without amendment or change to read as herein set forth in full.
 - 4. This Restated Certificate of Incorporation has been authorized by resolution duly adopted by the Corporation's Board of Directors.

Accordingly, the Certificate of Incorporation, as heretofore amended, is hereby restated to be and read in its entirety as follows:

"ARTICLE I

NAME OF CORPORATION

The name of the corporation is Regeneron Pharmaceuticals, Inc. (the "Corporation").

ARTICLE II

CORPORATE PURPOSES

The purpose or purposes for which the Corporation is formed is as follows, to wit:

1

To own, operate, manage and do everything normally associated with conducting the business of chemists, druggists, manufacturers, researchers, distributors, and dealers in medical, pharmaceutical, chemical and other preparations and compounds.

To engage in any lawful act or activity for which corporations may be formed under the Business Corporation Law. The Corporation is not formed to engage in any act or activity requiring the consent or approval of any state official, department, board, agency or other body without such consent or approval first being obtained.

To own, operate, manage, acquire and deal in property, real and personal, which may be necessary to the conduct of the business.

The Corporation shall have all of the powers enumerated in Section 202 of the Business Corporation Law, subject to any limitations provided in the Business Corporation Law or any other statutes in the State of New York.

ARTICLE III

COUNTY OF OFFICE

The county in which the office of the Corporation is to be located in the State of New York is New York.

ARTICLE IV

STOCK

The aggregate number of shares of all classes of capital stock which the Corporation shall have the authority to issue is two hundred and thirty million (230,000,000) shares, consisting of (a) 160,000,000 shares of common stock, par value \$.001 per share ("Common Stock"), (b) 40,000,000 shares of Class A Stock, par value \$.001 per share (the "Class A Stock", and collectively, such Common Stock and Class A Stock are referred to herein as the "Common Shares"), and (c) 30,000,000 shares of preferred stock, par value \$.01 per share.

1. Preferred Stock

The Board of Directors is hereby expressly authorized, by resolution or resolutions, to provide, out of the unissued and undesignated shares of preferred stock, for one or more series of preferred stock. Before any shares of any such series are issued, the Board of Directors shall fix, and hereby is expressly empowered to fix, by resolution or resolutions, the following provisions of the shares thereof:

- (a) the designation of such series, the number of shares to constitute such series, and the stated value thereof if different from the par value thereof;
- (b) whether the shares of such series shall have voting rights, in addition to any voting rights provided by law, and, if so, the terms of such voting rights, which may be general or limited;

- (c) the dividends, if any, payable on such series, whether any such dividends shall be cumulative, and, if so, from what dates, the conditions and dates upon which such dividends shall be payable, the preference or relation which such dividends shall bear to the dividends payable on any shares of stock of any other class or any other series of this class;
- (d) whether the shares of such series shall be subject to redemption by the Corporation, and, if so, the terms and conditions of such redemption, including the manner of selecting shares for redemption if less than all shares of such series are to be redeemed, the date or dates upon or after which they shall be redeemable, and the amount per share payable in case of redemption, which amount may vary under different conditions and at different redemption dates;
- (e) the amount or amounts payable upon shares of such series upon, and the rights of the holders of such series in, the voluntary or involuntary liquidation, dissolution or winding up, or upon any distribution of the assets, of the Corporation, and whether such rights shall be in preference to, or in another relation to, the comparable rights of any other class or classes or series of stock;
- (f) whether the shares of such series shall be subject to the operation of a retirement or sinking fund and, if so, the extent to and manner in which any such retirement or sinking fund shall be applied to the purchase or redemption of the shares of such series for retirement or other corporate purposes and the terms and provisions relative to the operation thereof;
- (g) whether the shares of such series shall be convertible into, or exchangeable for, shares of stock of any other series of this class or any other securities and, if so, the price or prices or the rate or rates of conversion or exchange and the method, if any, of adjusting the same, and any other terms and conditions of conversion or exchange;
- (h) the limitations and restrictions, if any, to be effective while any shares of such series are outstanding upon the payments of dividends or the making of other distributions on, and upon the purchase, redemption or other acquisition by the Corporation of, the Common Stock or shares of stock of any other class or any other series of this class;
- (i) the conditions or restrictions, if any, upon the creation of indebtedness of the Corporation or upon the issue of any additional stock, including additional shares of such series or of any other series of this class or of any other class; and
- (j) any other powers, preferences and relative, participating, optional and other special rights, and any qualifications, limitations and restrictions thereof.

The powers, preferences and relative, participating, optional and other special rights of each series of preferred stock, and the qualifications, limitations of restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. All shares of any one series of preferred stock shall be identical in all respects with all other shares of such series, except that shares of any one series issued at different times may differ as to the dates from which dividends thereon shall accrue and/or be cumulative.

2. Common Stock and Class A Stock

- (a) <u>General</u>. Except as hereinafter expressly set forth in Section 2, and subject to the rights of the holders of preferred stock at any time outstanding, the Class A Stock and the Common Stock, both of which are classes of common stock, shall have the same rights and privileges and shall rank equally, share ratably and be identical in respects as to all matters, including rights in liquidation.
- (b) <u>Voting Rights</u>. Except as otherwise expressly provided by law, and subject to any voting rights provided to holders of preferred stock by this Certificate of Incorporation the Common Shares have exclusive voting rights on all matters requiring a vote of shareholders.

The holders of Common Stock shall be entitled to one vote per share on all matters to be voted on by the shareholders of the Corporation. The holders of Class A Stock shall be entitled to ten votes per share on all matters to be voted on by the shareholders of the Corporation.

Except as otherwise provided in this Certificate of Incorporation or as required by law, the holders of shares of Class A Stock and the holders of shares of Common Stock shall vote together as one class on all matters submitted to a vote of shareholders of the Corporation.

(c) <u>Dividends and Distributions</u>. Subject to the rights of the holders of preferred stock, and subject to any other provisions of this Certificate of Incorporation, as it may be amended from time to time, holders of Class A Stock and Common Stock shall be entitled to receive such dividends and other distributions in cash, in property or in shares of the Corporation as may be declared thereon by the Board of Directors from time to time out of assets or funds of the Corporation legally available therefore; provided, however, that no cash, property or share dividend or distribution may be declared or paid on the outstanding shares of either the Class A Stock or the Common Stock unless an identical per share dividend or distribution is simultaneously declared and paid on the outstanding shares of the other such class of common stock; provided, further, however, that a dividend of shares may be declared and paid in Class A Stock to holders of Class A Stock and in Common Stock to holders of Common Stock if the number of shares paid per share to holders of Class A Stock and to holders of Common Stock shall be the same. If the Corporation shall in any manner subdivide, combine or reclassify the outstanding shares of Class A Stock or Common Stock, the outstanding shares of the other such class of common stock shall be subdivided, combined or reclassified proportionally in the same manner and on the same basis as the outstanding shares of Class A Stock or Common Stock, as the case may be, have been subdivided, combined or reclassified.

(d) Optional Conversion.

- (1) The shares of Common Stock are not convertible into or exchangeable for shares of Class A Stock or any other shares of securities of the Corporation.
- (2) Each share of Class A Stock may be converted, at any time and at the option of the holder thereof, into one fully paid and nonassessable share of Common Stock.

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(e) Mandatory Conversion.

- (1) Upon a Transfer by a Holder, other than to a "Permitted Transferee" of such Holder, shares of Class A Stock so Transferred shall, at midnight on the thirtieth day after delivery of written notice by the Corporation to such Holder that such Transfer has been made to a person other than a Permitted Transferee (for purposes of this paragraph (1), the "Conversion Time"), be automatically converted, without further act on anyone's part, into an equal number of shares of Common Stock, and the stock certificates formerly representing such shares of Class A Stock shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of Class A Stock shall not occur if such shares of Class A Stock, prior to the Conversion Time, are Transferred back to such Holder or to one or more Permitted Transferees of such Holder.
 - (2) For purposes of this Section 2(e): A "Permitted Transferee" of a Holder shall mean, the following:
 - (i) In the case of any Holder, the Corporation or any one or more of its directly or indirectly wholly owned subsidiaries;
 - (ii) In the case of a Holder who is a natural person:
 - (A) The spouse of such Holder (the "Spouse"), any lineal ancestor of such Holder or of the Spouse, and any person who is a lineal descendent of a grandparent of such Holder or of the Spouse, or a spouse of any such lineal descendent or such lineal ancestor (collectively, the "Family Members");
 - (B) A trust (including a voting trust) exclusively for the benefit of one or more of (x) such Holder, (y) one or more of his or her Family Members or (z) any organization to which contributions are deductible under 501(c)(3) of the Internal Revenue Code of 1986, as amended or any successor provision (the "Internal Revenue Code") or for estate or gift tax purposes (a "Charitable Organization"); provided that such trust may include a general or special power of appointment for such Holder or Family Members (a "Trust"); provided, further, that if by reason of any change in the beneficiaries of such Trust, such Trust would not have qualified, at the time of the Transfer of Class A Stock to such Trust (for purposes of this sub-paragraph (B), the "Transfer Date"), as a Permitted Transferee, all shares of Class A Stock so Transferred to such Trust shall, at midnight on the thirtieth day after delivery of written notice by the Corporation to the trustee of such Trust of such change of beneficiary (for purposes of this sub-paragraph (B), the "Conversion Time"), be automatically converted, without further act on anyone's part, into an equal number of shares of Common stock, and the stock certificates formerly representing such shares of Class A Stock

shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; <u>provided</u>, <u>however</u>, that such automatic conversion of such shares of Class A Stock shall not occur if, prior to the Conversion Time, (x) by reason of additional changes in the beneficiary of such Trust, such Trust would again have qualified as a "Permitted Transferee" of such Holder on the Transfer Date, or (y) such Trust Transfers such shares of Class A Stock to one or more persons who would qualify as a Permitted Transferee of the Holder who Transferred such shares to such Trust as if such Holder did not so Transfer such shares;

- (C) A Charitable Organization established solely by one or more of such Holder or a Family Member;
- (D) An Individual Retirement Account, as defined in Section 408(a) of the Internal Revenue Code, of which such Holder is a participant or beneficiary, provided that such Holder has the power to direct the investment of funds deposited into such Individual Retirement Account (an "IRA"):
- (E) A pension, profit sharing, stock bonus or other type of plan or trust of which such Holder is a participant or beneficiary and which satisfies the requirements for qualification under Section 401(k) of the Internal Revenue Code, provided that such Holder has the power to direct the investment of funds deposited into such plan or trust and to control the voting of securities held by such plan or trust (a "Plan");
- (F) Any corporation or partnership directly or indirectly controlled, individually or as a group, only by such Holder and/or any of his Permitted Transferees as determined under this clause (ii); <u>provided</u> that if by reason of any change in the direct or indirect control of such corporation or partnership, such corporation or partnership would not have qualified, at the time of the Transfer of Class A Stock to such corporation or partnership, as a Permitted Transferee of such Holder, all shares of Class A Stock so Transferred to such corporation or partnership shall in the manner set forth in paragraph (d) hereof, be converted into an equal number of shares of Common Stock; and
 - (G) The estate, executor, executrix or other personal representative, custodian, administrator or guardian of such Holder.

- (iii) In the case of a Holder holding the shares of Class A Stock in question as trustee of an IRA, a Plan or a Trust, "Permitted Transferee" means (x) the person who transferred Class A Stock to such IRA, such Plan or such Trust, (y) any Permitted Transferee of any such person determined pursuant to this Section 2(e) and (z) any successor trustee or trustees in such capacity of such IRA, such Plan or such Trust.
- (iv) In the case of a Holder which is a partnership, "Permitted Transferee" means any other person, directly or indirectly controlling, controlled by or under direct or indirect common control with such partnership, <u>provided</u> that, if by reason of any change in the direct or indirect control of such person, such person would not have qualified, at the time of the Transfer of the Class A Stock to such person, as a Permitted Transferee of such partnership, all shares of Class A Stock so Transferred to such person shall, in the manner set forth in paragraph (4) hereof, be converted into an equal number of shares of Common Stock;
- (v) In the case of a Holder which is a corporation (other than a Charitable Organization) "Permitted Transferee" means any other person directly or indirectly controlling, controlled by or under direct or indirect common control with such corporation; provided that if by reason of any change in the direct or indirect control of such person, such person would not have qualified, at the time of the Transfer of the Class A Stock to such person, as a Permitted Transferee of such corporation, all shares of Class A Stock so Transferred to such person shall, in the manner set forth in paragraph (4) hereof, be converted into an equal number of shares of Common Stock; and
- (vi) In the case of a Holder which is the estate of a deceased Holder or who is the executor, executrix or other personal representative, custodian or administrator of such Holder, or guardian of a disabled or adjudicated incompetent Holder or which is the estate of a bankrupt or insolvent Holder, which owns the shares of Class A Stock in question, "Permitted Transferee" means a Permitted Transferee of such deceased, or adjudicated incompetent, disabled, bankrupt or insolvent Holder as otherwise determined pursuant to this Section 2(e).

As used in this Section 2(e), the term "control" means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of the controlled person or entity.

As used in this Section 2(e), the term "Holder" means any holder of Class A Stock or of the proxy to vote shares of Class A Stock.

As used in this Section 2(e), the term "person" shall mean both natural persons and legal entities, unless otherwise specified. The relationship of any person that is derived by or through legal adoption shall be considered a natural relationship.

Each joint owner of shares or owner of a community property interest in shares of Class A Stock shall be considered a "Holder" of such shares. A minor for whom shares of Class A Stock are held pursuant to a Uniform Transfer to Minors Act or similar law shall be considered a Holder of such shares.

As used in this Section 2(e), a "Transfer" shall mean any Type of transfer of shares of Class A Stock, whether by sale, exchange, gift, operation of law, pledge, or otherwise or any transfer of the power to vote such shares by proxy or by transferring any proxy, and shares of Class A Stock shall refer to either (i) such shares of Class A Stock so transferred, (ii) the power to vote such shares so transferred or (iii) shares of Class A Stock for which the power to vote was so transferred, as the case may be.

- (3) Notwithstanding anything to the contrary set forth herein, any Holder may pledge the shares of Class A Stock belonging to such Holder to a pledgee pursuant to a bona fide pledge of such shares as collateral security for indebtedness due to the pledgee, provided that such pledgee does not have the power to vote such shares and such shares remain subject to the provisions of this Section. In the event of foreclosure or other similar action by the pledgee, such shares, at midnight on the thirtieth day after delivery of notice by the Corporation to the pledgor of such foreclosure or other similar action (for purposes of this paragraph (3) the "Conversion Time"), shall be automatically converted, without further act on anyone's part, into an equal number of shares of Common Stock and the stock certificates formerly representing such shares of Class A Stock shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of such shares of Class A Stock shall not occur if, prior to the Conversion Time, (x) such pledged shares of Class A Stock are transferred to a Permitted Transferee of the pledgor or (y) such foreclosure or other similar action is cancelled or annulled so that the pledgor retains the right to vote such shares.
- (4) If by reason of any change of the direct or indirect control of a person subsequent to any Transfer to such person, such person would not have qualified, at the time of the Transfer of the Class A Stock to such person (the "Transfer Date"), as a Permitted Transferee under clause (ii) (F), clause (iv) or clause (v), as the case may be, all shares of Class A Stock Transferred pursuant to the relevant clause to such person shall, at midnight on the thirtieth day after delivery of written notice by the Corporation to such person of such change of the direct or indirect control of such person (the "Conversion Time"), be automatically converted, without further act on anyone's part, into an equal number of shares of Common Stock, and the stock certificates formerly representing such shares of Class A Stock shall thereupon and thereafter be deemed to represent the like number of shares of Common Stock; provided, however, that such automatic conversion of Class A Stock shall not occur if, prior to the Conversion Time, (x) by reason of additional changes in the direct or indirect control of such person, such person would again have qualified on the Transfer Date as a "Permitted Transferee" under clause (ii)(F), clause (iv) or clause (v), as the case may be, or (y) such person Transfers all such shares of Class A Stock owned by such person to one or more persons who would qualify as a "Permitted Transferee" of the transferor of the Class A Stock to such person as if the transferor did not Transfer such shares on the Transfer Date.

- (5) A good faith determination by the Board of Directors of the Corporation (x) that a transferee of shares of Class A Stock is or is not a Permitted Transferee of the transferor of such shares to such transferee on the date of Transfer, or (y) that, by reason of any change in the direct or indirect control of such transferee subsequent to such Transfer, such person would have or have not qualified at the time of the Transfer of the Class A Stock to such person as a Permitted Transferee shall be conclusive.
- (6) All notices provided for herein shall be deemed to have been delivered three days after being sent by registered or certified mail, return receipt requested, postage prepaid, to the person to whom it is directed. If notice is to a Holder, such notice should be sent to him at the address set forth at the office of the Transfer Agent of the Corporation. If notice is to any other person, such notice should be sent to him at the address known by the Corporation at the time the notice is sent.
- (7) The Corporation may, as a condition to the transfer or the registration of transfer of shares of Class A Stock to a purported Permitted Transferee, require the furnishing of such affidavits or other proof as it deems necessary to establish that such transferee is a Permitted Transferee. Each certificate representing shares of Class A Stock shall be endorsed with a legend that states that shares of Class A Stock are not transferable other than to certain transferees and are subject to certain restrictions as set forth in the Certificate of Incorporation of the Corporation filed with the Secretary of the State of New York.
- (8) This Section 2(e) may not be amended without the affirmative vote of holders of the majority of the shares of Class A Stock and the affirmative vote of the holders of two-thirds of the shares of Common Stock, each voting separately as a class.

(f) Conversion Procedures.

(1) Each conversion of shares pursuant to Section 2(d) hereto will be effected by the surrender of the certificate or certificates, duly endorsed, representing the shares to be converted at the principal office of the Corporation at any time during normal business hours, together with a written notice by the holder stating the number of shares that such holder desires to convert and the names or name in which he wishes the certificate or certificates for the Common Stock to be issued. Such conversion shall be deemed to have been effected as of the close of business on the date on which such certificate or certificates have been surrendered, and at such time, the rights of any such holder with respect to the converted shares of such holder will cease and the person or persons in whose name or names the certificate or certificates for shares are to be issued upon such conversion will be deemed to have become the holder or holders of record of such shares represented thereby.

Promptly after such surrender, the Corporation will issue and deliver in accordance with the surrendering holder's instructions the certificate or certificates for the Common Stock issuable upon such conversion and a certificate representing any Class A Stock which was represented by the certificate or certificates delivered to the Corporation in connection with such conversion, but which was not converted.

- (2) The issuance of certificates upon conversion of shares pursuant to Section 2(d) hereto will be made without charge to the holder or holders of such shares for any issuance tax (except stock transfer tax) in respect thereof or other costs incurred by the Corporation in connection therewith.
- (3) The Corporation shall at all times reserve and keep available out of its authorized but unissued shares of Common Stock or its treasury shares, solely for the purpose of issuance upon the conversion of the Class A Stock, such number of shares of Common Stock as may be issued upon conversion, of all outstanding Class A Stock.
- (4) Shares of the Class A Stock surrendered for conversion as above provided or otherwise acquired by the corporation shall be cancelled according to law and shall not be reissued.

ARTICLE V

DESIGNATION OF SECRETARY OF STATE AS AGENT FOR SERVICE OF PROCESS

The Secretary of State is designated as agent of the Corporation upon whom process against it may be served. The post office address to which the Secretary of State shall mail a copy of any process against the Corporation served upon him is:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591

Attention: Secretary

ARTICLE VI

BOARD OF DIRECTORS

The number of Directors of the Corporation constituting the entire Board of Directors shall be not less than three or more than fifteen. The Board of Directors shall determine from time to time the number of Directors who shall constitute the entire Board of Directors. Any such determination made by the Board of Directors shall continue in effect unless and until changed by the Board of Directors, but no such change shall affect the term of any Directors then in office. Directors need not be shareholders of the Corporation.

Commencing at the Annual Meeting of Shareholders held in 1991, the terms of office of the Board of Directors shall be divided into three classes, Class I, Class II and Class III, as shall be determined by the Board of Directors. All classes shall be as nearly equal in number as possible, and no class shall include less than three nor more than nine Directors. Any vacancy on the Board of Directors that results from an increase in the number of Directors and any other vacancy on the Board may be filled only by the Board provided that a quorum is then in office and present, or only by a majority of the Directors then in office, if less than a quorum is then in

office, or by a sole remaining Director. Directors elected to fill a newly created directorship or other vacancies shall be classified and hold office as provided by statute.

The terms of office of the respective classes of directors initially classified shall be as follows: (1) Class I shall expire at the Annual Meeting of Shareholders to be held in 1992; (2) Class II shall expire at the Annual Meeting of Shareholders to be held in 1993; and (3) Class III shall expire at the Annual Meeting of Shareholders to be held in 1994. At each Annual Meeting of Shareholders after the aforementioned initial classification, the successors to Directors whose terms shall then expire shall be elected to serve from the time of election and qualification until the third Annual Meeting following election and until a successor shall have been duly elected and shall have qualified.

The Directors of any class of Directors of the Corporation may not be removed prior to the expiration date of their terms of office except for cause and by an affirmative vote of at least eighty percent (80%) of the outstanding shares of all classes of capital stock of the Corporation entitled to vote for such member(s) of the Board of Directors at the Annual Meeting of Shareholders or at any Special Meeting of Shareholders called by the Board of Directors or by the Chairman of the Board or by the President for this purpose.

ARTICLE VII

LIMITATION OF DIRECTOR AND OFFICER LIABILITY

To the fullest extent now or hereafter permitted under the New York Business Corporation Law, no director or officer of the Corporation shall be personally liable to the Corporation or its shareholders for monetary damages for any breach of fiduciary duty in such capacity. No amendment or repeal of this Article 7 shall adversely affect any right or protection of any director or officer of the Corporation existing at the time of such amendment or repeal with respect to acts or omissions occurring prior to such amendment or repeal.

ARTICLE VIII

PREEMPTIVE RIGHTS

No holder of Common Shares, or preferred stock of any designation or series shall, as such holder, have any right to purchase or subscribe for (i) any stock of any class, or any warrant or warrants, option or options, or other instrument or instruments that shall confer upon the holder or holders thereof the right to subscribe for or purchase or receive from the Corporation any stock of any class or classes which the Corporation may issue or sell, whether or not such stock shall be convertible into or exchangeable for any other stock of the Corporation of any class or classes and whether or not such stock shall be unissued shares authorized by the Certificate of Incorporation or by any amendment thereto or shares of stock of the Corporation acquired by it after the issuance thereof, or (ii) any obligation which the Corporation may issue or sell that shall be convertible into or exchangeable for any shares of stock of the Corporation of any class or classes, or to which shall be attached or appurtenant to any warrant or warrants, option or options or other instrument or instruments that shall confer upon the holder or holders of such obligation the right to subscribe for or purchase or receive from the Corporation any shares of its stock of any class or classes.

Upon any issuance for money or other consideration of any stock of the Corporation that may be authorized from time to time, no holder of stock, irrespective of the kind of such stock, shall have any preemptive or other right to subscribe for, purchase or receive any proportionate or other share of the stock so issued, and the Board of Directors may dispose of all or any portion of such stock as and when it may determine free of any such rights, whether by offering the same to shareholders or by sale or other disposition as said Board may deem advisable."

IN WITNESS WHEREOF, this Restated Certificate of Incorporation has been signed as of the 25th day of January, 2008, and affirmed that the statements made herein are true under penalties of perjury.

onard S. Schleifer, President
Stuart A. Kolinski
art A. Kolinski, Secretary

RESTATED CERTIFICATE OF INCORPORATION

OF

REGENERON PHARMACEUTICALS, INC.

UNDER SECTION 807 OF THE BUSINESS CORPORATION LAW

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP ONE RODNEY SQUARE WILMINGTON, DELAWARE 19801

Portions of this Exhibit Have Been
Omitted and Separately Filed with the Securities
And Exchange Commission with a Request
For Confidential Treatment

DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT By and Between

AVENTIS PHARMACEUTICALS INC.

and

REGENERON PHARMACEUTICALS, INC.

Dated as of November 28, 2007

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DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT

THIS DISCOVERY AND PRECLINICAL DEVELOPMENT AGREEMENT ("<u>Agreement</u>"), dated as of November 28, 2007 (the "<u>Effective Date</u>"), is by and between AVENTIS PHARMACEUTICALS INC. ("<u>Sanofi</u>"), a corporation organized under the laws of Delaware, having a principal place of business at 55 Corporate Boulevard, Bridgewater, New Jersey 08807, an indirect wholly owned subsidiary of Sanofi-Aventis, a company organized under the laws of France with its principal headquarters at 174, avenue de France, 75103 Paris, France ("Sanofi Parent"), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of New York and having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591, USA ("<u>Regeneron</u>") (with each of Sanofi and Regeneron referred to herein individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>").

WHEREAS, Regeneron plans to undertake a broad therapeutic antibody discovery and development program with the objective of identifying and validating potential drug discovery targets for the purpose of discovering fully human monoclonal antibody product candidates against those targets using its proprietary VelocImmune® and related suite of technologies; and

WHEREAS, Sanofi is interested in funding and assisting with Regeneron's plans to discover and validate potential drug discovery targets for the purpose of discovering fully human monoclonal antibody product candidates in exchange for an option to license certain rights to the resulting fully human monoclonal antibodies under the terms set forth in this Agreement and in the License and Collaboration Agreement (as further defined in Article 1 below) to be entered into between the parties contemporaneously with the execution of this Agreement;

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by, or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract, or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of

certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, <u>provided</u> that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates nor shall Regeneron or any of its Affiliates be deemed Affiliates of Sanofi or any of its Affiliates. For purposes of this Agreement, neither Sanofi Pasteur nor Merial Limited, nor any of their respective subsidiaries or joint ventures, shall be deemed to be Affiliates of Sanofi or any of its Affiliates.

- 1.2 "Agreement" shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.
- 1.3 "Alliance Manager" shall have the meaning set forth in Section 3.2.
- 1.4 "Antibody" shall mean *****************************, and any composition or formulation that incorporates or includes any of the foregoing.
- 1.5 "Aventis Collaboration Agreement" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between sanofi-aventis US (as successor in interest to Sanofi) and Regeneron, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, and Section 11.2 of the Stock Purchase Agreement, as the same may be further amended from time to time.
- 1.6 "Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, United States or Paris, France are authorized or required by Law to remain closed.
- 1.7 "Commercially Reasonable Efforts" shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a Target-by-Target and Antibody-by-Antibody (including MTCs) basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors.
- 1.8 "Competing Refused Candidate" shall mean any Refused Candidate having the same Target as a Licensed Product (as long as such Licensed Product is licensed to Sanofi under the License and Collaboration Agreement).
 - 1.9 "Confidential Information" shall have the meaning set forth in Section 9.1.
- 1.10 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2008, and each succeeding twelve (12) month period thereafter during the term

of the Discovery Program (except that the last Contract Year shall end on the effective date of any termination or expiration of this Agreement).

- 1.11 "CPI" shall mean the Consumer Price Index All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).
 - 1.12 "Damages" shall have the meaning set forth in Section 10.1(a).
 - 1.13 "Default Interest Rate" shall have the meaning set forth in Section 4.7.
 - 1.14 "Disclosing Party" shall have the meaning set forth in Section 9.1
 - 1.15 "Discovery Plan" shall have the meaning set forth in Section 2.3.
- 1.17 "<u>Discovery Program Costs</u>" shall mean all Out-of-Pocket Costs, FTE Costs and Manufacturing Costs incurred by Regeneron, after the Effective Date directly in connection with the performance of the Discovery Program (and, as such costs relate to a particular Licensed Product, ending on the last day of the month preceding the month in which the Opt-In Notice for such Licensed Product is received by Regeneron).
 - 1.18 "Effective Date" shall have the meaning set forth in the introductory paragraph.
- 1.19 "Excluded Candidates" shall mean Antibodies (including MTCs) against Targets set forth in Schedule 1.19 as of the Effective Date and those Targets that will be notified by Sanofi to Regeneron pursuant to the second sentence of Section 2.8(b)(i).
- 1.20 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the most senior Research and Development Officer of Sanofi Parent, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.
 - 1.21 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.
 - 1.22 "Force Majeure" shall have the meaning set forth in Article 11.
- 1.23 "FTE" shall mean a full time equivalent employee (i.e., one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed by Regeneron (or its Affiliate) who performs work under the Discovery Program, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be ******* hours per year.
- 1.24 "FTE Cost" shall mean, for all activities performed under the Discovery Program, the product of (a) the number of FTEs performing activities under the Discovery Program and (b) the FTE Rate.

- - 1.26 "GAAP" shall mean generally accepted accounting principles as applicable in the United States.
- 1.27 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body, or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city, or other political subdivision of any such government or any supranational organization of which any such country is a member.
 - 1.28 "IAS/IFRS" shall mean International Financial Reporting Standards adopted by the International Accounting Standards Board.
 - 1.29 "IFM" shall have the meaning set forth in Section 2.11(d)(ii).
- 1.30 "Immunoconjugate" shall mean an Antibody (or derivative or fragment thereof) linked to a cytotoxic or any molecule potentially able to enhance the therapeutic activity of such Antibody (or derivative or fragment thereof).
- 1.31 "IND" shall mean, with respect to each Product Candidate, an Investigational New Drug Application filed with the FDA with respect to such Product Candidate pursuant to 21 C.F.R. § 312 before the commencement of clinical trials involving such Product Candidate, including all amendments and supplements to such application, or any equivalent filing with any Regulatory Authority outside the United States.
- 1.32 "IND Preparation" shall mean all drug development activities in support of a Lead Candidate or Product Candidate up to the filing of the IND for the Phase I Clinical Trial, including, but not limited to, assay development, sample analysis, preclinical toxicology, preclinical pharmacokinetics and toxicokinetics, pharmacological assessment (if applicable), cell line development and protein chemistry sciences, formulation development, clinical trial protocol development, IND drafting and data compilation, and manufacturing preclinical and clinical supplies.
 - 1.33 "Indemnified Party" shall have the meaning set forth in Section 10.2(a).
 - 1.34 "Indemnifying Party" shall have the meaning set forth in Section 10.2(a).
 - 1.35 "Initial Development Plan" shall have the meaning set forth in Section 5.3.
- 1.36 "Investor Agreement" shall mean the Investor Agreement by and between (a) Sanofi, Sanofi Parent, sanofi-aventis US LLC, and Sanofi-Aventis Amerique du Nord and (b) Regeneron, substantially in the form of Exhibit B to the Stock Purchase Agreement, which will be entered into concurrently with the closing under the Stock Purchase Agreement.

- 1.37 "Joint Research Committee" or "JRC" shall mean the Joint Research Committee described in Section 3.1(a).
- 1.38 "Joint Inventions" shall have the meaning set forth in Section 6.1(b).
- 1.39 "Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.
- 1.40 "Know-How" shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information (whether or not patentable or otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party's Patents or Patent Applications.
- 1.41 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions, and/or ordinances of any Governmental Authority in the Territory.
- 1.42 "<u>Lead Candidate</u>" shall mean, for any Program Target, each Antibody, including MTCs, that satisfies the applicable criteria set forth in Schedule 1.42 and is selected by Regeneron to begin IND Preparation under this Agreement.
- 1.43 "<u>License and Collaboration Agreement</u>" shall mean the License and Collaboration Agreement between the Parties, dated as of the date of this Agreement, the terms of which are incorporated by reference into, and are part of, this Agreement.
 - 1.44 "Licensed Product" shall mean any Product Candidate for which Sanofi has exercised its Opt-In Rights pursuant to Section 5.4 below.
 - 1.45 "Licensed Refused Sanofi Candidate" shall have the meaning set forth in Section 2.12.
- 1.46 "Manufacturing Cost" shall mean the fully burdened cost (without mark-up) of manufacturing Product Candidates and Lead Candidates for preclinical activities and Phase I Clinical Trials (and, if agreed by the Parties other clinical trials), and the cost for providing dedicated manufacturing capacity for Lead Candidates and Product Candidates, in each case, as calculated in accordance with Schedule 1.46.
 - 1.47 "Maximum Annual Discovery Program Costs" shall have the meaning set forth in Section 4.2.
 - 1.48 "Mice" shall mean *******************
 - 1.49 "Mice-Derived Therapeutic (or Diagnostic) Candidate" or "MTC" shall mean any Antibody derived from Mice.
 - 1.50 "Modified Clause" shall have the meaning set forth in Section 14.7.
- 1.51 "Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of Royalty Products in the Territory by or on behalf of a Party, or its Affiliates or sublicensees to

Third Parties, less the following deductions, determined in accordance with IAS/IFRS (or GAAP for the US) consistently applied:

- (a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Royalty Products;
 - (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;
 - (c) chargebacks and other amounts paid on sale or dispensing of Royalty Products;
 - (d) Third Party cash rebates and chargebacks related to sales of Royalty Products, to the extent allowed;
 - (e) retroactive price reductions that are actually allowed or granted;
- (f) compulsory refunds, credits and rebates directly related to the sale of Royalty Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or governmental regulations;
- (g) freight, postage, shipment and insurance costs (or wholesaler fees in lieu of those costs) and customs duties incurred in delivering Royalty Products that are separately identified on the invoice or other documentation;
- (h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of Royalty Products, which are separately identified on the invoice or other documentation;
- (i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such Royalty Product falling within categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof;
- (j) invoiced amounts that are written off as uncollectible in accordance with a Party's or its Affiliates' or sublicensees' respective accounting principles as applied consistently

Net Sales in currency other than United States Dollars shall be translated into United States Dollars according to the provisions of <u>Section 4.6</u> of this Agreement.

Sales between the Parties, or between the Parties and their Affiliates or sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Royalty Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if a Party or its Affiliates or sublicensee sells such Royalty Products in the form of a combination

product containing any Royalty Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), then prior to the first commercial sale of such Combination Product, the Parties shall agree on the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, Immunoconjugates shall not be deemed Combination Products.

- 1.52 "Opt-In Notice" shall have the meaning set forth in Section 5.4.
- 1.53 "Opt-In Period" shall have the meaning set forth in Section 5.4.
- 1.54 "Opt-In Report" shall have the meaning set forth in Section 5.2.
- 1.55 "Opt-In Rights" shall have the meaning set forth in Section 5.1.
- 1.56 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP) by Regeneron (or its Affiliate) directly in connection with the performance of the Discovery Program.
 - 1.57 "Party" or "Parties" shall have the meaning set forth in the introductory paragraph.
 - 1.58 "Patent Application" shall mean any application for a Patent.
 - 1.59 "Patent Rights" shall mean unexpired Patents and Patent Applications.
- 1.60 "Patents" shall mean patents together with all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations, extensions, registrations, patent term adjustments or extensions, supplemental protection certificates and renewals of any of the foregoing, and all counterparts thereof in any country in the Territory.
- 1.61 "Person" shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.
 - 1.62 "Phase I Clinical Trial" shall mean the first clinical trial of a Product Candidate following IND Preparation.
- 1.63 "Product Candidate" shall mean any Lead Candidate that substantially completes IND Preparation and is ready to be offered for license to Sanofi under the Opt-In Rights.
- 1.64 "Product Patent Rights" shall mean any Patent or Patent Application having a specification which supports a claim that may be infringed by making, using, selling, importing or exporting a Lead Candidate or Product Candidate in the Discovery Program, including, without limitation, any derivatives, fragments, compositions of matter or uses, thereof.

- 1.65 "Program Target" shall mean a Target that is selected by Regeneron, subject to Section 2.4, as a Target against which Antibodies are to be generated under the Discovery Program.
 - 1.66 "Publishing Party" shall have the meaning set forth in Section 9.3.
 - 1.67 "Receiving Party "shall have the meaning set forth in Section 9.1.
 - 1.68 "Refused Candidate" shall have the meaning set forth in Section 5.6 (i).
 - 1.69 "Regeneron" shall have the meaning set forth in the introductory paragraph.
 - 1.70 "Regeneron Indemnitees" shall have the meaning set forth in Section 10.1(a).
 - 1.71 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and the Regeneron Know-How.
- 1.72 "Regeneron Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Know-How and Know-How included in Joint Inventions) with the right to sublicense the same necessary or useful for the performance of the Discovery Program.
- 1.73 "Regeneron Patent Rights" shall mean those Patent Rights now or hereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Patent Rights and Patent Rights included in Joint Inventions) with the right to sublicense the same and which include at least one (1) claim which would be infringed by the research, development, manufacture or use of the Mice or any Target, Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program.
 - 1.74 "Regeneron Sole Inventions" shall have the meaning set forth in Section 6.1(a).
 - 1.75 "Regeneron Target IP" shall mean ***********************
- 1.76 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the activities conducted under the Discovery Program.

 - 1.78 " Royalty Term "shall have the meaning set forth in Section 4.5.
 - 1.79 "Sanofi "shall have the meaning set forth in the introductory paragraph.
 - 1.80 "Sanofi Divested Antibody" shall have the meaning set forth in Section 2.8(b)(vii).
 - 1.81 "Sanofi Indemnitees" shall have the meaning set forth in Section 10.1(b).

- 1.82 "Sanofi Intellectual Property" shall mean the Sanofi Patent Rights and the Sanofi Know-How.
- 1.83 "Sanofi Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program (including the Tail Period) owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Know-How and Know-How included in Joint Inventions) with the right to sublicense the same necessary or useful for the performance of the Discovery Program.
- 1.84 "Sanofi Patent Rights" shall mean those Patent Rights now or hereafter during the term of the Discovery Program owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Patent Rights and Patent Rights included in Joint Inventions) with the right to sublicense the same and which include at least one (1) claim which would be infringed by the research, development, manufacture or use of the Mice or any Target, Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program.
 - 1.85 "Sanofi Sole Inventions" shall have the meaning set forth in Section 6.1(a).
 - 1.86 "Sanofi Sole Projects" shall have the meaning set forth in Section 2.8(b)(iii).
 - 1.87 "Sanofi Targets" shall have the meaning set forth in Section 2.4.

 - 1.89 "Sole Inventions" shall have the meaning set forth in Section 6.1(a).
 - 1.90 "Solely Developed ***********." shall have the meaning set forth in Section 2.11(b).
- 1.91 "Stock Purchase Agreement" shall mean the Stock Purchase dated as of the Effective Date by and between (a) Sanofi, sanofi-aventis US LLC, and Sanofi-Aventis Amerique du Nord and (b) Regeneron.
 - 1.92 "Tail Period" shall have the meaning set forth in Section 2.9
- 1.93 "Target" shall mean any gene, receptor, ligand, or other molecule (a) potentially associated with a disease activity, and (b) which potentially has a biological activity that is modified by direct interaction with an Antibody, including any MTC, or (c) to which an Antibody, including any MTC, binds.
- 1.94 "<u>Target List</u>" shall mean the list of Targets in the Discovery Program, including a description of the stage of discovery or pre-clinical development of each such Target in the Discovery Program, which list shall be in the form attached as Schedule 1.94, and which list shall be updated by the JRC on a quarterly basis in accordance with <u>Section 3.1(c)</u> below.
 - 1.95 "Term" shall have the meaning set forth in Section 12.1.
 - 1.96 "Territory" shall mean all the countries and territories of the world.

- 1.97 "Third Party" shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.
- 1.98 "Third Party Opportunities" shall have the meaning set forth in Section 2.8(a)(ii).
- 1.99 "Valid Claim" shall mean a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Government Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise.

ARTICLE 2 DISCOVERY PROGRAM

- 2.1 <u>Discovery Program</u>. The objective of the Parties during the Discovery Program is for Regeneron to discover, identify and/or validate Targets from which to select Program Targets, generate Antibodies, including MTCs, against such Program Targets (including Program Targets that are Sanofi Targets) from which to select Lead Candidates, and develop them through IND Preparation to offer to Sanofi for joint development and commercialization under the terms set forth herein and in the License and Collaboration Agreement. During the first five (5) years of the Discovery Program, Regeneron will use Commercially Reasonable Efforts (i) to discover, identify and validate Targets and (ii) to select Program Targets for review and discussion by the JRC pursuant to Section 3.1 herein. *******************************. Regeneron will use Commercially Reasonable Efforts to manufacture preclinical and clinical supplies of the Lead Candidates and Product Candidates for the Discovery Program and the Phase 1 Clinical Trial. The JRC will prioritize the Antibodies, including MTCs, to be further pursued as Lead Candidates, and Regeneron will commence IND Preparation activities only for those Antibodies, including MTCs, that meet the applicable criteria set forth in Schedule 1.42. The JRC will evaluate, select and prioritize Targets for the Target List. However, Regeneron will have the right to conduct Target discovery and validation on Targets as part of the Discovery Program before they are formally approved by the JRC for selection on the Target List but shall notify the JRC of any new Target at the next meeting of the JRC. Subject to Sanofi's selection rights under Section 3.1(e) and the other terms of this Agreement, Regeneron will have sole responsibility for the design and conduct of all activities under the Discovery Program, including, without limitation, decisions relating to initiation and termination of programs and activities, manufacturing activities, and staffing and resource allocation between different programs and activities in the Discovery Program. Sanofi, through the JRC, will provide consultation and advice to support Regeneron's efforts.
- 2.2 <u>Term of the Discovery Program</u>. The Discovery Program shall commence on the Effective Date and shall end on December 31, 2012 unless (a) terminated earlier in accordance with the provisions of this Agreement or (b) extended by Sanofi for the Tail Period pursuant to the terms of Section 2.9.
- 2.3 <u>Discovery Plans</u>. Regeneron will prepare an annual research discovery and pre-clinical development plan (the "<u>Discovery Plan</u>") for the Discovery Program setting forth the

overall strategy, plans, and estimated budget for the Discovery Program for the ensuing Contract Year, which it will submit to the JRC for review and comment. For each Lead Candidate, the Discovery Plan will include activities and a planned timeline for IND Preparation. Regeneron shall consider in good faith comments on the Discovery Plan from Sanofi's representatives on the JRC. Except for the initial Discovery Plan (which will be provided to the JRC within sixty (60) days of the Effective Date), Regeneron will present an updated Discovery Plan to the JRC at least two (2) months prior to the end of each Contract Year.

- 2.5 <u>Commercially Reasonable Efforts</u>; Compliance with Laws. During the term of the Discovery Program, Regeneron will use Commercially Reasonable Efforts to discover and develop Product Candidates to offer for license to Sanofi pursuant to the Opt-In Rights. Without limiting the foregoing, Regeneron will use Commercially Reasonable Efforts to identify Lead Candidates and complete IND Preparation for Lead Candidates in a timely manner during the term of the Discovery Program. Each Party hereby covenants and agrees to comply with applicable Laws in performing activities connected with the Discovery Program.
- 2.6 Exchange of Information. Regeneron will share information with the JRC in a timely manner concerning the progress of the Discovery Program consistent with Section 3.1(b). Without limiting the foregoing, at least five (5) calendar days prior to each regular quarterly meeting of the JRC, Regeneron will use its Commercially Reasonable Efforts to provide to Sanofi's representatives on the JRC a written report (in electronic form) summarizing the material activities undertaken by Regeneron in connection with the Discovery Plan, including information concerning new Targets proposed for the Target List, new Program Targets, new Lead Candidates and new Product Candidates. In addition, Regeneron will provide Sanofi with proposed Targets for inclusion on the updated Target List and Target proposed not to be pursued further under the Discovery Program at least ten (10) Business Days prior to each regular quarterly meeting of the JRC. Sanofi shall have the right to reasonably request and to receive in a timely manner clarifications and answers to questions with respect to such reports and any other data or information it reasonably requests with respect to the conduct of the Discovery Program.
- 2.7 <u>Further Assurances and Transaction Approvals</u>. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals,

authorizations, or orders required to be obtained or made in connection with the authorization, execution, and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement, and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings, including by providing copies of all such non-confidential documents to the other Party and its advisors prior to the filing and, if requested, by accepting all reasonable additions, deletions, or changes suggested in connection therewith. Each Party will furnish all information required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

2.8 Exclusive Discovery Program.

- (a) Exclusivity.
- - (b) Exclusions. Notwithstanding subsection (a) above, the following shall apply:

2.9 <u>Tail Period</u>. At Sanofi's sole option, upon prior written notice to Regeneron, such notice to be delivered no later than June 30, 2012 (***************) (as applicable, the "<u>Tail Period Notice Date</u>"), the term of the Discovery Program may be extended for up to three (3) additional years (as designated by Sanofi in its notice) (the "<u>Tail Period</u>"). If Sanofi fails to provide such written notice by the applicable Tail Period Notice Date, the Discovery Program shall expire on December 31, 2012 (*******************************.) Sanofi

shall identify in its written notice the specific Program Targets, Lead Candidates, and Product Candidates to be included in the Discovery Program during the Tail Period. Within ninety (90) days of receipt of Sanofi's notice, the Parties shall agree on a plan and budget (which shall be on a cost basis) to perform the activities set forth below and as requested by Sanofi to be carried out for each Contract Year of the Tail Period. In the event the Parties do not agree on the commercial reasonableness of such budget, then such dispute shall be referred to binding arbitration pursuant to the provisions of Article 13. During the Tail Period, Regeneron will use Commercially Reasonable Efforts

- 2.10 Research Licenses; Licenses Generally. Each Party hereby grants to the other Party and its Affiliates a non-exclusive, non-transferable, worldwide, royalty-free, research license, without the right to sublicense, under the Regeneron Intellectual Property and the Sanofi Intellectual Property, respectively, solely to perform the Discovery Program. For the avoidance of doubt, neither Party shall use the licenses granted in this Section 2.10 for the benefit, directly or indirectly, of any Third Party. Except as expressly provided for herein, nothing in this Agreement grants either Party any right, title or interest in and to the intellectual property rights of the other Party (either expressly or by implication or estoppel). Except as expressly provided for in this Section 2.10 or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights or Know-How, either expressly or by implication, estoppel or otherwise. Upon expiration or earlier termination of the Discovery Program, the licenses granted in Section 2.10 herein shall automatically terminate.
- 2.12 <u>Sanofi Target Licenses</u>. With respect to any Product Candidate against a Sanofi Target that becomes a Refused Candidate ("<u>Licensed Refused Sanofi Candidate</u>") or any Sanofi Divested Antibody, Sanofi hereby grants to Regeneron a non-transferable, non-exclusive, worldwide, royalty-bearing (in accordance with <u>Section 4.4</u> herein) license, with the right to sublicense, under the Sanofi Target IP solely to make, have made, use, sell, offer to sell and import such Licensed Refused Sanofi Candidate or Sanofi Divested Antibody, as the case may be.

- 2.13 <u>Non-Exclusive License to Sanofi</u>. Regeneron hereby grants Sanofi and its Affiliates a worldwide, non-exclusive, non-transferable, royalty-free license, without the right to sublicense, under Regeneron Intellectual Property discovered directly in connection with the performance of the Discovery Program claiming Targets on the Target List and/or methods of use related to the inhibition or use of such Targets for use by Sanofi and its Affiliates in connection with the manufacture, use, sale, offer to sell, and import of small molecule drug and diagnostic products.
- 2.14 <u>Invention Assignment</u>. All of the employees, officers and consultants of each Party that are supporting the performance of its obligations under this Agreement shall have executed agreements or have existing obligations under law requiring, in the case of employees

and officers, assignment to such Party of all inventions made during the course of and as the result of their association with such Party and, in the case of employees, officers and consultants, obligating the individual to maintain as confidential such Party's Confidential Information which such Party may receive, to the extent required to support such Party's obligations under this Agreement.

- 2.15 <u>Supply of VelociGene® Mice</u>. Within ninety (90) days of the Effective Date or as otherwise mutually agreed by the Parties in writing, the Parties shall enter into a "Mouse Purchase Agreement" pursuant to which Regeneron will use its proprietary technology for the production of genetically modified mouse embryonic stem cell lines and mice derived from the corresponding mouse stem cell lines for Sanofi. The commercial terms of the "Mouse Purchase Agreement" are outlined in <u>Exhibit B</u>.

ARTICLE 3 JOINT RESEARCH COMMITTEE

3.1 The Joint Research Committee.

(a) <u>Formation, Composition and Membership</u>. Within thirty (30) days after the Effective Date, the Parties will establish the JRC, which shall consist of at least three (3) senior representatives appointed by each of Regeneron and Sanofi. Each Party may replace its Committee members upon written notice to the other Party; provided that such replacement is of

comparable standing and authority within that Party's organization as the person he or she is replacing (or is otherwise reasonably acceptable to the other Party). The JRC will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi.

- (b) Meetings of the JRC. The JRC shall hold an initial joint meeting within forty-five (45) days of the Effective Date or as otherwise agreed by the Parties. Thereafter, the JRC shall meet at least once every calendar quarter, unless the JRC co-chairpersons otherwise agree. All JRC meetings may be conducted by telephone, video-conference or in person as determined by the JRC co-chairpersons; provided, however, that the JRC shall meet in person at least once each calendar year, unless the Parties mutually agree to meet by alternative means. Unless otherwise agreed by the Parties, all in-person meetings for JRC shall be held on an alternating basis between Regeneron's facilities and Sanofi's facilities. Further, each co-chairperson shall be entitled to call meetings in addition to the regularly scheduled quarterly meetings. The co-chairpersons, with the assistance of the Alliance Managers, shall coordinate activities to prepare and circulate an agenda in advance of each meeting and prepare and issue draft minutes of each meeting within fourteen (14) days thereafter and final minutes within thirty (30) days thereafter, such final minutes to include the updated Target List. With the consent of the Parties (not to be unreasonably withheld or delayed), a reasonable number of other representatives of a Party may attend any JRC meeting as non-voting observers (provided that such additional representatives are under obligations of confidentiality and non-use applicable to the Confidential Information of the other Party that are at least as stringent as those set forth in Article 9 below). Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in JRC meetings.
 - (c) <u>Duties</u>. The JRC shall:
 - (i) discuss the objectives of the Discovery Program;
 - (ii) review and comment on the Discovery Plan;
- (iii) exchange and review scientific information and data relating to the activities being conducted under, and the then-current progress of, the Discovery Program, including the exchange and review of data and other information resulting from the Discovery Program, and establish processes for the exchange of information relating to the progress of the Discovery Program;
- (iv) discuss experiments believed by a Party's representatives on the JRC to be necessary to properly evaluate Program Targets, Lead Candidates and Product Candidates;
 - (v) provide assistance and recommendations on the direction of the Discovery Program;
- (vi) evaluate, select and prioritize Targets proposed by each Party for inclusion on the initial Target List and all quarterly updates thereto (subject to Section 2.4, which updates shall conform to the format of the Target List;

- (vii) discuss whether an Antibody, including any MTC, satisfies the criteria of Lead Candidates attached in Schedule 1.42;
- (viii) review and prioritize Lead Candidates;
- (ix) consider and act upon such other matters as specified in this Agreement or as otherwise agreed to by the Parties;
- (x) make any such decisions as are expressly allocated to the JRC under this Agreement; and

At the request of either Party's representatives to the JRC, conduct ad hoc meetings in addition to the quarterly meetings of the JRC as reasonably necessary to coordinate and expedite all decisions made by the JRC.

- (d) <u>Decision Making</u>. The JRC shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; <u>provided</u> that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on the JRC and leave decisions of the JRC to representatives of the other Party.
- 3.2 <u>Alliance Management</u>. Each of Sanofi and Regeneron shall appoint a senior representative who possesses a general understanding of research, clinical, and regulatory issues to act as its Alliance Manager ("<u>Alliance Manager</u>"). Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment between the Parties. Each Alliance Manager will also be responsible for providing single-point communication for seeking consensus both internally within the respective Party's organization and with the other Party's organization, including facilitating review of external corporate communications.

3.3 Resolution of Governance Matters.

- (a) <u>Generally</u>. The Parties shall cause their respective representatives on the JRC to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible.
- (b) Executive Officers' Resolution of Disputes. In the event that the JRC is, after a period of thirty (30) days from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, or the Parties are unable to agree on the budget for the Initial Development Plan for a Product Candidate in accordance with Section 5.3 below, either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, the co-chairpersons of the JRC, by written notice to each Party delivered within five (5) days after receipt of the notice from a Party pursuant to the immediately preceding sentence, shall formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within thirty (30) days of receiving such written notification or such

longer period of time as the Executive Officers may agree in writing. Regeneron's Executive Officer shall have the deciding vote over all matters referred to the Executive Officers by the JRC, other than matters related to the commercial reasonableness of the budget for the Initial Development Plan for a Product Candidate which shall be resolved in accordance with Section 13.1 below should the Executive Officers fail to resolve such matter.

3.4 <u>Obligations of the Parties and their Affiliates</u>. The Parties shall cause their respective designees on the JRC and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein.

ARTICLE 4 PAYMENTS

- 4.1 <u>Upfront Payment</u>. Within five (5) Business Days of the Effective Date, Sanofi will pay to Regeneron the non-refundable, non-creditable amount of US \$85,000,000 (which will not be reduced by any withholding or similar taxes) as consideration for access to Regeneron's research capabilities and suite of discovery technologies and the co-exclusive (with Regeneron) rights granted to Sanofi hereunder during the term of the Discovery Program, including the Tail Period, if any.
- 4.2 <u>Discovery Program Costs</u>. Commencing on the Effective Date and continuing during the term of the Discovery Program, Sanofi shall be responsible for paying one hundred percent (100%) of all Discovery Program Costs, including Discovery Program Costs incurred for a Product Candidate until the anticipated IND filing date for such Product Candidate, regardless of whether Sanofi exercises its Opt-In Rights in accordance with <u>Section 5.1</u>; <u>provided</u> that, except as set forth below, the total annual Discovery Program Costs to be paid by Sanofi in each of the first five (5) years of the Discovery Program (the "<u>Maximum Annual Discovery Program Costs</u>") shall not exceed the following amounts (as calculated for each Contract Year):

Contract Year	Maximum Annual Discovery Program Costs
1	******
2	******
3	*****
4	*****
5	*****

In the event that the Discovery Program Costs incurred in any Contract Year are less than the Maximum Annual Discovery Program Costs for such Contract Year, the amount of such shortfall up to ten percent (10%) of the Maximum Annual Discovery Program Costs stated immediately above for each Contract Year may be carried over to the ensuing Contract Year and added to the Maximum Annual Discovery Program Costs for such ensuing Contract Year except for any such shortfall at the end of Contract Year 5, such that Regeneron's right to carry over any shortfall shall not be applicable into or during the Tail Period. At least sixty (60) days prior to the end of each Contract Year, Regeneron shall notify Sanofi if it reasonably believes that the total Discovery Program Costs for such Contract Year will be less than the Maximum Annual

Discovery Program Costs for such Contract Year and whether Regeneron intends to apply such shortfall amount to the Discovery Program Costs for the ensuing Contract Year.

To the extent that Sanofi performs any activities under the Discovery Program, it shall do so at its sole cost and expense and such costs and expenses shall not be treated as Discovery Program Costs for purposes of calculating the Maximum Annual Discovery Program Costs unless the JRC expressly requests Sanofi to perform any such activities, in which case the mutually agreed upon costs directly related to such activities shall be included in the calculation of the Maximum Annual Discovery Program Costs. The Parties acknowledge that payments made by Sanofi pursuant to this Section 4.2 are being made as research and development expenses, as defined in the U.S. Internal Revenue Code Section 41, and agree that any and all credits or deductions to which either party may be entitled on account of research performed pursuant to such payments shall be allocated to Sanofi to the extent of such payments.

- 4.3 Reports and Discovery Program Cost Payments. Within forty-five (45) days following the end of each calendar quarter, Regeneron shall deliver electronically to Sanofi a written report setting forth in reasonable detail the Discovery Program Costs incurred by Regeneron in such calendar quarter along with an invoice therefore. Sanofi shall reimburse Regeneron for all undisputed Discovery Program Costs set forth in each report within thirty (30) days after its receipt thereof. Any disputed, unpaid Discovery Program Costs that are determined to be due and payable to Regeneron under this Agreement shall be paid with the Default Interest Rate.

In the event that any Royalty Product requires a sub-license to Sanofi Patent Rights or Regeneron Patent Rights, as applicable, and such sub-license is granted under this Agreement, then any financial remuneration that the licensing Party is required to pay to a Third Party for its license from the Third Party shall be considered a pass-through cost to be borne by the Party developing and/or commercializing the Royalty Product.

the other Party with each royalty payment a report detailing in reasonable detail the information necessary to calculate the royalty payments due under this Agreement for such calendar quarter, including the following information, specified on a Royalty Product-by-Royalty Product and country-by-country basis: (a) total gross invoiced amount from sales of each Royalty Product by a Party, its Affiliates and sublicensees; (b) all relevant deductions from gross invoiced amounts to calculate Net Sales; (c) Net Sales; and (d) royalties payable.

- 4.6 <u>Payment Method and Currency</u>. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars using the average of the buying and selling exchange rate for conversion of the applicable foreign currency into United States Dollars, using the spot rates (the "Closing Mid-Point Rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties) from the last Business Day of the preceding month.
- 4.7 <u>Late Payments</u>. All late payments made under this Agreement (including payments made pursuant to <u>Sections 4.4</u> and <u>4.5</u> above), shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (U.S., Eastern Edition) effective for the date on which the payment was due ********** (such sum being referred to as the "<u>Default Interest Rate</u>").
- 4.8 <u>Taxes</u>. Except as set forth in <u>Section 4.1</u>, any withholding or other taxes that a Party is required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to such other Party; <u>provided</u>, <u>however</u>, that the remitting Party shall furnish the other Party with proper evidence, including any self-reporting documentation, of the taxes so paid. Each Party shall cooperate with the other and furnish the other Party with appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable).

ARTICLE 5 OPT-IN RIGHTS TO LICENSE PRODUCT CANDIDATES

5.1 Opt-In Rights to License Product Candidates. Subject to the last sentence of this Section 5.1 and the other terms of this Agreement, Sanofi shall have the exclusive right during the term of the Discovery Program to elect to jointly (with Regeneron) develop and commercialize each Product Candidate as set forth below, under the terms and conditions set forth in the License and Collaboration Agreement (the "Opt-In Rights"). While the Opt-In Rights are in effect with respect to an Antibody from the Discovery Program, including a MTC in the Discovery Program, Regeneron will not grant to any Third Party rights to any such Antibody. The Opt-In Rights will expire and Sanofi will no longer have any rights or licenses to any Antibodies, including MTCs, under this Agreement upon the expiration or earlier

termination of the Discovery Program. After the first five (5) years of the Discovery Program (or if the Discovery Program is earlier terminated by Sanofi under the terms of Section 12.4), the Opt-In Rights shall remain in effect during the Tail Period solely with respect to Lead Candidates and other Antibodies and MTCs against any applicable Targets properly identified by Sanofi in its notice to extend the Discovery Program through the Tail Period provided under Section 2.9.

- 5.3 Initial Development Plan. Within thirty (30) days after Sanofi's receipt of the Opt-In Report, the Parties shall jointly commence, and thereafter as promptly as practicable complete, preparation of a plan and budget for the planned development activities for such Product Candidate through the completion of the Phase I Clinical Trial (the "Initial Development Plan"), the final budget included in which shall be subject to Sanofi's written approval, not to be unreasonably withheld or delayed; provided, however, that (i) the Parties shall not be required to continue or complete such preparation if the Opt-In Period for such Product Candidate has expired without Sanofi having timely exercised its Opt-In Rights with respect thereto or Sanofi shall have otherwise advised Regeneron in writing that it will not exercise its Opt-In Rights with respect to such Product Candidate and (ii) if the Parties are unable to agree on a final budget the matter shall first be referred to the Executive Officers in accordance with Section 3.3(b) above, and if such Executive Officers are unable to resolve such matter, it shall be submitted to binding arbitration to be conducted in accordance with Section 13.1 below. If Sanofi properly exercises its Opt-In Rights with respect to a Product Candidate, such Product Candidate shall be developed in accordance with the Initial Development Plan until the Parties agree to the "Global Development Plan" as such term is defined in the License and Collaboration Agreement.
- 5.5 <u>DII4</u> and <u>REGN-88</u>. Sanofi exercised its Opt-In Rights to REGN-88 as of the Effective Date and shall be deemed to have exercised its Opt-In Right with respect to Delta-like ligand-4 (DII4) MTCs as of the Effective Date. For clarification, development of the Delta-like ligand-4 (DII4) MTCs shall be conducted under this Agreement until such time as an IND is filed.
- 5.6 <u>Refused Candidates</u>. If Sanofi does not provide Regeneron with an Opt-In Notice within the Opt-In Period with respect to a particular Product Candidate, or Sanofi notifies Regeneron that it will not exercise Opt-In Rights with respect to the Product Candidate, then the following shall apply:
- (i) <u>Refused Candidate</u>. The Opt-In Rights shall expire with respect to that Product Candidate (a "<u>Refused Candidate</u>"). All licenses granted in <u>Section 2.10</u> shall automatically expire with respect to each Product Candidate upon such Product Candidate becoming a Refused Candidate. Following such time as a Product Candidate becomes a Refused Candidate, except as set forth below, the applicable Target

shall no longer be deemed a Program Target and shall be removed from the Target List and Sanofi shall no longer have any rights to any Antibodies, including MTCs, against such Target under this Agreement. Sanofi shall have a one-time right within four (4) weeks of the date a Product Candidate becomes a Refused Candidate to designate the Target for such Refused Candidate as one of its Sanofi Targets.

- (ii) Regeneron Rights. Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any Refused Candidate without restriction outside the Discovery Program and this Agreement, unless the Refused Candidate is a Competing Refused Candidate, in which case, Section 2.8(b)(ii) shall apply. In addition, unless Sanofi has exercised its right under Section 5.6(i) to designate the applicable Target for a Refused Candidate as one of its Sanofi Targets, then Regeneron may continue to develop and commercialize (on its own or with one or more Third Parties) any MTCs or other Antibodies against such Target and may practice and use any Regeneron Intellectual Property, including, without limitation, the Mice, in connection with such activities. If Sanofi has designated the applicable Target for the Refused Candidate as a Sanofi Target pursuant to Section 5.6(i), then all Antibodies (including MTCs) against such Target that were generated under the Discovery Program other than the Refused Candidate shall remain part of the Discovery Program.

ARTICLE 6 NEWLY CREATED INVENTIONS

6.1 Ownership of Newly Created Intellectual Property.

- (a) Each Party shall exclusively own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created solely by such Party, its employees, agents and consultants under the Discovery Program ("Sole Inventions"). Sole Inventions made solely by Sanofi, its employees, agents and consultants are referred to herein as "Sanofi Sole Inventions made solely by Regeneron, its employees, agents and consultants are referred to herein as "Regeneron Sole Inventions." The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder.
- (b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Discovery Programs that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Sanofi (or for which ownership vests in Sanofi by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron (or for

which ownership vests in Regeneron by operation of law), on the other hand, on the basis of each Party having an undivided interest in the whole ("Joint Inventions").

- (c) Notwithstanding the foregoing in Section 6.1(b), (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, as determined, if necessary, by an independent third party, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws, and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.
- (d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under this Agreement vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.
- (e) The Parties hereby agree that each Party's use of the Joint Inventions shall be governed by the terms and conditions of this Agreement including the following: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement or the License and Collaboration Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as otherwise set forth herein or in the License and Collaboration Agreement, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 6.1(e), (iii) during the Discovery Program, each Party agrees not to license its interest in any Joint Invention with the right to use such Joint Invention for developing, manufacturing or commercializing antibodies (except for developing, manufacturing or commercializing a Party's Antibodies that may be included in the exclusions described in Section 2.8 (b) of the Agreement), and (iv) nothing in this Article 6 shall relieve a Party or its Affiliates of their obligations under Article 9 with respect to Confidential Information provided by the other Party or such other Party's Affiliates. Neither Party hereto shall have the obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Discovery Program. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. The provisions governing Joint Inventions set forth in this Section 6.1(e) shall survive the expiration or termination of this Agreement.

6.2 Prosecution and Maintenance of Patent Rights.

- (a) Subject to the terms of the License and Collaboration Agreement with respect to Licensed Products, Regeneron shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights and Regeneron shall confer with and keep Sanofi reasonably informed regarding the status of such activities to the extent they are Product Patent Rights.
- (b) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of Regeneron. Regeneron shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners

(c) The Parties shall have the following obligations with respect to the filing, prosecution and maintenance of any Joint Patent Rights, as well as any Product Patent Rights: (i) the prosecuting Party (the "Prosecuting Party") shall provide the other Party (the "Non-Prosecuting Party") with notice and a copy of a substantially completed draft of any Patent Application at least thirty (30) days prior to the filing of any such Patent Application by the Prosecuting Party and incorporate all reasonable comments provided by the Non-Prosecuting Party within such thirty (30) day period unless the Prosecuting Party reasonably believes that such comments will adversely affect the scope or validity of the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) the Prosecuting Party shall notify the Non-Prosecuting Party prior to its filing of a Patent Application; (iii) the Prosecuting Party shall consult with the Non-Prosecuting Party promptly following the filing of the Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv) the Prosecuting Party shall provide the Non-Prosecuting Party promptly with copies of all material communications received from or filed in patent offices with respect to such applications and incorporate all reasonable comments provided by the Non-Prosecuting Party, unless the Prosecuting Party reasonably believes that such comments will adversely affect the validity or scope of the Patent Application or resulting Patent for both Parties; and (v) the Prosecuting Party shall provide the Non-Prosecuting Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office, (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the Non-Prosecuting Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances, including assuming the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right or Joint Patent Right and becoming the Prosecuting Party. With respect to Joint Inventions, it is understood that the Prosecuting Party and Non-Prosecuting Party shall use all reasonable efforts to reach agreement on all material filings and amendments and no such material filings or amendments shall be made by the Non-Prosecuting Party without the prior written agreement of

the Non-Prosecuting Party, such agreement not to be unreasonably withheld or delayed. In addition, in the event that the Prosecuting Party materially breaches the foregoing obligations and such material breach is not cured within thirty (30) days of a written notice from the Non-Prosecuting Party describing such breach in reasonable detail, or in the event that the Prosecuting Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the Non-Prosecuting Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the Non-Prosecuting Party may assume the Prosecuting Party's responsibility for filing, prosecution and maintenance of any such Product Patent Right and will thereafter be deemed the Prosecuting Party for purposes hereof. Notwithstanding the foregoing, the Prosecuting Party may withdraw from or abandon any Patent or Patent Application on thirty (30) days' prior notice to the Non-Prosecuting Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the Non-Prosecuting Party a free-of-charge option to assume the prosecution or maintenance thereof. The Parties will file and prosecute Patent Applications described in this Section 6.2(a) in the list of countries set forth in Exhibit C, unless otherwise agreed upon by the Parties.

- (d) All costs incurred in the filing, prosecution and maintenance of any Joint Patent Rights and Product Patent Rights and in performing freedom to operate analyses on Program Targets or Lead Candidates shall be shared equally by the Parties.
- 6.3 <u>Third Party Claims</u>. In the normal course of business, Regeneron shall carry out patent searches in relation to the Program Targets, Lead Candidates, and Product Candidates, as well as the technologies used to discover, develop and commercialize any of the foregoing, and will disclose, along with any analysis, to Sanofi's counsel any conflict or likely conflict of which Regeneron is aware with respect to the Patent Rights of any Third Party with respect to any such Program Targets, Lead Candidates and Product Candidates prior to selection to enter IND Preparation. If either Party or its Affiliates shall learn of a Third Party claim that the activities under the Discovery Program infringe or otherwise violate the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this claim, assertion or certification. As soon as reasonably practical after the receipt of such notice, the Parties shall cause their respective legal counsel to meet to confer on such allegation of infringement. In particular, with regard to issues related to freedom to operate concerning Targets pursued under this Agreement, the Parties shall conduct and maintain ongoing and regular communications between their legal/intellectual property departments.

ARTICLE 7 BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

7.1 <u>Books and Records</u>. Each Party shall keep proper books of record and account in which full, true and correct entries (in conformity with GAAP) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall permit auditors, as provided in <u>Section 7.2</u>, to visit and inspect, during regular business hours and under the guidance of its employees, the books of record and account of such Party to the extent relating to this Agreement and discuss its affairs, finances and accounts to the extent relating to this Agreement.

7.2 Audits and Adjustments.

- (a) Each Party shall have the right, upon no less than thirty (30) days' advance written notice and at such reasonable times and intervals and to such reasonable extent as the Party shall request, not more than once during any Contract Year, to have the books and records of the other Party to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable, appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.
- (b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days of delivery. If a Party over billed or underpaid an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than **************************, it shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the Party initiating the audit in all other cases). Such accountants shall not reveal to the Party requesting the audit the details of its review, except for the findings of such review and such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article 9.
- (c) If any examination or audit of the records described above discloses an over billing or underpayment of amounts due hereunder, then unless the result of the audit is contested pursuant to Section 7.2(b) above, the Party that overbilled or underpaid shall pay the same (plus interest thereon at the Default Interest Rate from the date of such over billing or underpayment through the date of payment of the amount required to be paid pursuant to this Section 7.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section 7.2.
- (d) <u>Disputes</u>. Any disputes with respect to the results of any audit conducted under <u>Section 7.2</u> above shall be resolved by binding arbitration in accordance with <u>Section 13.1</u> below.
- 7.3 <u>IAS/IFRS/GAAP</u>. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with IAS/IFRS, and for the US, if desired, GAAP, as generally and consistently applied.

ARTICLE 8 REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 <u>Joint Representations and Warranties</u>. Each Party hereto represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement;

- (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other material agreement or arrangement, whether written or oral, by which it is bound or requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from performing the Discovery Program or granting the rights and/or licenses hereunder; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf.
- 8.2 <u>Knowledge of Pending or Threatened Litigation</u>. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any court, arbitrator, or Governmental Authority that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the term of the Discovery Program, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.
- 8.3 <u>Additional Regeneron Representations, Warranties and Covenants</u>. Regeneron additionally represents and warrants to Sanofi that, as of the Effective Date:
 - (a) Regeneron owns or has a valid license to all Regeneron Patent Rights in existence as of the Effective Date;
- (b) Regeneron has the right and authority to grant the rights (including the Opt-In Rights) granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted, and will not grant during the term of this Agreement, any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;
- (c) there is no pending litigation of which Regeneron has received notice or is otherwise aware that alleges that any of Regeneron's activities relating to the Mice or the Regeneron Intellectual Property have violated, or would violate, the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation);
- (d) to Regeneron's knowledge, no litigation has been otherwise threatened which alleges that any of its activities relating to the Mice or the Regeneron Intellectual Property have violated or would violate, any intellectual property rights of any Third Party;
- (e) to Regeneron's knowledge, after due inquiry, the use of the Mice and the Regeneron Intellectual Property generally in the Discovery Program (but not with respect to a specific MTC or Target) does not and will not infringe or otherwise violate any valid Patent or provisional rights to applications or other intellectual property of any Third Party claiming genetically modified mice or the use thereof to make antibodies;

- (f) neither the development or reproduction of the Mice nor the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Effective Date has constituted or involved the misappropriation of trade secrets or other rights of any Person;
- (g) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Effective Date are not invalid or unenforceable, in whole or part;
- (h) Regeneron has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings;
- (i) The commercial terms of the "Mouse Purchase Agreement" referred to in <u>Section 2.15</u> and as outlined in <u>Exhibit B</u> hereto are consistent with those contained in Regeneron's existing agreements with other commercial entities, and
- (j) neither Regeneron nor any of its Affiliates shall transfer ownership, assign ownership, grant a security interest in or otherwise encumber any of its rights in, to or under any Regeneron Intellectual Property in a way that will impair Sanofi's rights or Regeneron ability to perform its obligations under this Agreement.

8.4 <u>Disclaimer of Warranties</u>. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY PRODUCT. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 9 CONFIDENTIALITY

9.1 <u>Confidential Information</u>. During the term of this Agreement and for a period of five (5) years thereafter, each Party (in such capacity, the "<u>Receiving Party</u>") shall keep confidential, and other than as provided herein or in the License and Collaboration Agreement, shall not use or disclose, directly or indirectly, any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, documents, ideas, information, discoveries, or materials, owned, developed, or possessed by the other Party (in such capacity, the "<u>Disclosing Party</u>"), whether in tangible or intangible form, the confidentiality of which the Disclosing Party takes reasonable measures to protect, including but not limited to Regeneron Know-How and Sanofi Know-How disclosed by the Disclosing Party under this

Agreement (the "Confidential Information"). For purposes of this Agreement, all confidential information disclosed by Regeneron under the terms of the confidentiality agreements between Sanofi Parent and Regeneron dated February 1, 2007 and October 23, 2007 is hereby deemed Confidential Information of Regeneron. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any Confidential Information of the other Party to any Third Party except to its employees, agents, consultants or any other Person under its authorization; provided such employees, agents, consultants or other Persons are subject in writing to confidentiality obligations applicable to the Disclosing Party's Confidential Information no less strict than those set forth herein.

- (a) Notwithstanding the foregoing, Confidential Information shall not be deemed to include information and materials (and such information and materials shall not be considered Confidential Information under this Agreement) to the extent that it can be established by written documentation by the Receiving Party that such information or material is: (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the Receiving Party or any Person to whom the Receiving Party provided such information; (ii) is or was already in the possession of the Receiving Party at the time of disclosure by the Disclosing Party; (iii) is disclosed to the Receiving Party on an unrestricted basis from a Third Party not under an obligation of confidentiality to the Disclosing Party or any Affiliate of the Disclosing Party with respect to such information; (iv) information that has been independently created by the Receiving Party (or its Affiliate), as evidenced by written or electronic documentation, without any aid, application or use of the Disclosing Party's Confidential Information; or (v) required by Law to be disclosed, provided that the Receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the Disclosing Party to seek confidential treatment for such information, and provided further that the Receiving Party provides all reasonable cooperation to assist the Disclosing Party to protect such information and limits the disclosure to that information which is required by Law to be disclosed.
- (b) Information and other Know-How that is discovered by Regeneron in connection with the Discovery Program will be considered Regeneron's Confidential Information, except to the extent it relates to a Licensed Product, in which case it shall be Confidential Information of both Parties, subject to the terms of the License and Collaboration Agreement.
- (c) Specific aspects or details of Confidential Information will not be deemed to be within the public knowledge or in the prior possession of a Person merely because such aspects or details of the Confidential Information are embraced by general disclosures in the public domain. In addition, any combination of Confidential Information will not be considered in the public knowledge or in the prior possession of either Person merely because individual elements thereof are in the public domain or in the prior possession of a Person unless (i) the combination and its principles are in the public knowledge or in the prior possession of that Person and (ii) the combination is documented, in a single contemporaneous document, as in the public knowledge or in the prior possession of a Person.
- (d) Notwithstanding anything else in this Agreement to the contrary, each Party hereto (and each employee, representative, or other agent of any Party) may disclose to any and all Persons, without limitation of any kind, the Federal income tax treatment and Federal

income tax structure of any and all transaction(s) contemplated herein and all materials of any kind (including opinions or other tax analyses) that are or have been provided to any Party (or to any employee, representative, or other agent of any party) relating to such tax treatment or tax structure, provided, however, that this authorization of disclosure shall not apply to restrictions reasonably necessary to comply with securities laws. This authorization of disclosure is retroactively effective immediately upon commencement of the first discussions regarding the transactions contemplated herein, and the Parties aver and affirm that this tax disclosure authorization has been given on a date which is no later than thirty (30) days from the first day that any Party hereto (or any employee, representative, or other agent of any party hereto) first made or provided a statement as to the potential tax consequences that may result from the transactions contemplated hereby.

- 9.2 <u>Injunctive Relief.</u> The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.
- 9.3 <u>Publications</u>. If either Sanofi or Regeneron (the "<u>Publishing Party</u>") desires to publish or publicly present any results from the Discovery Program in scientific journals, publications or scientific presentations or otherwise, the Publishing Party shall provide the other Party an advance final copy of any proposed publication or summary of a proposed oral presentation relating to the information from the Discovery Program prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to preserve the confidentiality of its Confidential Information and to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it as a result of the publication or disclosure, to which the Publishing Party shall give due consideration. If such other Party informs the Publishing Party, within thirty (30) days of receipt (or such other period agreed to by the JRC) of an advance copy of a proposed publication or summary of a proposed oral presentation, that such publication in its reasonable judgment should not be published or presented, the Publishing Party shall delay or prevent such disclosure or publication as proposed by the other Party. In the case of patentable inventions, the delay shall be sufficiently long to permit the timely preparation and filing of a patent application(s) or application(s) for a certificate of invention on the information involved. The Parties shall establish a publication review process to ensure compliance with this <u>Section 9.3</u>.
- 9.4 <u>Disclosures Concerning this Agreement</u>. The Parties will mutually agree upon the contents of a their respective press releases with respect to the execution of this Agreement and

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the License and Collaboration Agreement which shall be issued simultaneously by both Parties on the Effective Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or any other activities contemplated hereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement or any activities contemplated hereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding this Agreement. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article 9 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. Each Party acknowledges that the other Party as a publicly traded company is legally obligated to make timely disclosures of all material events relating to its business. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall cooperate with one another and use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the nonfiling Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE 10 INDEMNITY

10.1 Indemnity and Insurance.

(a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines and expenses, including reasonable attorneys' fees and costs (collectively, "Damages"), arising from or occurring as a

result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:

- (i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Sanofi or its Affiliates in connection with the Discovery Program, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Regeneron or its Affiliates; or
 - (ii) material breach by Sanofi of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.
- (b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and their respective officers, directors, employees and agents ("Sanofi Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Sanofi Indemnitee that is due to or based upon:
- (i) the negligence, recklessness, bad faith, intentional wrongful acts or omissions of Regeneron or its Affiliates in connection with the Discovery Program, except to the extent that Damages arise out of the negligence, recklessness, bad faith or intentional wrongful acts, or omissions committed by Sanofi or its Affiliates; or
 - (ii) material breach by Regeneron of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.

10.2 Indemnity Procedure.

- (a) The Party entitled to indemnification under this <u>Article 10</u> (an "<u>Indemnified Party</u>") shall notify the Party potentially responsible for such indemnification (the "<u>Indemnifying Party</u>") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened in writing against the Indemnified Party which could give rise to a right of indemnification under this Agreement; <u>provided</u>, <u>however</u>, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder.
- (i) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) the Indemnified Party consents to such compromise or settlement, which consent shall not be withheld or delayed unless such compromise or settlement involves (A) any admission of legal wrongdoing by the Indemnified Party, (B) any payment by the Indemnified Party that is not indemnified hereunder or (C) the imposition of any equitable relief against the

Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed), provided, that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

- (ii) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this <u>Section 10.2</u> and shall bear its own costs and expenses with respect to such participation; <u>provided</u>, <u>however</u>, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.
- (iii) The amount of any Damages for which indemnification is provided under this <u>Article 10</u> will be reduced by the insurance proceeds received, and any other amount recovered, if any, by the Indemnified Party in respect of any Damages.
- (iv) If an Indemnified Party receives an indemnification payment pursuant to this <u>Article 10</u> and subsequently receives insurance proceeds from its insurer with respect to the damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this <u>Article 10</u> and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this <u>Article 10</u>.

ARTICLE 11 FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions, or acts of God ("Force Majeure"). Such excuse from liability and responsibility

shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and <u>provided</u> that the affected party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

ARTICLE 12 TERM AND TERMINATION

- 12.1 <u>Term</u>. The "<u>Term</u>" of this Agreement shall commence on the Effective Date and end on the later to occur of (a) the expiration or earlier termination of the Discovery Program, including any Tail Period, unless this Agreement is earlier terminated in accordance with this <u>Article 12</u> in which event the Term shall end on the effective date of such termination.
- 12.2 <u>Termination For Material Breach</u>. Upon and subject to the terms and conditions of this <u>Section 12.2</u>, this Agreement shall be terminable by a Party in its entirety if the other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period. Notwithstanding the foregoing, in the case of breach of a payment obligation not subject to a bona fide dispute hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be forty-five (45) days. For purposes of this <u>Section 12.2</u>, the term "material breach" shall mean an intentional, continuing (and uncured within the time period described above), material breach by a Party as determined by binding arbitration consistent with the provisions of <u>Section 13.1</u> of this Agreement.
- 12.3 <u>Termination for Insolvency</u>. Either Party shall have the right to terminate this Agreement in its entirety if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, or (b) if the other Party proposes a written agreement of composition or extension of its debts, or (c) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or (d) if the other Party shall propose or be a party to any dissolution or liquidation, or (e) if the other Party shall make an assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(52) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any Patent Rights in any country of a Party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code subject to

the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

12.5 Termination for Breach of Standstill. Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have breached their obligations under any of Sections 3, 4 or 5 of the Investor Agreement (to the extent such sections of the Investor Agreement is then in effect). Furthermore, Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have (a) breached their obligations under Section 20.16 of the Aventis Collaboration Agreement, to the extent that such Section 20.16 remains in effect after the Effective Date, or (b) breached its obligations under Section 5.3 of the Stock Purchase Agreement, dated as of September 5, 2003, by and between Sanofi and Regeneron (the "Aventis Stock Purchase Agreement"), to the extent that such Section 5.3 remains in effect after the Effective Date. Any such breach of the Investor Agreement, the Aventis Stock Purchase Agreement or the Aventis Collaboration Agreement, as the case may be, shall be treated as a breach of this Agreement. Notwithstanding the foregoing and for the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of (i) a de minimus breach of Section 3.1(a) of the Investor Agreement (to the extent such Section 3.1(a) is in effect after the Effective Date) or of Section 20.16(a) of the Aventis Collaboration Agreement (to the extent such Section 20.16(a) remains in effect after the Effective Date) or (ii) an inadvertent breach of Section 3.1(g) of the Investor Agreement (to the extent such Section 3.1(g) is in effect after the Effective Date) or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement (to the extent such Section 20.16(g) remains in effect after the Effective Date), arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of such Section 20.16 or of paragraphs (a) through (e) of Section 3.1 of the Investor Agreement, as applicable. Sanofi's rights under Sections 2.16 and 2.17 shall survive termination for breach of the standstill or lock-up under Section 12.5 of the Agreement

12.6 <u>Termination for Breach of License and Collaboration Agreement.</u> Notwithstanding anything to the contrary herein, (a) Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Sanofi, if Regeneron has terminated the License and Collaboration Agreement, in its entirety, pursuant to Section 19.3, 19.4, or 19.5 of the License and Collaboration Agreement, and (b) Sanofi shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon providing written notice to Regeneron, if Sanofi has terminated the License and Collaboration Agreement, in its entirety, pursuant to Section 19.3 or 19.4 of the License and Collaboration Agreement.

12.7 <u>Effect of Termination by Sanofi for Breach</u>. In addition to the provisions of <u>Section 12.9</u> below, notwithstanding anything herein to the contrary, in the event that Sanofi terminates this Agreement pursuant to Section 12.2 of this Agreement the following shall apply:

- (a) Sanofi shall be granted a non-exclusive, non-transferable, royalty free, worldwide license, without the right to sublicense, for a period that shall expire six (6) years from the Effective Date, to the Mice and the underlying Regeneron Intellectual Property for Sanofi and its Affiliates to use to discover and develop MTCs for any and all purposes;
- (b) Regeneron shall perform a timely and expeditious technology transfer as required by Sanofi to pursue its rights under <u>subsection (a)</u> without delay above subject to the execution of a material transfer agreement containing non-financial terms and conditions related to the use of the Mice consistent with Regeneron's commercial license agreements for the Mice;
 - (c) the licenses granted to Regeneron under this Agreement shall automatically terminate;
- (d) Sanofi shall be granted an exclusive, fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense, under Regeneron Target IP existing at the effective time of termination solely for use to develop and commercialize Antibodies against Sanofi Discovery Targets (and for no other uses), and the co-exclusive (with Regeneron and its Affiliates) fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense under Regeneron Target IP to develop and commercialize Antibodies against all other Program Targets at the time of termination (and for no other uses); and
 - (e) Sanofi's rights under Sections 2.15, 2.16 and 2.17 shall survive; and
 - (f) Sanofi shall have no further funding obligations under <u>Section 4.2</u> of the Agreement.
- 12.8 Effect of Termination by Regeneron for Breach. In addition to the provisions of Sections 12.9 and 12.11 below, notwithstanding anything herein to the contrary, in the event that Regeneron terminates this Agreement pursuant to Section 12.2 or 12.5 of this Agreement, the following shall apply:
 - (a) the licenses granted to Sanofi under this Agreement shall automatically terminate;
 - (b) the rights granted to Sanofi under this Agreement in Sections 2.15, 2.16, and 2.17 and Article 5 shall automatically terminate;
- (c) Regeneron shall be granted an exclusive, fully paid-up, non-transferable, royalty-free, worldwide, exclusive license, with the right to sublicense, under Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize Antibodies against Program Targets other than Sanofi Discovery Targets (and for no other uses), and the co-exclusive (with Sanofi and its Affiliates) fully paid-up, non-transferable, royalty-free, worldwide license, with the right to sublicense under Sanofi Target IP to develop and commercialize Antibodies against all Sanofi Discovery Targets at the time of termination (and for no other uses).

- 12.9 <u>Survival of Obligations</u>. Subject to <u>Sections 12.7</u> and <u>12.8</u> above and except as otherwise provided below, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate, and this Agreement shall cease to be of further force or effect, <u>provided</u> that notwithstanding any expiration or termination of this Agreement:
- (a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of the Discovery Program (even if such costs and expenses arise following termination or expiration, as the case may be); provided, however, that Sanofi shall not be obligated to pay or reimburse Regeneron for any such costs or expenses in the event Sanofi terminates this Agreement pursuant to Section 12.2 above (and with respect to 12.4, Sanofi shall have no further obligations to pay for costs and expenses beyond the effective date of its termination notice);
- (b) the obligations of the Parties with respect to the protection and nondisclosure of the other Party's Confidential Information in accordance with Article 9, as well as other provisions (including, without limitation, Sections 2.11(b), 2.11(c), 2.12 (except as set forth in Section 12.8 above), 2.13 (except as set forth in Section 12.8 above), 2.16, 2.17, 6.1(e), 6.2(b), 6.2(c), 6.2(d)(as it relates to Joint Patent Rights), 7.2, 10.1, 10.2, this Article 12, and Article 13) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable;
- (c) for the avoidance of doubt, the early termination of this Agreement by either Party, and the expiration of this Agreement shall not relieve either Party of any of its royalty or other obligations under <u>Article 4</u> with respect to any Royalty Product, for which royalties remain payable to the other Party under this Agreement; and such royalty provisions of Article 4 shall survive;
- (d) for the avoidance of doubt, the obligations of the Parties with respect to the licenses granted in <u>Sections 2.10</u>, <u>2.11 (b)</u>, <u>2.11 (c)</u>, <u>2.12</u>, <u>2.13</u> shall survive the termination or expiration of this Agreement; and
- (e) such expiration or termination and this <u>Article 12</u> shall be without prejudice to any rights or remedies a Party may have for breach of this Agreement.
- 12.10 Return of Confidential Information. Subject to either Parties' licenses that survive termination or expiration, Confidential Information disclosed by the Disclosing Party, including permitted copies, shall remain the property of the Disclosing Party. Subject to the terms of the License and Collaboration Agreement (with respect to Licensed Products), upon the earlier to occur of (a) the termination of this Agreement or (b) the expiration of the Discovery Program, or upon written request of the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or, at the Disclosing Party's request, destroy, all documents or other tangible materials representing the Disclosing Party's Confidential Information (or any designated portion thereof); provided that one (1) copy may be maintained in the confidential files of the Receiving Party for the purpose of complying with the terms of this Agreement. An officer of the

Receiving Party also shall certify in writing that it has satisfied its obligations under this <u>Section 12.10</u> within ten (10) days of a written request by the Disclosing Party.

- 12.11 Special Damages. If Regeneron terminates this Agreement pursuant to Section 12.2 or 12.5, then Sanofi shall pay to Regeneron, within sixty (60) days of the termination of this Agreement, in addition to any other amount payable by Sanofi to Regeneron under this Agreement under Laws, or pursuant to any contractual remedies available to Regeneron, an amount equal to the sum of the Maximum Annual Discovery Program Costs for each of the years, including the remaining unpaid Maximum Annual Discovery Program Cost for the Contract Year in which such termination is effective, that would have been the remainder of the term of the Discovery Program but for the termination of this Agreement.
- 12.12 <u>Termination by Sanofi At Will</u>. Sanofi shall be entitled to terminate this Agreement at any time (except following a material breach of this Agreement by Sanofi pursuant to <u>Section 12.2</u>) without cause upon three months' written notice to Regeneron. If Sanofi terminates the Agreement under this <u>Section 12.12</u>, then Sanofi shall pay to Regeneron within five (5) days of its notice of termination, an amount equal to the sum of the Maximum Annual Discovery Program Costs for each of the years, including the Remaining Unpaid Maximum Annual Discovery Program Cost for the Contract Year in which such termination is effective, that would have been the remainder of the term of the Discovery Program but for the termination of this Agreement. In addition, Sanofi shall complete GLP toxicology studies conducted by Sanofi at the time of termination, if applicable, and such other critical activities conducted by Sanofi at the time of termination that cannot be transferred to Regeneron without a material adverse effect on the completion of such activities. In the event of such termination, in addition to the provisions of <u>Section 12.9</u>, the following shall apply:
 - (a) the rights granted to Sanofi under Sections 2.16, and 2.17 and Article 5 shall automatically terminate; and
- (b) Regeneron shall be granted a non-exclusive, non-transferable, royalty bearing (in accordance with Section 4.4) worldwide license with the right to sublicense under Sanofi Target IP existing at the effective time of termination solely for use to develop and commercialize (i) MTCs against Program Targets, and (ii) any other Antibodies against Program Targets in the Discovery Program in existence at the effective time of termination of this Agreement.

ARTICLE 13 ARBITRATION

13.1 <u>Binding Arbitration</u>. In the event the Parties cannot reach agreement with respect to (i) the commercial reasonableness of the budget for the Initial Development Plan for a Product Candidate, (ii) the royalty on Net Sales of Immunoconjugates under Section 2.11(d)(i) and (iii) of this Agreement, (iii) whether a breach constitutes a "material breach" as described in Section 12.2 of this Agreement, and (iv) audits under Section 7.2 (d) above, and such disputes are not resolved by the Executive Officers in accordance with Section 3.3(b) above, then the following shall apply:

- (a) General. The respective disputed issue shall be referred to binding arbitration by one (1) arbitrator who shall be an independent expert in the pharmaceutical or biotechnology industry mutually acceptable to the Parties. The Parties shall use their best efforts to mutually agree upon one (1) arbitrator; provided, however, that if the Parties have not done so within ten (10) days after initiation of arbitration hereunder, or such longer period of time as the Parties have agreed to in writing, then such arbitrator shall be an independent expert as described in the preceding sentence selected by the New York office of the American Arbitration Association. Such arbitration shall be limited to casting the deciding vote with respect to the disputed issues as more fully described in Sections 13.1 (b)-(e) below. In connection therewith, each Party shall submit to the arbitrator in writing its position on and desired resolution of such matter. Such submission shall be made within ten (10) days of the selection or appointment of the arbitrator, and the arbitrator shall rule on such matter within ten (10) days of receipt of the written submissions by both Parties. The arbitrator shall select one of the Party's positions as his or her decision, and shall not have authority to render any substantive decision other than to so select the position of either Regeneron or Sanofi. Except as provided in the preceding sentence, such arbitration shall be conducted in accordance with the then-current Commercial Arbitration Rules of the American Arbitration Association. The arbitrator's ruling shall be final and binding upon the Parties. The costs of any arbitration conducted pursuant to this Section 13.1 shall be borne equally by the Parties. The Parties shall use diligent efforts to cause the completion of any such arbitration within sixty (60) days following a request by any Party for such arbitration.
- (b) <u>Initial Development Plan Budget</u>. The specific issue that shall be submitted to the arbitrator shall be limited to determining the overall commercial reasonableness of the budget that is the subject of the dispute. If the arbitrator determines that such budget is commercially reasonable, then the dispute shall be deemed finally resolved and such resolution shall be binding on the Parties. However, if the arbitrator determines that such budget is not commercially reasonable, then the arbitrator shall, within fifteen (15) days after such determination, render a final decision as to what modifications must be made to such budget in order for it to be commercially reasonable (the "Budget Modification Decision"). In connection with reaching a Budget Modification Decision, the arbitrator may order the Parties to produce any documents or other information which are relevant to such final decision, and the Parties shall submit such documents or other information, together with their respective proposed resolutions which shall consist of their respective proposed modifications to the budget in order for it to be commercially reasonable, at least five (5) days prior to the date a Budget Modification Decision is required to be rendered as provided above. In rendering the final decision, the arbitrator shall be limited to choosing a resolution proposed by a Party without modification.
- (c) <u>Royalty on Net Sales *****************************</u>: The issue that shall be submitted to the arbitrator shall be the royalty rate to apply under Section 2.11(d)(i).
- (d) <u>Material Breach Under Section 12.2:</u> The issue that shall be submitted to the arbitrator shall be whether the breach committed by a Party meets the requirements for a material breach under Section 12.2 of this Agreement.
 - (e) Audit Disputes. The issue that shall be submitted to the arbitrator shall be disputes as described under Section 7.2(d) of this Agreement.

ARTICLE 14 MISCELLANEOUS

- 14.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Except as set forth in Article 13 and 7.2(d), the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.
- 14.2 <u>Waiver</u>. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.
- 14.3 Notices. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 14.3 attached hereto and shall be (a) delivered personally, (b) sent via a reputable nationwide overnight courier service, or (c) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, one (2) Business Days after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.
- 14.4 Entire Agreement. This Agreement and the License and Collaboration Agreement contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersede all prior understandings and writings relating to the subject matter hereof and thereof. It is understood and agreed that in the event of any conflict or inconsistency between this Agreement and the License and Collaboration Agreement, this Agreement shall control regarding the Parties' rights and obligations with respect to any Antibody (including any MTC), Lead Candidate or Product Candidate in the Discovery Program (prior to Sanofi's exercise of its Opt-In Rights with respect to such Product Candidate), and the License and Collaboration Agreement shall control regarding the Parties' rights and obligations with respect to any Licensed Product from and after the time a Product Candidate becomes a Licensed Product.
- 14.5 <u>Amendments</u>. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.

- 14.6 <u>Interpretation</u>. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) the words "herein" or "hereunder" relate to this Agreement. Each accounting term used herein that is not specifically defined herein shall have the meaning given to it under GAAP, but only to the extent consistent with its usage and the other definitions in this Agreement.
- 14.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.
- 14.8 <u>Assignment</u>. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, <u>provided</u> that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any Third Party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or Third Party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.
- 14.9 <u>Successors and Assigns</u>. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of <u>Section 14.12</u> below.
- 14.10 <u>Affiliates</u>. Each Party may carry out its obligations under this Agreement through its Affiliates and absolutely, unconditionally and irrevocably guarantees to the other Party prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. Sanofi shall not, directly or indirectly, cause or direct Sanofi Pasteur or Merial Limited to take any action for which Sanofi and its Affiliates are prohibited hereunder from committing. Each Party represents and warrants to the other Party that it has licensed or

will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

- 14.11 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.
- 14.12 Third Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Article 10 is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.
- 14.13 <u>Relationship of the Parties</u>. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as expressly provided in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.
- 14.14 Limitation of Damages. EXCEPT AS SET FORTH IN SECTION 12.11, IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 14.14 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD PARTY CLAIMS .
- 14.15 <u>Non-Solicitation</u>. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the performance of the Discovery Program to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

1.	4.16 No.	Strict Construction	This Agreemen	it has been prepa	red jointly and wil	I not be construed	Lagainst either Party
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[Remainder of page intentionally left blank; signature page follows]

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IN WITNESS WHEREOF, Sanofi and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMACEUTICALS INC.

By /s/ Karen Linehan

Name: Karen Linehan Title: Authorized Signatory

By /s/ Robin White

Name: Robin White

Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By /s/ Leonard Schleifer

Name: Leonard Schleifer Title: President & CEO

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SCHEDULE 1.19

Excluded Candidates

Regeneron's Excluded Candidates

Sanofi's Excluded Candidates

SCHEDULE 1.42
Lead Candidate Criteria

	SCHEDULE 1.46
	Manufacturing Cost

SCHEDULE 1.94
Form of Target List

Schedule 4.4

SCHEDULE 8.3

SCHEDULE 14.3

<u>Notices</u>

If to Sanofi:

Aventis Pharmaceuticals Inc. 200 Crossing Boulevard Bridgewater, New Jersey 08807 United States

Attn: President US Research and Development

Copy: Sanofi Aventis

174 Avenue de France

75013 Paris France

Attn: Senior Vice President and General Counsel

If to Regeneron:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 Attention: President & CEO Copy: General Counsel

EXHIBIT A

Form of Opt-In Notice

[Sanofi Letterhead]

[DATE]

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 Attention: President & CEO

Copy: General Counsel Regeneron Pharmaceuticals, Inc.

Reference is hereby made to the Discovery and Preclinical Development Agreement (the "Discovery Agreement") by and between Aventis Pharmaceuticals Inc., a [], corporation with a principal place of business located at [], and Regeneron Pharmaceuticals, Inc., a New York corporation with a principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Capitalized terms used herein shall have the defined meanings set forth in the Discovery Agreement.

Pursuant to Section 5.4 of the Discovery Agreement, Sanofi hereby provides this Opt-In Notice to Regeneron to license [INSERT PRODUCT CANDIDATE] under the License and Collaboration Agreement. Effective immediately, [INSERT PRODUCT CANDIDATE] shall be considered a Licensed Product.

AVENTIS PHARMACEUTICALS INC.
Name: Title:

EXHIBIT C

Portions of this Exhibit Have Been
Omitted and Separately Filed with the Securities
And Exchange Commission with a Request
For Confidential Treatment

LICENSE AND COLLABORATION AGREEMENT

By and Among

AVENTIS PHARMACEUTICALS INC.,

SANOFI-AVENTIS AMERIQUE DU NORD

and

 $REGENERON\,PHARMACEUTICALS, INC.$

Dated as of November 28, 2007

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LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT (this "<u>Agreement</u>"), dated as of November 28, 2007 (the "<u>Effective Date</u>"), is by and between AVENTIS PHARMACEUTICALS INC., a corporation organized under the laws of the state of Delaware having a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807 ("<u>Sanofi</u>"), an indirect wholly owned subsidiary of sanofi-aventis, a company organized under the laws of France with its principal headquarters at 174, avenue de France, 75013 Paris, France ("<u>Sanofi Parent</u>"), SANOFI-AVENTIS AMERIQUE DU NORD, a partnership organized under the laws of France with its principal headquarters at 174 avenue de France, 75013 Paris, France ("<u>Sanofi Amerique</u>"), and REGENERON PHARMACEUTICALS, INC., a corporation organized under the laws of the state of New York having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("<u>Regeneron</u>") (with each of Sanofi and Regeneron being sometimes referred to herein individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>", and with Sanofi Amerique being a party to this Agreement for purposes of Sections 15.1, 15.2 and 20.11 only).

WHEREAS, concurrently with the execution and delivery of this Agreement, the Parties have entered into a Discovery and Preclinical Development Agreement (the "<u>Discovery Agreement</u>") whereby, upon the terms and conditions set forth therein, Regeneron will use its proprietary VelocImmune® technology and related suite of technologies with the objective of discovering Product Candidates (as defined below) which Sanofi may elect, in accordance with the Discovery Agreement, to advance into Development (as defined below) and thereupon automatically obtain from Regeneron a license of certain rights thereto upon the terms and conditions set forth herein;

WHEREAS, Sanofi and its Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory (each as defined below);

WHEREAS, Regeneron and Sanofi desire to collaborate on the Development, Manufacture and Commercialization of Licensed Products (each as defined below) in the Field in the Territory upon the terms and conditions set forth herein (the "Collaboration"); and

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Additional Major Market Country" shall mean any country in the Territory, other than the Major Market Countries referred to in clause (i) of the definition thereof, in which Net Sales in the immediately preceding Contract Year were ********* or more of

aggregate Net Sales in the Territory, and such designation shall remain effective from and after the determination of such Net Sales amount; provided, however, that a country shall not be deemed an Additional Major Market Country if, at the time that Net Sales in such country in a given Contract Year first exceed ********* of aggregate Net Sales in the Territory, the Parties mutually agree otherwise.

- 1.2 "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For purposes of this Agreement, in no event shall Sanofi or any of its Affiliates be deemed Affiliates of Regeneron or any of its Affiliates. For purposes of Sanofi or any of its Affiliates.
 - 1.3 "Ancillary Agreements" means the Sanofi Stock Purchase Agreement and the Investor Agreement.
- 1.4 "Anticipated First Commercial Sale" shall mean, with respect to a Licensed Product in the Field, the date agreed upon by the JSC in advance as the expected date of First Commercial Sale of such Licensed Product in the Field in a country in the Territory.
- 1.5 "Approval" shall mean, with respect to each Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the Development, Manufacture or Commercialization of such Licensed Product in the Field in a regulatory jurisdiction anywhere in the world, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.
- 1.6 "Aventis LLC" shall mean sanofi-aventis US LLC (successor in interest under the Aventis Collaboration Agreement to Aventis Pharmaceuticals Inc.).
- 1.7 "Aventis Collaboration Agreement" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Aventis LLC and Regeneron, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth

Amendment, dated as of January 31, 2006, and Section 11.2 of the Sanofi Stock Purchase Agreement, as the same may be further amended from time to time.

- 1.8 "Aventis Stock Purchase Agreement" shall mean the Stock Purchase Agreement dated as of September 5, 2003 by and between Aventis Pharmaceuticals Inc. and Regeneron, as amended by Sections 4.2(b) and 4.4 of the Investor Agreement effective upon the execution and delivery of the Investor Agreement, and as may be further amended from time to time.
- 1.9 "BLA" shall mean, with respect to each Licensed Product, a biologics license application filed with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority.
- 1.10 "Business Day" shall mean any day other than a Saturday, a Sunday or a day on which commercial banks in New York, New York, the United States or Paris, France are authorized or required by Law to remain closed.
- 1.11 "Clinical Supply Cost" shall mean (a) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture Formulated Bulk Product for Clinical Supply Requirements under the applicable Global Development Plan, (b) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture, comparator agent or placebo requirements for activities contemplated under the applicable Global Development Plan, (c) the Out-of-Pocket Cost and/or the Manufacturing Cost for filling, packaging, labeling and delivery of such Clinical Supply Requirements, comparator agent, combination agent and/or placebo, as the case may be, for activities contemplated under the applicable Global Development Plan and (d) any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of Clinical Supply Requirements. To the extent that manufacturing cost for comparator agent, combination agent or placebo includes any markup over Manufacturing Cost to the benefit of one of the Parties or its Affiliates, such markup shall be deducted in the calculation of Clinical Supply Cost.
- 1.12 "Clinical Supply Requirements" shall mean, with respect to a Licensed Product, the quantities of such Licensed Product which are required by a Party or the Parties for Development in the Field under this Agreement, including, without limitation, the conduct of research, preclinical studies and clinical trials in connection with a Development Plan and quantities of such Licensed Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the Territory.
 - 1.13 "Co-Commercialize" or "Co-Commercialization" shall mean the act of Co-Promoting in a Co-Commercialization Country.
- 1.14 "Co-Commercialization Country" shall mean each country in which Regeneron has elected to Co-Promote a Licensed Product, so long as, after commencing such Co-Promotion, Regeneron is Co-Promoting at least one Licensed Product in such country.

- 1.15 "COGS" for a Licensed Product for a Quarter shall mean cost (calculated in accordance with IAS/IFRS) of Manufacturing the Licensed Product sold in the Field in the Territory in the Quarter.
- 1.17 "Commercial Supply Cost" shall mean the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost for the Manufacture of Commercial Supply Requirements, including, without limitation, scale-up after First Commercial Sale, any filling, packaging and labeling costs, and any irrecoverable VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.
- 1.18 "Commercial Supply Requirements" shall mean, with respect to each Licensed Product, quantities of Finished Product as are required to fulfill requirements for commercial sales, Non-Approval Trials and product sampling with respect to such Licensed Product in the Field in the Territory.
- 1.20 "Commercially Reasonable Efforts" shall mean the carrying out of obligations or tasks by a Party in a sustained manner using good faith commercially reasonable and diligent efforts, which efforts shall be consistent with the exercise of prudent scientific and business judgment in accordance with the efforts such Party devotes to products or research or development projects owned by it of similar scientific and commercial potential. Commercially Reasonable Efforts shall be determined on a market-by-market and Licensed Product-by-Licensed Product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of the Licensed Product or alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitiveness factors. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the profit sharing nor other payments made or required to be made hereunder shall be factor weighed (that is, a Party may not apply lesser resources or efforts in support of a Licensed Product because it must share profits from sales of such Licensed Product or make any other payments hereunder).

- 1.21 "Committee" means any of the JSC, JDC, JCC, JMC, JFC, any CRCC, and any other committee established by the Parties or by the Committees referenced above, each as described in Article III (together with Working Groups or other committees contemplated herein or established in accordance with this Agreement).
 - 1.22 "Competing Opt-Out Product" shall mean any Opt-Out Product having the same Target as a Licensed Product.
- 1.24 "Confidentiality Agreements" shall mean the confidentiality agreements between Regeneron and Sanofi Parent dated February 1, 2007 and October 23, 2007, respectively.
- 1.25 "Consolidated Payment Report" shall mean a consolidated Quarterly report prepared by Sanofi (based on information reported under Sections 5.4 and 9.5) setting forth in reasonable detail, for each Major Market Country in the Territory, for each Region in the Territory, and in the aggregate for all countries in the Territory, (a) Net Sales, COGS and Shared Commercial Expenses incurred by each Party for such Quarter, (b) Development Costs incurred by each Party for such Quarter, (c) Other Shared Expenses incurred by each Party for such Quarter, and (d) the Quarterly True-Up, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 2.
 - 1.26 "Contract Sales Force" shall mean sales representatives employed by a Third Party.
- 1.27 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2008, and each succeeding consecutive twelve (12) month period thereafter during the Term. The last Contract Year of the Term shall begin on January 1 for the year during which termination or expiration of the Agreement will occur, and the last day of such Contract Year shall be the effective date of such termination or expiration.
 - 1.28 "Controlling Party" shall mean ***************************.
- 1.29 "Co-Promote" or "Co-Promotion" shall mean the joint marketing and promotion of Licensed Product(s) by the Parties (or their respective Affiliates) under the same trademark in a Major Market Country pursuant to the applicable Country/Region Commercialization Plan.
- 1.30 "Country/Region Commercialization Budget" shall mean the budget for a particular calendar year approved by the JCC for the applicable Country/Region Commercialization Plan.
- 1.31 "Country/Region Commercialization Plan" shall mean, for each Reporting Country/Region, the three (3) year rolling plan for Commercializing Licensed Products in the Field in such country or Region and the related Country/Region Commercialization Budget and a

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non-binding budget forecast for the next two (2) calendar years, approved by the JCC, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Country/Region Commercialization Plan shall set forth, for each Licensed Product, the information, plans and forecasts set forth in Section 6.3.

- 1.32 "Country/Region Commercialization Committee", or "CRCC", shall mean the committee established by the JCC for a particular Reporting Country/Region as described in Section 3.5.
- 1.33 "Detail" shall mean, with respect to each Licensed Product in the Field, a selling presentation for such product by a representative of each Party's sales force, or another employee of each Party who may be deemed to be part of the Commercialization effort for such Licensed Product (e.g., such as a key account manager, etc.).
- 1.35 "Development Costs" shall mean costs incurred by a Party (for each Licensed Product, commencing with the first (1st) day of the month in which the Opt-In Notice (as such term is defined in the Discovery Agreement) for such Licensed Product is received by Regeneron) directly in connection with the Development of Licensed Products in the Field in accordance with this Agreement and the applicable Global Development Plan, including without limitation:
 - (a) all Out-of-Pocket Costs, including, without limitation, fees and expenses associated with obtaining Registration Filings and Marketing Approvals necessary for the Development and Commercialization of the Licensed Products in the Field under this Agreement;
 - (b) Development FTE Costs;
 - (c) Clinical Supply Costs;

- (d) the costs and expenses incurred in connection with (i) Manufacturing process, formulation, cleaning, and shipping development and validation (other than validation batches which are sold), (ii), Manufacturing scale-up and improvements, (iii) stability testing, (iv) quality assurance/quality control development (including management of Third Party fillers, packagers and labelers), and (v) internal and Third Party costs and expenses incurred in connection with (A) qualification and validation of Third Party contract manufacturers and vendors and (B) subject to the terms of this Agreement, establishing a primary or secondary source supplier, including, without limitation, the transfer of process and Manufacturing technology and analytical methods, scale-up up to First Commercial Sale, process and equipment validation, cleaning validation and initial Manufacturing licenses, approvals and Regulatory Authority inspections (in each case, to the extent not included in Clinical Supply Costs or Commercial Supply Costs);
- (e) any license fees and other payments under Licenses to the extent attributable to the Manufacture of Clinical Supply Requirements and/or the Development of Licensed Products in the Field under the Plans for the Territory subject to Section 13.3(e) in this Agreement; and
- (f) any other costs or expenses specifically identified and included in the applicable Development Plan or included as Development Costs under this Agreement.
- 1.36 "<u>Development FTE Cost</u>" shall mean, for all Development activities performed in accordance with the Development Plan(s), including regulatory activities, the product of (a) the number of FTEs required for such Development activity as set forth in the approved Development Plan and (b) the Development FTE Rate. For the avoidance of doubt, the activity of contract personnel shall be charged as Out-of-Pocket Costs.
- - 1.38 "Development Plan" shall mean a Global Development Plan or an Initial Development Plan, as the context requires.
 - 1.39 "Discovery Program" shall have the meaning set forth in the Discovery Agreement.
 - 1.40 "EMEA" shall mean the European Medicines Evaluation Agency or any successor agency thereto.

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- 1.41 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Sanofi Parent, or their respective designees with equivalent decision-making authority with respect to matters under this Agreement.
 - 1.42 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.
 - 1.43 "Field" shall mean the treatment, prevention, palliation and/or diagnosis of any disease.
- 1.44 "Finished Product" shall mean a Licensed Product in the Field in its finished, labeled and packaged form, ready for sale to the market or use in clinical or pre-clinical trials, as the case may be.
- 1.45 "<u>First Commercial Sale</u>" shall mean, with respect to a Licensed Product in a country in the Territory, the first commercial sale of the Finished Product to non-Sublicensee Third Parties for use in the Field in such country (or group of countries) following receipt of Marketing Approval. Sales for test marketing or clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.
- 1.46 "Formulated Bulk Product" shall mean Licensed Product in the Field formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.
- 1.47 "<u>FTE</u>" shall mean a full time equivalent employee (<u>i.e.</u>, one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes of Development shall be ***** per year.
 - 1.48 "GAAP" shall mean generally accepted accounting principles as applicable in the United States.
- 1.49 "Global Commercialization Budget" shall mean the budget(s) for a particular Contract Year approved by the JCC for the applicable Global Commercialization Plan.
- 1.50 "Global Commercialization Plan" shall mean, with respect to a Licensed Product, the three (3) year rolling plan approved by the JSC for Commercializing such Licensed Product throughout the world, including the related Global Commercialization Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Global Commercialization Plan shall set forth (if not otherwise set forth in the applicable Country/Region Commercialization Plan(s)) for a Licensed Product, the information, plans and forecasts set forth in Section 6.2.
- 1.51 "Global Development Budget" shall mean the budget(s) for a particular Contract Year approved by the JSC for the applicable Global Development Plan.

- 1.52 "Global Development Plan" shall mean, with respect to a Licensed Product, the Initial Development Plan and the three (3) year rolling plan approved by the JSC for the worldwide Development of such Licensed Product, including the related Global Development Budget and a non-binding budget forecast for the next two (2) Contract Years, as the same may be amended from time-to-time in accordance with the terms of this Agreement. For the avoidance of doubt, a Global Development Plan will not include Non-Approval Trials.
- 1.53 "Good Practices" shall mean compliance with the applicable standards contained in then-current "Good Laboratory Practices," "Good Manufacturing Practices" and/or "Good Clinical Practices," as promulgated by the FDA and all analogous guidelines promulgated by the EMEA or the ICH, as applicable.
- 1.54 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.
- 1.55 "IAS/IFRS" shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.
- 1.56 "ICH" shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- 1.57 "IND" shall mean, with respect to each Licensed Product in the Field, an Investigational New Drug Application filed with respect to such Licensed Product, as described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside the United States.
 - 1.58 "Indication" means any disease.
 - 1.59 "Initial Development Plan" shall have the meaning set forth in the Discovery Agreement.
 - 1.60 "Initial IND Filing Date" means, with respect to a Licensed Product, the date an IND for such Licensed Product is first filed.
- 1.61 "Investor Agreement" means the Investor Agreement by and among Sanofi Parent, Sanofi, Aventis LLC, Sanofi Amerique and Regeneron, substantially in the form of Exhibit B to the Sanofi Stock Purchase Agreement, which will be entered into concurrently with the closing under the Sanofi Stock Purchase Agreement.
 - 1.62 "Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.
- 1.63 "Know-How" shall mean, with respect to each Party and its Affiliates, any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information, including marketing and supply information, (whether or not patentable or

otherwise protected by trade secret Law) and that are not disclosed or claimed by such Party's Patents or Patent Applications.

- 1.64 "<u>Law"</u>" or "<u>Laws</u>" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.
- 1.65 "<u>Lead Regulatory Party</u>" shall mean the Party having responsibility for preparing, prosecuting and maintaining Registration Filings and any Approvals for Licensed Products in the Field under this Agreement, and for related regulatory duties.
- 1.66 "<u>Legal Dispute</u>" shall mean any dispute related to a Party's alleged failure to comply with this Agreement or the validity, breach, termination or interpretation of this Agreement.
- 1.67 "<u>License</u>" shall mean any license from a Third Party approved by the JSC required for the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.
- 1.70 "Manufacture" or "Manufacturing" shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and/or storage of Formulated Bulk Product, Finished Product, placebo or a comparator agent, as the case may be.
- 1.71 "Marketing Approval" shall mean an approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in an indication in the Field in any country, but excluding any separate Pricing Approval.
 - 1.72 "Manufacturing Plan" shall mean the manufacturing plan as prepared by the JMC as described in Section 8.5.
- 1.73 "Medical Post-Approval Cost" shall mean, for Licensed Product(s) in each country in the Territory, the product of (a) the number of office-based people supporting (i) the coordination of Non-Approval Trials, (ii) post-Approval non-clinical pharmacovigilance, (iii) the maintenance of Approvals, and (iv) Pricing Approvals (with the number and the method of calculating such number set forth in the applicable Country/Region Commercialization Plan or Global Commercialization Plan) and (b) the applicable Medical Post-Approval FTE Rate. The calculation of the number of people in (a) above will be designed to ensure the proper reporting

and auditing of such information in accordance with this Agreement. For the avoidance of doubt, the activities of contract personnel shall be charged as an Out-of-Pocket Cost.

- 1.74 "Medical Post-Approval FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis in the Territory (determined based on the location of the medical affairs professional), a rate agreed upon in local currency by the Parties prior to the expected start of the first Non-Approval Trial in such Region or Major Market Country, as applicable, based upon the fully burdened cost of medical affairs professionals of pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Medical Post-Approval FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.
- 1.75 "Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of Licensed Products in the Field in the Territory by or on behalf of a Party or its Affiliates or Sublicensees to Third Parties, less the following deductions, determined in accordance with IAS/IFRS (or GAAP for the US) consistently applied:
 - (a) normal and customary trade, cash, quantity and free-goods allowances granted and taken directly with respect to sales of such Licensed Products;
 - (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates, allowances and billing errors;
 - (c) chargebacks and other amounts paid on sale or dispensing of Licensed Products;
 - (d) Third Party cash rebates and chargebacks related to sales of Licensed Products, to the extent allowed;
 - (e) retroactive price reductions that are actually allowed or granted;
 - (f) compulsory refunds, credits and rebates directly related to the sale of Licensed Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or government regulations;
 - (g) freight, postage, shipment and costs (or wholesale fees in lieu of those costs) and customs duties incurred in delivering Licensed Products that are separately identified on the invoice or other documentation;
 - (h) sales taxes, excess duties, or other consumption taxes and compulsory payments to Governmental Authorities or other governmental charges imposed on the sale of Licensed Products, which are separately identified on the invoice or other documentation; and
 - (i) as agreed by the Parties, any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Product falling within

categories substantially equivalent to those listed above and ultimately credited to customers or a Governmental Authority or agency thereof.

Net Sales in currency other than United States Dollars shall be translated into United States Dollars according to the provisions of Section 9.8 of this Agreement. Sales between the Parties, or between the Parties and their Affiliates or Sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if Sanofi or its Affiliate or Sublicensee sells such Licensed Products in the form of a combination product containing any Licensed Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), then prior to the First Commercial Sale of such Combination Product, the Parties shall agree through the JFC to the value of each component of such Combination Product and the appropriate method for accounting for sale of such Combination Product. For the avoidance of doubt, for the purposes of this Agreement, Immunoconjugates (as such term is defined in the Discovery Agreement) shall not be deemed Combination Products.

Solely for the purposes of Section 2.6(d) of this Agreement, the term "Licensed Product" as used in the definition of Net Sales shall refer to Opt-Out Products.

- 1.76 "New Information" shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public, which may arise or be conceived or developed by either Party or its Affiliates, or by the Parties or their Affiliates jointly, during the Term pursuant to this Agreement, to the extent specifically related to any Licensed Product in the Field, including, without limitation, information and data included in any Plans or Registration Filings made under this Agreement.
- 1.77 "Non-Approval Trials" shall mean any post-marketing surveys, registries and clinical trials post-first Marketing Approval not intended to gain additional labeled Indications, but excluding any post-first Marketing Approval clinical trials required by Regulatory Authorities to maintain Marketing Approvals of existing labeled Indication(s).
 - 1.78 "Opt-In Right" shall have the meaning set forth in the Discovery Agreement.
- 1.79 "Opt-Out Product" shall mean a Licensed Product as to which this Agreement has been terminated in accordance with Section 19.2. For clarity, an Early Development Opt-Out Product shall not constitute an Opt-Out Product.
- 1.80 "Other Shared Expenses" shall mean those costs and expenses specifically referred to in Sections 7.6, 12.1(a), 12.2(e), 12.3(b), 13.1(c), 13.3(b), 13.3(d) and 17.1(c).

- 1.81 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates in accordance with a Plan, if applicable.
- 1.82 "Party Information" shall mean any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, ideas, discoveries and materials (whether or not patentable or protectable as a trade secret) not generally known to the public regarding a Party's or its Affiliates' technology, products, business or objectives, in each case, other than New Information, which are disclosed or made available by a Party or such Party's Affiliates to the other Party or the other Party's Affiliates in connection with this Agreement.
 - 1.83 "Patent Application" shall mean any application for a Patent.
 - 1.84 "Patent Rights" shall mean unexpired Patents and Patent Applications.
- 1.85 "Patents" shall mean patents and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof and supplemental protection certificates relating thereto, and all counterparts thereof in any country in the world.
- 1.86 "Person" shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.
- 1.87 "Phase 3 Trial" shall mean a clinical trial that is designed to gather further evidence of safety and efficacy of a Licensed Product in the Field (and to help evaluate its overall risks and benefits) and is intended to support Marketing Approval for a Licensed Product in the Field in one or more countries in the Territory. A Phase 3 Trial typically follows at least one dose ranging clinical trial to evaluate further the efficacy and safety of a Licensed Product in the Field in the targeted patient population and to help define the optimal dose and/or dosing regimen.
- 1.88 "Plan" shall mean any Country/Region Commercialization Plan, Global Commercialization Plan, Global Development Plan, Initial Development Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.
- 1.89 "Positive Phase 3 Trial Results" shall mean a Phase 3 Trial that meets its primary end-point as defined in the study protocol for such Phase 3 Trial, and the safety profile supports continued clinical testing in the applicable Indication and/or filing of an application for Marketing Approval.

- 1.91 "Pricing Approval" shall mean such approval, agreement, determination or governmental decision establishing prices for a Licensed Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.
 - 1.92 "Product Candidate" shall have the meaning set forth in the Discovery Agreement.
- 1.93 "Product Trademark" shall mean, with respect to each Licensed Product in the Field in the Territory, the trademark(s) selected by the JCC and approved by the JSC for use on such Licensed Product throughout the Territory and/or accompanying logos, slogans, trade names, trade dress and/or other indicia of origin, in each case as selected by the JCC and approved by the JSC.
- 1.94 "Promotional Materials" shall mean, with respect to each Licensed Product, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, promotion and sale of such Licensed Product in the Field in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.
- 1.95 "Quarter" or "Quarterly" shall refer to a calendar quarter, except that the first (1st) Quarter shall commence on the Effective Date and extend to the end of the then-current calendar quarter and the last calendar quarter shall extend from the first day of such calendar quarter until the effective date of the termination or expiration of the Agreement.
 - 1.96 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and any Know-How of Regeneron or any of its Affiliates.
- 1.97 "Regeneron Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program or the Collaboration owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Know-How and Know-How included in Joint Inventions) with the right to sublicense the same that relate to a Licensed Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Licensed Product in the Field, including, without limitation, New Information.
- 1.98 "Regeneron Patent Rights" shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than Sanofi Patent Rights and Patent Rights included in Joint Inventions), with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Licensed Product in the Field, but only to such extent.
 - 1.99 "Region" shall mean such countries or group of countries as determined by the JCC.

- 1.100 "Registration Filing" shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any IND or Marketing Approval application in the Field.
- 1.101 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement. The term "Regulatory Authority" includes, without limitation, the FDA, the EMEA and the Japanese Ministry of Health, Labour and Welfare.
- 1.102 "Reporting Country/Region" shall mean each Major Market Country, and each other country or Region for which a Country/Region Commercialization Committee has been established by the JCC.
 - 1.103 "Rest of World" or "ROW" shall mean all Rest of World Countries.
 - 1.104 "Rest of World Country" shall mean any country in the Territory other than the United States.
- 1.105 "ROW CPI" shall mean the "EU15 CPI" (or its successor equivalent index), which is published monthly and available via *The Bloomberg Professional*, as published by Bloomberg L.P.
- 1.107 "Sales Force FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis (determined based on the location of the sales representative), a rate agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale in the Region or Major Market Country, as applicable, based upon the fully burdened cost of sales representatives of pharmaceutical companies in the Field in the applicable country, and including an allocation of regional and country sales force management cost, to be approved six (6) months prior to the first Commercial Sale, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Sales Force FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs, information systems and allocated costs, such as, for example, allocated overhead costs.

- 1.108 "Sanofi Intellectual Property" shall mean the Sanofi Patent Rights and the Sanofi Know-How.
- 1.109 "Sanofi Know-How" shall mean any and all Know-How now or hereafter during the term of the Discovery Program or the Collaboration owned by, licensed to or otherwise held by Sanofi or its Affiliates (other than Regeneron Know-How and Know-How included in Joint Inventions) with the right to sublicense the same that relate to a Licensed Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Licensed Product in the Field, including, without limitation, New Information.
- 1.110 "Sanofi Patent Rights" shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Sanofi or any of its Affiliates (other than Regeneron Patent Rights and Patent Rights included in Joint Inventions), with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Licensed Product in the Field, but only to such extent.
- 1.111 "Sanofi Stock Purchase Agreement" means the Stock Purchase Agreement dated as of the Effective Date by and between Sanofi Amerique, Aventis LLC and Regeneron.
- 1.112 "<u>Shared Commercial Expenses</u>" shall mean the sum of the following items, in each case to the extent directly attributable to Commercialization of Licensed Products in the Field in the Territory in accordance with an approved Country/Region Commercialization Plan or Global Commercialization Plan:
 - - (b) bad debt attributable to Licensed Products in the Field sold in the Territory;
 - (c) Sales Force Cost;
 - (d) Medical Post-Approval Cost;
 - (e) Out-of-Pocket Costs related to (i) the marketing, advertising and/or promotion of Licensed Products in the Field in the Territory (including, without limitation, pricing activities, commercial pharmacovigilance, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for Licensed Products in the Field in the Territory and (iii) the preparation of training and communication materials for Licensed Products in the Field in the Territory;
 - (f) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of Licensed Products in the Field in the

Territory (including, without limitation, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion relate to both Licensed Products and other products developed or commercialized by Sanofi or its Affiliates as agreed upon in an approved Global Commercialization Plan or Country/Region Commercialization Plan;

- (g) Out-of-Pocket Costs related to Non-Approval Trials for Licensed Products in the Field in the Territory, including, without limitation, the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies, in each case, to the extent not included in Commercial Supply Cost;
- (h) Out-of-Pocket Costs related to Pricing Approvals and the maintenance of all Approvals directly related to the Commercialization of Licensed Products in the Field in the Territory;
 - (i) Commercial Overhead Charge;
 - (j) Pre-Launch Marketing Expenses;
- (k) Out-of-Pocket Costs related to regulatory affairs activities, other than activities to secure Registration Filing of indications and line extensions; and
- (l) any other costs or expenses directly related to the Commercialization of a Licensed Product after First Commercial Sale of such Licensed Product and not included in clauses (a) through (k) above.

The foregoing shall not include any costs which have been included in Development Costs. For clarity, it is the intent of the Parties that costs and headcount included in the foregoing will be fairly allocated to the Licensed Products in the Field in the Territory (to the extent that any Shared Commercial Expense is attributable, in part, to products or activities other than the Licensed Products in the Field in the Territory) and, in each case, will only be included once in the calculation of the Quarterly True-Up.

- 1.113 "Shared Phase 3 Trial Costs" shall mean Development Costs associated with Phase 3 Trials of any Licensed Product incurred after the receipt of first Positive Phase 3 Trial Results for such Licensed Product.
- 1.114 "<u>Sublicensee</u>" shall mean a Third Party or an Affiliate to whom Sanofi will have granted a license or sublicense under Sanofi's rights pursuant to Section 4.3 to Commercialize Licensed Products in the Field in the Territory. For the avoidance of doubt, a "Sublicensee" will include a Third Party to whom Sanofi will have granted the right to distribute Licensed Products in the Field wherein such distributor pays to Sanofi a royalty (or other amount) based upon the revenues received by the distributor for the sale (or resale) of Licensed Products by such distributor.

- 1.115 "Target" shall mean any gene, receptor, ligand or other molecule (a) associated with a disease activity that may be modified by direct interaction with a Licensed Product or (b) to which a Licensed Product binds.
- 1.116 "Terminated Licensed Product" shall mean a Licensed Product as to which this Agreement has been terminated in accordance with its terms in accordance with Article XIX, and shall include any Opt-Out Product.
- 1.117 "Termination Notice Period" shall mean the Sanofi Termination Notice Period or the Regeneron Termination Notice Period, as applicable.
 - 1.118 "Territory" shall mean all the countries and territories of the world.
 - 1.119 "Third Party" shall mean any Person other than Sanofi or Regeneron or any Affiliate of either Party.
 - 1.120 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.
- 1.121 "<u>US CPI</u>" shall mean the Consumer Price Index All Urban Consumers published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index).
- 1.122 "Valid Claim" shall mean (a) a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise; or (b) a claim of a Patent Application, which claim has been pending less than five (5) years from the original priority date of such claim in a given jurisdiction, unless or until such claim thereafter issues as a claim of an issued Patent (from and after which time the same shall be deemed a Valid Claim subject to paragraph (a) above).
 - 1.123 Additional Definitions. Each of the following definitions is set forth in the Sections (or Schedules) of this Agreement indicated below:

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Acquired Entity
Acquiring Party
Agreement
Alliance Manager
Annual True-Up
Applicable ROW Percentages
Budget Dispute
Collaboration
Collaboration Purpose

SECTION/SCHEDULE

2.6(c)
2.6(c)
Preamble
3.2(a)
SCHEDULE 2
SCHEDULE 2
Section 3.11(b)
Preamble
3.1(b)

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DEFINITION SECTION/SCHEDULE

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DEFINITION SECTION/SCHEDULE

Regeneron Commitment Level 6.5(e)(i) Regeneron Early Development Opt-Out Right 5.6 Regeneron Early Opt-Out Notice 5.6 Regeneron Indemnitees 17.1(a) Regeneron Profit Split SCHEDULE 2 Regeneron Reimbursement Amount SCHEDULE 2 Regeneron Sole Inventions 12.1(a)Regeneron Termination Notice Period 19.2(b) Reimbursement Payment SCHEDULE 2 Required Divestiture Notice Period 2.6(c)Rest of World Profit Split SCHEDULE 2 Royalty Term 9.3 **ROW Profit Split** SCHEDULE 2 ROW Profit Split Annual True-Up SCHEDULE 2 Sanofi Preamble Sanofi Amerique Preamble Sanofi Indemnitees 17.1(b) Preamble Sanofi Parent Sanofi Sole Inventions 12.1(a)Sanofi Termination Notice Period 19.2(a) **SDEA** 7.4 Shared Phase 3 Trial Costs Balance SCHEDULE 2 Sole Developer 2.6(d)Sole Inventions 12.1(a)Succeeding Year(s) 5.3 **Target Labeling** 7.2(d)Target ROW Profit Split SCHEDULE 2 **Technical Development Matter** 10.2 Term 19.1(a) Third Party 2.6(c)Third Party Acquisition 2.6(c)U.S. Profit Split SCHEDULE 2 SCHEDULE 2 **US Profits** VelocImmune Royalties Section 13.3(e) Working Group 3.1(a)

ARTICLE II COLLABORATION

2.1 <u>Scope of Collaboration</u>. Upon and subject to terms and conditions of this Agreement, the Parties will cooperate in good faith to Develop, Manufacture and Commercialize Licensed Products in the Field in the Territory in such a manner so as to optimize the commercial potential of each Licensed Product. The Parties shall establish various Committees as set forth in Article III of this Agreement to oversee and/or coordinate the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory, and each

Party shall, subject to the terms and conditions set forth in Article XVI, provide (or cause its Affiliates to provide) to any relevant Committee any necessary Party Information, New Information and such other information and materials as may be reasonably required for the Parties to operate effectively and efficiently under and in accordance with the terms and conditions of this Agreement.

- 2.2 <u>Compliance With Law</u>. Both Sanofi and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.
- 2.3 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement and the consummation by such Party of the transactions contemplated by this Agreement and the reafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required to be made by such Party under applicable Laws. The Parties will cooperate with each other in connection with the making of all such filings. Each Party will furnish to the other Party all information in its possession or under its control required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.
- 2.4 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Licenses to which it is a party and to notify the other Party of any terms or conditions in any such License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement, including any sublicense under a License referenced in subsection (a) above, to which it is a party and that is related to the Collaboration, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder. Neither Party may terminate or amend any License or any other material agreement entered into pursuant to a Plan without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, if the amendment or termination imposes any material liability or restriction on either Party with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory.
- 2.5 <u>Plans</u>. The Parties shall undertake all Development and Commercialization activities under this Agreement solely in accordance with the Committee approved Plans. The Parties may agree to amend all Plans and budgets from time to time as circumstances may require.
 - 2.6 Limitation on Exercise of Rights Outside of Collaboration.

- (a) <u>Non-Compete</u>. Without limitation of and in addition and subject to Section 2.8 of the Discovery Agreement, during the Term, except as set forth in this Agreement or Section 2.8 of the Discovery Agreement, neither Party nor any of its Affiliates, either alone or through any Third Party, shall Develop or Commercialize any Competing Product.
- (b) Regeneron Sole Development. If Regeneron presents a proposal to the JDC to undertake additional clinical trials not contemplated in a Global Development Plan to support a Licensed Product in the Field and the JDC fails to approve the proposal within the timeframe established by the JDC pursuant to Section 5.5, then Regeneron may, at its option and at its sole expense, conduct such additional clinical trial(s) outside the scope of the applicable Global Development Plan; provided, however, Regeneron must first present the proposed protocols and clinical trial designs to Sanofi for approval, such approval not to be unreasonably withheld or delayed and, for other than Non-Approval Trials, shall also present to Sanofi the related budgets for Clinical Supply Costs and Out-of-Pocket Costs and applicable FTE costs (provided that such budgets shall be provided for informational purposes only and may not be used to disapprove such protocols and designs). Regeneron shall also provide to Sanofi drug safety data from such additional clinical trials in accordance with Section 7.4. The Sanofi representatives on the JDC may disapprove any such protocols or clinical trial designs for reasons of safety or Sanofi reasonably believes that the development as described in this Section 2.6(b) would have a material adverse effect on the overall development strategy for the Licensed Product and/or the commercial viability of such License Product, including the magnitude of sales for such Licensed Product. If, in compliance with this Section 2.6(b), Sanofi does not approve any such protocols or clinical trial designs for reasons as described herein, Regeneron may not proceed with the proposed clinical trials unless Regeneron disputes such disapproval and until the dispute has been resolved, as provided in Section 3.11(b) and, if necessary, Section 10.4, in Regeneron's favor. In the event that Regeneron conducts any such additional clinical trials, all results, Know-How and Patent Rights generated in or arising from any such clinical trial shall be subject to the grants of rights pursuant to Article IV of this Agreement. For the avoidance of doubt, no consideration or reimbursement shall be paid to Regeneron with respect to the conduct of any such additional clinical trials; provided, however, that if the Parties subsequently agree to commence a further clinical trial based on the results of such additional clinical trial(s) or data is used from such additional clinical trial(s) to support an Approval in the Territory, then Sanofi shall be required to reimburse Regeneron for ******** of the actual Out-of-Pocket Costs and Clinical Supply Costs and applicable FTE costs incurred in connection with the conduct of such additional clinical trial(s) that are consistent with the budgets provided to Sanofi pursuant to this Section 2.6(b) and the other terms of this Agreement. Publication of any results or data obtained in conducting the additional clinical trial(s) allowed under this Section 2.6(b) shall be subject to Article XVI.
- (c) <u>Company Acquisitions</u>. Notwithstanding Section 2.6(a), if as the result of an acquisition of a Third Party (such acquisition a "<u>Third Party Acquisition</u>) by a Party or one or more of its Affiliates (the "<u>Acquiring Party</u>"), the Acquiring Party

acquires rights to a product that is a Competing Product (the "<u>Acquired Competing Product</u>") to a Licensed Product (the "<u>Competing Licensed Product</u>"), the Acquiring Party, at its sole discretion, shall do one of the following: (W) present a proposal to the JDC to include the Acquired Competing Product in the Collaboration in accordance with Section 2.6(c)(i); (X) deliver to the other Party (the "<u>Non-Acquiring Party</u>") a termination notice, pursuant to Section 19.2(a) or 19.2 (b), as appropriate, and Section 2.6(c)(ii), with regard to the Competing Licensed Product; or (Y) transfer its rights in the Acquired Competing Product to a Third Party pursuant to Section 2.6(c)(iii).

- (i) <u>Proposal for Inclusion</u>. If the Acquiring Party chooses this alternative, within ten (10) Business Days after the closing of such Third Party Acquisition, the Acquiring Party shall present a proposal to the JDC to include such Acquired Competing Product in the Collaboration based on the terms of this Agreement. As part of such presentation, the Acquiring party shall provide the JDC with all information with respect to such Acquired Competing Product reasonably available to the Acquiring Party and material to a decision by the Non-Acquiring Party's representatives on the JDC as to whether to approve the inclusion of such Acquired Competing Product in the Collaboration. The JDC shall, on or before the date which is twenty (20) Business Days after the closing of such Third Party Acquisition, decide whether to approve the inclusion of such Acquired Competing Product in the Collaboration under the terms of this Agreement. If the JDC timely approves the inclusion of such Acquired Competing Product in the Collaboration, then upon the closing of such Third Party Acquisition the Acquired Competing Product shall automatically be included in the Collaboration as a Licensed Product hereunder. If the JDC does not approve such inclusion, the Acquiring Party shall elect whether to deliver to the Non-Acquiring Party a termination notice, pursuant to Section 19.2(a) or 19.2 (b), as appropriate, and Section 2.6(c)(ii), with regard to the Competing Licensed Product or transfer its rights to the Acquired Competing Product to a Third Party (without any consideration or payment to the Non-Acquiring Party in accordance with Section 2.6(c)(iii) below).
- (ii) <u>Termination of Licensed Product</u>. If the Acquiring Party chooses this alternative, the Acquiring Party shall deliver to the Non-Acquiring Party, within ten (10) Business Days after the decision of the JDC not to include the Acquired Competing Product in the Collaboration pursuant to Section 2.6(c)(i), a termination notice pursuant to Section 19.2(a) or 19.2(b), as applicable, with respect to the Competing Licensed Product (the "<u>Opt-Out Product Notice</u>"). The provisions of Section 19.2(a) or 19.2(b), as applicable, and the provisions of Sections 19.7, 19.8 and Schedule 4 or 5, as applicable, shall then apply to such Competing Licensed Product. For the avoidance of doubt, such Competing Licensed Product shall then be an Opt-Out Product, and notwithstanding any other provision of this Agreement, the Acquiring Party shall be deemed (without any requirement of notice to the Non-Acquiring Party) to have irrevocably ceded all decision-making authority with respect to such Opt-Out Product to the Non-Acquiring Party. In addition, if such Opt-Out Product is being marketed and sold

at the time of the closing of the Third Party Acquisition, then during the Sanofi Termination Notice Period or Regeneron Termination Notice Period, as applicable, the following shall apply:

- (1) In any Quarter in which the U.S. Profits are positive, the U.S. Profit Split shall be zero percent (0%) to the Acquiring Party and one hundred percent (100%) to the Non-Acquiring Party, and in any Quarter in which the ROW Profits are positive, the ROW Profit Split shall be zero percent (0%) to the Acquiring Party and one hundred percent (100%) to the Non-Acquiring Party.
- (2) In any Quarter, in which U.S. Profits are negative, the U.S. Profit Split shall be one hundred percent (100%) to the Acquiring Party and zero percent (0%) to the Non-Acquiring Party, and in any Quarter in which ROW Profits are negative, the ROW Profit Split shall be one hundred percent (100%) to the Acquiring Party and zero percent (0%) to the Non-Acquiring Party.
- (iii) <u>Transfer of Rights</u>. If the Acquiring Party chooses this alternative, the Acquiring Party shall commit in writing to the Non-Acquiring Party, within ten (10) Business Days after the closing of such Third Party Acquisition, to license or otherwise transfer rights to such Acquired Competing Product to a Third Party (without any consideration or payment to the Non-Acquiring Party) and/or cease all development, manufacturing and/or commercialization, as applicable, of such Acquired Competing Product within six (6) months after the closing of the Third Party Acquisition, and shall do so within such six (6) month period.
- (iv) Required Divestiture of Licensed Product. Notwithstanding any of the foregoing in this Section 2.6(c), in the event the Acquiring Party believes, based on the written advice of its counsel, that it is required by Law to divest its interest either in the Acquired Competing Product or the Competing Licensed Product, the Acquiring Party may terminate this Agreement with respect to such Competing Licensed Product pursuant to Section 19.2(a) or 19.2 (b), as appropriate, Section 2.6(c)(ii) and this Section 2.6(c)(iv), with regards to the Competing Licensed Product, or transfer its interest in the Competing Licensed Product pursuant to Section 2.6(c)(iii). If the Acquiring Party terminates this Agreement with respect to the Competing Licensed Product pursuant to this Section 2.6(c)(iv), it shall give the Non-Acquiring Party the maximum advance notice (up to twelve (12) months) of termination consistent with such divestiture requirement imposed by Law (the "Required Divestiture Notice Period"), following which the provisions of 2.6(c)(ii) shall apply and the Competing Licensed Product shall be an Opt-Out Product. During this period, the Acquiring Party will reasonably cooperate (at the Acquiring Party's sole cost and expense) with the Non-Acquiring Party to enable the Non-Acquiring Party to assume, within the Required Divestiture Notice Period, the continued Development,

Manufacture and Commercialization of such Opt-Out Product in the Field in the Territory. The Acquiring Party shall also be responsible for, and shall promptly pay upon demand, all reasonable costs and expenses incurred by the Non-Acquiring Party in assuming such continued Development, Manufacture and Commercialization of such Opt-Out Product to the extent such costs and expenses, other than capital investments, would not have been incurred and/or would have been paid by the Acquiring Party, absent such Acquiring Party's termination with respect to such Opt-Out Product pursuant to Section 19.2(a) or (b). For the avoidance of doubt, if the Required Divestiture Notice Period is less than the twelve (12) months required by Section 19.2, the Acquiring Party shall have continuing payment obligations (though no performance obligations beyond those described above) to the Non-Acquiring Party with respect to such Opt-Out Product for the entire Sanofi Termination Notice Period (if Sanofi is the Acquiring Party) or Regeneron Termination Notice Period (if Regeneron is the Acquiring Party).

(d) Subject to the further provisions of this Section 2.6(d), in the case of any Opt-Out Product, the non-terminating Party (the "Sole Developer") shall have the right to Develop and Commercialize such Opt-Out Product, unless such Opt-Out Product is (or becomes) a Competing Opt-Out Product, in which case the Sole Developer may not (either directly or through an Affiliate or Third Party), Develop or Commercialize such Competing Opt-Out Product for a period of ******** following the date it becomes a Competing Opt-Out Product (or, if shorter, such period ending on the date such Competing Opt-Out Product ceases to be a Competing Opt-Out Product), unless otherwise agreed by the terminating Party (the "Opt-Out Partner"). If an Opt-Out Product is Commercialized by the Sole Developer (either directly or through an Affiliate or Third Party) in compliance with this Section 2.6(d), then the Sole Developer shall pay the Opt-Out Partner royalties based on Net Sales of such Opt-Out Product and the stage of Development of the Licensed Product at the time it became an Opt-Out Product, at the royalty rate(s) described on Exhibit A. Notwithstanding the foregoing or any other provision of this Agreement, in the case of any Opt-Out Product, including any Competing Opt-Out Product, resulting from termination of this Agreement with respect to a Licensed Product pursuant to Section 19.2 in the circumstances described in Section 2.6(c), the Sole Developer shall have no obligation either to delay Developing or Commercializing, or to pay royalties with respect to, such Opt-Out Product.

(e) Clinical Trials for Combination Products. Notwithstanding anything in this Section 2.6(e) to the contrary, each Party and/or its respective Affiliates shall be entitled to (i) initiate, sponsor and/or conduct a clinical trial and/or (ii) participate, directly or indirectly, whether through the provision of funds, grants or otherwise, in any clinical trial, initiated, sponsored and/or conducted by any Third Party, in each of the foregoing cases with respect to the combination of any Party's (or its Affiliate's) product, together with any Competing Product that has been granted a Marketing Approval for at least one Indication in the applicable country, unless (A) a Licensed Product Developed under this Agreement has been granted a Marketing Approval in the applicable country for use in combination with such Party's (or its Affiliate's) product in the same

Indication(s) as the one to be studied in the intended clinical trial with the Competing Product which is not approved in such Indication or (B) both the Competing Product and a Licensed Product Developed under this Agreement have been granted a Marketing Approval in the applicable country for use in combination with such Party (or its Affiliate's) product as the same Indication to be studied in the intended clinical trial with the Competing Product and the relevant labeling of both the Licensed Product and the Competing Product for such Indication is substantially similar. For any combination study with a Competing Product covered by this Section 2.6(e), the applicable Party shall notify the other Party prior to initiating such trial, such notice to include a brief synopsis of the protocol and a description of the Party's (or its Affiliate's) role(s) and responsibilities in connection with the study. Further, for any combination study with a Competing Product covered by this Section 2.6(e), each Party shall promptly provide the other Party with available results of such combination study, unless such disclosure is prohibited by Law or contract. Each Party and/or its Affiliates shall be entitled to use data from clinical trials permitted by this Section 2.6(e) to promote the combination of such Party product together with such Competing Product, unless a Licensed Product Developed has been granted a Marketing Approval in the applicable country for use in combination with such Third Party product, in the same Indication. Neither Party nor its respective Affiliates shall receive any compensation or other payments (either in cash or in kind) based on the development, promotion, or sale of a Competing Product. Neither Party will intentionally delay the commencement, enrollment or completion of a clinical study of a Licensed Product as a result of any ongoing or pending clinical trial permitted by this Section 2.6(e). For the avoidance of doubt, neither Party nor its respective Affiliates shall use or disclose any Party Information or New Information subject to the confidentiality provisions of Article XVI in connection with any of the activities described in this Section 2.6(e).

ARTICLE III MANAGEMENT

3.1 Committees/Management.

(a) The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee (the "JSC"), a Joint Development Committee (the "JDC"), a Joint Commercialization Committee (the "JC"), CRCCs to the extent provided in Section 3.5, and such other commercialization sub-committee as JCC shall deem to be appropriate, a Joint Manufacturing Committee ("JMC"), a Joint Finance Committee (the "JFC") and such other Committees as the Parties deem appropriate. The JSC, JDC, JFC and JMC shall each be established within thirty (30) days after the Effective Date. The JCC shall be established at least two (2) years prior to the anticipated filing date for Marketing Approval for the first Licensed Product under this Agreement. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future and not described herein) and may be further designated by the JSC. From time to time, each Committee may establish working groups (each, a "Working Group") to oversee particular projects or

activities, and each such Working Group shall be constituted and shall operate as the Committee which establishes the Working Group determines.

(b) Each of the Committees and the Executive Officers shall exercise its decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential of and financial returns from the Licensed Products in the Field in the Territory consistent with Commercially Reasonable Efforts and without regard to any other pharmaceutical product being developed or commercialized in the Field by or through a Party or any of its Affiliates (the "Collaboration Purpose"). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

3.2 Joint Steering Committee.

- (a) Composition and Purpose. The JSC shall have overall responsibility for the oversight of the Collaboration. The purpose of the JSC shall be (i) to review and approve the overall strategy for an integrated worldwide Development program for each Licensed Product, including the Manufacture of Licensed Products in the Field for use in activities under the Plans and for the Commercialization of Licensed Products in the Field in the Territory; (ii) to review the efforts of the Parties in performing their responsibilities under the Plans and (iii) to oversee the Committees and resolve matters pursuant to the provisions of Section 3.11 below on which such Committees are unable to reach consensus. The JSC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). In addition, each Party shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Alliance Manager ("Alliance Manager") to the JSC. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among all Committees and providing single-point communication for seeking consensus both within the respective Party's organization and with the other Party's organization.
- (b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the JSC shall in particular (i) annually review and approve the Global Development Plan(s) if any, Manufacturing Plan(s), Global Commercialization Plan(s) and Country/Region Commercialization Plan(s); (ii) at least semi-annually review the efforts of the Parties in performing their respective Development and Commercialization activities under the then-effective Plans; (iii) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point of communication for seeking consensus regarding key global strategy and Plan issues; (iv) establish sub-committees of the JSC, as the JSC deems appropriate and (v) consider and act upon such other matters as are specifically assigned to the JSC under this Agreement or otherwise agreed by the Parties.

3.3 Joint Development Committee.

- (a) <u>Composition and Purpose</u>. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the worldwide Development of each Licensed Product in the Field; (ii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Global Development Plan(s) (and related Global Development Budget(s)) and (iii) to oversee the implementation of the Global Development Plan(s) and the Development operational aspects of the Collaboration. The JDC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).
 - (b) Specific Responsibilities. In particular, the JDC shall be responsible for:
 - (i) advising the JSC on the overall global Development strategy for each Licensed Product in the Field;
 - (ii) developing (or overseeing the development of), and updating at least annually, the Global Development Plan(s) (and related Global Development Budget(s)), as described in Sections 5.2 and 5.3, for final approval by the JSC;
 - (iii) reviewing and overseeing the implementation of, and compliance with, the Global Development Plan(s) (including the Global Development Budget(s));
 - (iv) developing forecasts for Clinical Supply Requirements to enable the timely preparation of the Manufacturing Plan;
 - (v) overseeing clinical and regulatory matters pertaining to Licensed Products in the Field arising from the Plans, and reviewing and approving protocols, statistical analysis plans, clinical study endpoints, clinical methodology and monitoring requirements for clinical trials of Licensed Products in the Field as contemplated under the Global Development Plan(s) and for Non-Approval Trials;
 - (vi) reviewing and approving proposed target Licensed Product labeling and reviewing and, to the extent set forth herein, approving proposed changes to product labeling with respect to Licensed Products in the Field in accordance with Section 7.2;
 - (vii) developing a target profile for each Licensed Product;
 - (viii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of Licensed Products in the Field;

- (ix) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new formulations, delivery systems and improvements in concert with the JCC;
- (x) establishing a regulatory Working Group responsible for overseeing, monitoring and coordinating the submission of Registration Filings in countries in the Territory, including coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with the Licensed Products in the Field;
- (xi) establishing a Working Group responsible for overseeing all basic research activities for Licensed Products in the Field conducted under the Global Development Plan(s); and
 - (xii) considering and acting upon such other matters as specifically assigned to the JDC under this Agreement or by the JSC.
- 3.4 Joint Commercialization Committee.
- (a) <u>Composition and Purpose</u>. The purpose of the JCC shall be to develop and propose to the JDC and JSC the strategy for the global Commercialization of Licensed Products in the Field in the Territory, and to oversee the implementation of the Global Commercialization Plans and the Commercialization operational aspects of the Collaboration on a country-by-country basis. The JCC shall be composed of at least two (2) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).
 - (b) JCC Responsibilities. In particular, the JCC shall be responsible for:
 - (i) developing and proposing to the JSC the global strategy for the Commercialization of each Licensed Product in the Field in the Territory;
 - (ii) commencing no later than two (2) years prior to the Anticipated First Commercial Sale anywhere in the Territory, (A) developing (or overseeing the development of), and updating not less frequently than once per Contract Year, the Global Commercialization Plan(s) and related Global Commercialization Budget(s) on a country-by-country basis for final approval by the JSC and (B) establishing, to the extent provided in Section 3.5, Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any updates thereto and carry out the other activities described in Section 3.5;

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- (iv) Establishing the trade dress for each Licensed Product, consistent with the guidelines established by the JCC, in the applicable Major Market Country;
- (v) developing forecasts for Commercial Supply Requirements for the Territory to enable the timely preparation of the Manufacturing Plan(s) for review by the JMC and approval by the JSC;
- (vii) reviewing and overseeing compliance with the Global Commercialization Plan (including the related Global Commercialization Budget), and Country/Region Commercialization Plans (including the Country/Region Commercialization Budgets), to the extent applicable, for each Licensed Product, including ensuring that country specific launch plans are consistent with the Marketing Guidelines, and reviewing and validating latest annual estimates for the current calendar year compared to the Global Commercialization Budget and Country/Region Commercialization Budgets;
- (viii) establishing or validating the number and position of Details required to meet market and sales forecasts and their conversion into the equivalent number of Detailing FTEs according to applicable weighting factors, based upon sales force and market practices, on a country-by-country basis, consistent, however, with the applicable Marketing Guidelines;
- (ix) for each Licensed Product, selecting a Product Trademark in accordance with Section 11.2 and giving guidance on trade dress for such Licensed Product;
 - (x) determining the launch date for each Licensed Product on a country-by-country basis in Major Market Countries;
 - (xi) ***********************;
- (xii) preparing short-term and long-term sales forecasts for each Licensed Product on a country-by-basis for Major Market Countries and reviewing such forecasts for the remaining countries;
 - (xiii) *****************
 - (xiv) validating the contents, design and layout of packaging for each Licensed Product in the Field;
- (xv) validating plans and policies regarding journal and other publications with respect to each Licensed Product in the Field in concert with the JDC;

- (xvi) formulating a life-cycle management strategy for each Licensed Product in the Field and evaluating new opportunities for new indications, formulations, delivery systems and improvements in concert with the JDC;
- (xvii) matters relating to Regeneron's Commitment Level with respect to a Licensed Product in a Co-Commercialization Country, including consenting to changes therein; and
- (xviii) considering and acting upon such other matters as specifically assigned to the JCC under this Agreement or by the JSC, JDC JFCor JMC.
- 3.5 Country/Region Commercialization Committees. The JCC will establish a Country/Region Commercialization Committee in each Major Market Country, and in each other Reporting Country/Region as and when determined by the JCC. The Country/Region Commercialization Committees will be responsible for establishing the Country/Region Commercialization Plans (and related Country/Region Commercialization Budgets) and any updates thereto with respect to the applicable Reporting Countries/Region(s). The Country/Region Commercialization Committees will also serve as a forum to consider and discuss and, if so empowered by the JCC, decide, in a more detailed and focused manner with respect to the applicable Reporting Countries/Region(s), and make suggestions or recommendations to the JCC with respect to, the matters referred to in Section 3.4, as applicable, including the implementation of decisions with respect thereto made by the JCC as contemplated by such Section 3.4.
- 3.6 <u>Joint Finance Committee</u>. The JFC shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including such specific responsibilities set forth in Article IX and such other responsibilities determined by the JSC. The JFC also shall respond to inquiries from the JDC, the JMC and the JCC, as needed.
- 3.7 <u>Joint Manufacturing Committee</u>. Working with the JDC and JCC, as appropriate, the Joint Manufacturing Committee shall be responsible for overseeing process development and Manufacturing activities, including preparing and updating the Manufacturing Plan for approval by the JSC and carrying out such other responsibilities set forth in Article VIII, process and technology selection, process improvements and related intellectual property filing strategy and obtaining a common process for manufacturing, recalls, market withdrawals, and any other corrective actions related to any Licensed Product in the Territory, and for any other matters specifically assigned to the JMC by the JSC. For process development activities, the Joint Manufacturing Committee shall consult the appropriate expert functions within both Parties or their Affiliates as appropriate.
- 3.8 <u>Membership</u>. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Sanofi. Each Party may replace its Committee members upon written notice to the other Party. Each Committee will have two (2) co-chairpersons, one designated by each of Regeneron and Sanofi. Each co-chairperson shall be

entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of the meeting and prepare and issue final minutes within thirty (30) days thereafter.

- 3.9 Meetings. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than once every Quarter during the Term, commencing from and after the time such Committee is established as provided herein. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the Parties or their Affiliates) or when agreed by the Parties, by video or telephone conference. Other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of any Licensed Product in the Field (under obligations of confidentiality) may be invited by the Committee co-chairs to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least five (5) Business Days' prior written notice, except that emergency meetings may be called with at least two (2) Business Days' prior written notice.
- 3.10 <u>Decision-Making</u>. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on a Committee and leave decisions of such Committee(s) to representatives of the other Party.
- 3.11 <u>Resolution of Governance Matters</u>. As provided in Section 10.2, this Section 3.11 shall apply to matters constituting, or which if not resolved would constitute, a Governance Dispute.
 - (a) <u>Generally</u>. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible, provided that, in the case of any matter which cannot be resolved by the JDC, JCC, CRCC, JMC, JFC or other relevant Committee established hereunder, at the request of either Party, such matter shall promptly, and in any event within ten (10) Business Days (or two (2) Business Day in the event of an urgent matter) after such request, be referred to the JSC with a request for resolution.
 - (b) <u>Referral to Executive Officers</u>. In the event that the JSC is, after a period of five (5) Business Days from the date a matter is submitted to it for resolution pursuant to Section 3.11(a), unable to make a decision due to a lack of required unanimity, then either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in

good faith, attempt to resolve the referred dispute within five (5) Business Days of receiving such written notification, failing which,

- (c) Notwithstanding the foregoing, and subject to Section 10.4, Legal Disputes and disputes referred to in the third sentence of Section 2.6 (b) which involve a Technical Development Matter shall be referred to the Executive Officers with no Party's Executive Officer having final decision making authority.
- (d) Interim Budgets. Pending resolution by the Executive Officers of any referred dispute under Section 3.11(b) and subject to the terms of Section 19.2, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets and plans to allow the Parties to continue to use Commercially Reasonable Efforts to Develop, Manufacture and Commercialize the Licensed Products in the Field in the Territory pursuant to this Agreement. The most recent Committee approved Plan(s) shall be extended pending approval by the Executive Officers of the interim budget(s) and Plan(s) referred to in this Section 3.11(c).
- (e) Obligations of the Parties. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein. To the extent a Party performs any of its obligations hereunder through any Affiliate of such Party, such Party shall be fully responsible and liable hereunder and thereunder for any failure of such performance, and each Party agrees that it will cause each of its Affiliates to comply with any provision of this Agreement which restricts or prohibits a Party from taking any specified action.

ARTICLE IV LICENSE GRANTS

- 4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement (including, without limitation, Section 4.6) and any License to which Regeneron is a party, Regeneron hereby grants to Sanofi (a) the nontransferable (except as permitted by Section 20.9), coexclusive (with Regeneron and its Affiliates) right and license under the Regeneron Intellectual Property to make, have made, use, develop and import Licensed Products for use in the Field in the Territory, and (b) the nontransferable (except as permitted by Section 20.9), exclusive (except as otherwise provided below in this Section 4.1) right and license under the Regeneron Intellectual Property to sell and offer to sell Licensed Products in the Field in the Territory, except that the right and license granted pursuant to this clause (b) shall be co-exclusive (with Regeneron and its Affiliates) to the extent of Regeneron's right to Co-Promote Licensed Products and Regeneron's right to supply Licensed Products to Sanofi, as contemplated by this Agreement. Sanofi will have the right to grant sublicenses under the foregoing license only as set forth in Section 4.4.
- 4.2 <u>Sanofi License Grants</u>. Subject to the terms and conditions of this Agreement and any License to which Sanofi or any of its Affiliates is a party, Sanofi hereby grants to Regeneron the nontransferable (except as permitted by Section 20.9), royalty-free, co-

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exclusive (with Sanofi and its Affiliates) right and license under the Sanofi Intellectual Property to the extent necessary to make, have made, use, develop and import Licensed Products for use in the Field in the Territory and to Co-Promote Licensed Products to the extent provided in this Agreement.

- 4.3 Newly Created Intellectual Property. In addition to the other licenses granted under this Article IV and subject to the other terms and conditions of this Agreement, to the extent permitted under any relevant Third Party agreement, each Party grants to the other Party and its Affiliates the perpetual, royalty-free, paid-up, non-exclusive, worldwide right and license, with the right to grant sublicenses, to use and practice for any and all purposes: all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights), other than Know-How jointly owned pursuant to Section 12.1(e) and other than Excluded Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the Effective Date directly in connection with the performance of the research and clinical activities approved by the JDC, in each case, as included in the Global Development Plans. As used above, the term "Excluded Rights" shall mean any Patents or Know-How claiming or covering composition (including any formulation) of a Licensed Product. For the avoidance of doubt, nothing in this Section 4.3 shall be construed to grant either Party any license to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities approved by the JDC and/or the clinical development activities approved by the JDC, in each case, as included in Global Development Plans.
- 4.4 Sublicensing. Unless otherwise restricted by any License, Sanofi will have the right to sublicense any of its rights under the first sentence of Section 4.1 only with the prior written consent of Regeneron, such consent not to be unreasonably withheld or delayed with respect to rights outside the Major Market Countries (and only with the prior written consent of Regeneron, which consent may be withheld for any reason, in the Major Market Countries), except that Sanofi may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Regeneron's consent. Unless otherwise restricted by any License, Regeneron will have the right to sublicense any of its rights under Section 4.2 with the prior written consent of Sanofi, such consent not to be unreasonably withheld or delayed, except that Regeneron may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Sanofi's consent. Each Party shall remain responsible and liable for the compliance by its Affiliates and Sublicensees with applicable terms and conditions set forth in this Agreement. Any such sublicense agreement will require the Sublicensee of a Party to comply with the obligations of such Party as contained herein, including, without limitation, the confidentiality and non-use obligations set forth in Article XVI, and will include, with respect to a Sublicensee of Sanofi, an obligation of the Sublicensee to account for and report its sales of Licensed Products to Sanofi on the same basis as if such sales were Net Sales by Sanofi. For the avoidance of doubt, Regeneron shall be entitled to receive its share of the applicable Profit Split based on Net Sales of Licensed Products sold by Sublicensees under this Agreement. In the event of a breach by a Sublicensee of any sublicense agreement which has or is reasonably likely to have an adverse effect on either Party or any of its Affiliates or any Party's Intellectual Property, then the harmed Party may cause the other Party or its Affiliate to exercise, and the other Party or its Affiliate will promptly exercise, any termination rights it may have under the sublicense with the Sublicensee. Any

sublicense agreement will provide for the termination of the sublicense or the conversion of the sublicense to a license directly between the Sublicensee and the other Party, at the option of the other Party, upon termination of this Agreement. Furthermore, any such sublicense shall prohibit any further sublicense or assignment. Each Party will forward to the other Party a complete copy of each applicable fully executed sublicense agreement (and any amendment(s) thereto) within ten (10) days of the execution of such agreement.

- 4.5 <u>No Implied License</u>. Except as expressly provided in this Article IV or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.
- 4.6 Retained Rights. With respect to the licenses granted under this Article IV, and for the avoidance of doubt, Regeneron expressly reserves for itself and its Affiliates and Third Party licensees under the Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions, the right to Manufacture and to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the further avoidance of doubt, Regeneron retains all rights in Regeneron Intellectual Property, Regeneron's interest in the Joint Inventions and Licensed Products not expressly licensed hereunder, including, without limitation the right to exploit Regeneron Intellectual Property and Regeneron's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field. With respect to the licenses granted under this Article IV, and for the avoidance of doubt, Sanofi expressly reserves for itself and its Affiliates and Third Party licensees under the Sanofi Intellectual Property and Sanofi's interest in the Joint Inventions, the right to Manufacture and to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the avoidance of doubt, Sanofi retains all rights in Sanofi Intellectual Property, Sanofi's interest in the Joint Inventions and Licensed Products not expressly licensed hereunder, including, without limitation, the right to exploit Sanofi Intellectual Property and Sanofi's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field.

ARTICLE V DEVELOPMENT ACTIVITIES

- 5.1 <u>Development of Licensed Products</u>. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to Licensed Products in the Field pursuant to the Global Development Plans under the general direction and oversight of the JDC. Each Party shall use Commercially Reasonable Efforts to Develop Licensed Products in the Field, carry out the Development activities assigned to it in Development Plans in a timely manner and conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices.
- 5.2 Global Development Plans. With respect to each Licensed Product, the JDC shall prepare and present a Global Development Plan for approval by the JSC, and the JSC shall approve a Global Development Plan for such Licensed Product, within three (3) months after the time such Licensed Product first becomes a Licensed Product in accordance with the terms of the Discovery Agreement and this Agreement, and shall, subject to the further provisions of this Section 5.2, determine which Party will take the lead in the Development of

such Licensed Product. Prior to such JSC approval of the first Global Development Plan for any Licensed Product, the Parties shall Develop the Licensed Product in accordance with the applicable Initial Development Plan, including, in the case of REGN88 (IL-6RmAb), a summary outline of an Initial Development Plan attached hereto as Exhibit B. An updated Global Development Plan for such Licensed Product will be presented by the JDC for approval by the JSC, and approved by the JSC, at least two (2) months prior to the end of each Contract Year. Each Global Development Plan for a Licensed Product will set forth the plan for Development of such Licensed Product in the Field over at least three (3) Contract Years and will include (a) strategies and timelines for Developing and obtaining Approvals for such Licensed Product in the Field in the Territory, and (b) the allocation of responsibilities for Development activities between the Parties, and/or Third Party service providers. Each Global Development Plan will be reviewed and informally updated by the JDC not less frequently than once every six (6) months for the ensuing three (3) year period. Unless and to the extent otherwise agreed by the Parties with respect to a particular Licensed Product, (i) the Parties shall alternate, on a Licensed Product-by-Licensed Product basis, in being allocated principal responsibility for formulating, and carrying out, the principal Development activities for the applicable Licensed Product under the applicable Global Development Plan(s) from the time the applicable Product Candidate is advanced into Development in accordance with the Discovery Agreement (whereupon such Product Candidate automatically constitutes a Licensed Product) through proof of concept as defined in the Global Development Plan for the Licensed Product (the "POC Time") (with respect to any Licensed Product, the Party with such principal responsibility through the POC Time being referred to as the "POC Principal Party") and (ii) the Parties shall alternate being allocated principal responsibility for formulating, and carrying out, all clinical trials conducted subsequent to the POC Time for the applicable Licensed Product(s) under the applicable Global Development Plan(s) (with respect to a Licensed Product, the Party with such principal responsibility being referred to as the "Post-POC Principal Party"), with Sanofi being the Post-POC Principal Party for two (2), and Regeneron being the Post-POC Principal Party for one (1), out of each three (3) Licensed Products. The Parties shall cause their respective representatives on the JDC and the JSC, in preparing, updating and approving Global Development Plans, to allocate principal Development responsibilities thereunder as provided in this Section 5.2.

- 5.3 <u>Global Development Budgets</u>. Each Global Development Plan for a Licensed Product shall include a related Global Development Budget (each individually, a "<u>Global Development Budget</u>" and collectively, "<u>Global Development Budgets</u>") and each Global Development Budget shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Global Development Plan of which such Global Development Budget is a part in accordance with this Agreement. Amendments and updates to any Global Development Budget shall not be effective without the approval of the JSC.
- 5.4 <u>Development Reports</u>. Within forty-five (45) days after the end of each Quarter, commencing in the first Quarter in which Development activities commence hereunder with respect to the first Licensed Product, Regeneron and Sanofi shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Quarter in connection with each Global Development Plan, together with a statement of Development Costs incurred by such Party during such Quarter, which statement shall detail those amounts to be included in the Consolidated Payment Report for such Quarter

and shall be in such form, format and of such level of detail as approved by the JFC. At the next JSC meeting held following such forty-five (45) day period, the JSC will approve the final Development Costs which will be used in calculating the Global Development Balance.

- 5.5 <u>Review of Clinical Trial Protocols</u>. The JDC will establish procedures for the expeditious review of clinical trial protocols for the Licensed Products submitted to the JDC by Regeneron pursuant to Section 2.6(b), including, without limitation, pre-approval authorizations for Non-Approval Trials.
- 5.6 Regeneron Early Development Opt-Out. Within thirty (30) days of the date that Sanofi exercises its Opt-In Rights with respect to any Licensed Product thereby including such Licensed Product under this Agreement, Regeneron shall have a one-time right to opt-out of the further Development of such Licensed Product (such right of Regeneron, the "Regeneron Early Development Opt-Out Right", and each such Licensed Product as to which Regeneron has exercised the Regeneron Early Development Opt-Out Right, an "Early Development Opt-Out Product") by delivering written notice of such opt-out (a "Regeneron Early Opt-Out Notice") to Sanofi. Effective immediately upon the delivery by Regeneron to Sanofi of a Regeneron Early Opt-Out Notice with respect to a Licensed Product, (i) such Licensed Product shall automatically constitute an Early Development Opt-Out Product, (ii) the rights and licenses granted by Regeneron to Sanofi hereunder with respect to such Early Development Opt-Out Product shall automatically terminate, (iii) Sanofi and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than for amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or the Collaboration by Regeneron), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Regeneron Intellectual Property existing at the time the Regeneron Early Opt-Out Notice was delivered to Sanofi, to Develop, Manufacture and Commercialize in the Field in the Territory (and solely to the extent that such Regeneron Intellectual Property has, as of the date of the Regeneron Early Opt-Out Notice, actually been incorporated into such Early Development Opt-Out Product or otherwise claims or covers its use) the Early Development Opt-Out Product (v) Regeneron shall, as promptly as reasonably practicable, transfer to Sanofi all clinical activities related to the Early Development Opt-Out Product, (vi) except as set forth in this Section 5.6, Regeneron shall have no further rights or obligations with respect to such Early Development Opt-Out Product, (vii) Sanofi shall be free to Develop and Commercialize such Early Development Opt-Out Product in the Field in the Territory free of any obligations to Regeneron hereunder, except for reimbursing Regeneron for any pass through costs to Third Party licensors of Regeneron Intellectual Property, to the extent attributable to the Development or Commercialization of Licensed Products by Sanofi, and (viii) ******************* As used in clause (viii) immediately above, "antibody" shall mean any actual or potential therapeutic or diagnostic antibody (whether fully human, humanized, phage display, chimeric, polyclonal, or any other type of antibody), or any derivative, or fragment thereof, including any immunoconjugates or fusions comprising any such gene product, derivative or fragment, and any composition or formulation that incorporates or includes any of the foregoing. Except as provided in this Section 5.6, a Party's obligations under this Agreement with respect to the Development of a Licensed Product shall terminate only upon termination of this Agreement

with respect to such Licensed Product or in its entirety in accordance with, and only to the extent and upon the terms and conditions set forth in, Article XIX.

ARTICLE VI COMMERCIALIZATION

6.1 Commercialization of Licensed Products in the Field in the Territory. Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to Licensed Products in the Field in the Territory under the direction and oversight of the JCC. Sanofi shall be the lead Party with respect to the Commercialization of Licensed Products in the Field. Sanofi shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field, and carry out the Commercialization activities in accordance with the applicable Global Commercialization Plan and the applicable Country/Region Commercialization Plans in a timely manner and conduct all such activities in compliance with applicable Laws. Except as otherwise provided in this Agreement, Sanofi shall bear all costs and expenses to Commercialize the Licensed Products in the Field in the Territory. Sanofi or its Affiliate shall invoice and book all sales of the Licensed Products in the Field in the Territory and shall appropriately record all such sales. Sanofi or its Affiliate shall also be responsible for the distribution of the Licensed Products in the Field in the Territory and for paying all governmental rebates which are due or owing with respect to the Licensed Products in the Field in the Territory. Commencing with the initiation of Phase 3 Trials for a Licensed Product in the Territory, the Parties will commence regular ad hoc discussions concerning the Commercialization strategy for the Licensed Product.

(a) the overall global strategy for Commercializing such Licensed Product is	n the Field in the	Territory, including	target product profile
branding, positioning, promotional materials and core messages for such License	ed Product;		

- (c) the related Global Commercialization Budget;
- (d) anticipated launch dates for such Licensed Product for Major Market Countries;

- (e) market and sales forecasts for such Licensed Product in the Field in the Territory in a form to be agreed between the Parties;
- (f) strategies for the detailing and promotion of such Licensed Product in the Field in the Territory;
- (g) anticipated major advertising, public relations and patient advocacy programs for such Licensed Product in the Field in the Territory;
- (h) Non-Approval Trials; and
- (i) all other Marketing Guidelines.

6.4 Commercialization Efforts; Sharing of Commercial Information.

(a) Sanofi (through its Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory in accordance with the Global Commercialization Plans, the Marketing Guidelines and, as applicable, the Country/Region Commercialization Plan(s). Without limiting the generality of the foregoing, (i) Sanofi will, as necessary, build, train and apply a field force necessary to Commercialize the Licensed Products in the Field in accordance with the applicable Global Commercialization Plans and Country/Region

Commercialization Plans, (ii) Sanofi's, and in the Co-Commercialization Countries each Party's, sales representatives shall provide the FTE effort and detail the Licensed Products in the Field in accordance with the approved Country/Region Commercialization Plan (if applicable), Global Commercialization Plan(s) and all applicable Laws.

- (b) Sanofi will provide Regeneron with full access to material information directly relating to the Commercialization of each Licensed Product in the Field, including, without limitation, information relating to anticipated launch dates, key market metrics, market research, and sales. Without limiting the foregoing, beginning in the Quarter of the First Commercial Sale in each Major Market Country, Sanofi will provide Regeneron, and with respect to each Co-Commercialization Country, Regeneron will provide Sanofi, on a quarterly basis, with reports of the activity within its field force in each such Major Market Country, which will include reasonable data from reports created by Sanofi or Regeneron for its internal management purposes.
- (c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the Licensed Products in the Field, Licensed Product quality complaints and similar information.
- (d) No Party may initiate or support any Non-Approval Trial for a Licensed Product in the Field in the Territory without the prior approval of the JDC.
 - 6.5 Co-Commercialization of Licensed Products.
- (b) <u>Co-Commercialization</u>. Sanofi and Regeneron (through their respective Affiliates where appropriate) shall Co-Commercialize Licensed Products under the applicable Product Trademarks in each Co-Commercialization Country in accordance with the then-current and applicable Country/Region Commercialization Plan. Each Party shall use, or shall cause its local Affiliates to use, Commercially Reasonable Efforts to Co-Commercialize the Licensed Products in the Co-Commercialization Countries, and carry out the activities assigned to it in the applicable Country/Region Commercialization Plan. Each Party shall ensure that its Co-Commercialization activities conform with the parameters in the applicable approved Country/Region Commercialization Plan and the applicable Global Commercialization Plan.
- (c) <u>Decision to Discontinue Co-Commercialization</u>. In the event that Regeneron decides it no longer wishes to Co-Commercialize a Licensed Product in a

(d) <u>Field Force Coordination</u>. The JCC or the applicable Committee shall coordinate the Co-Promotion of each Licensed Product by Sanofi, Regeneron, their respective local Affiliates and their respective sales representatives in each Co-Commercialization Country. The Parties will cooperate in the conduct of such activities with respect to scheduling, geographical allocation, and Professional or other customer targeting in order to optimize profits under the applicable Country/Region Commercialization Plan. Without limiting the generality of the foregoing, in each Co-Commercialization Country the Parties will share and, to the extent appropriate, cooperate to implement consistent policies and procedures with respect to the manner in which details and other sales visits are conducted.

(e) Co-Commercialization FTE Efforts.

with Sanofi and shall be intended to coordinate and integrate the Parties' respective FTE efforts and detailing activities) for ensuring that Regeneron will have in place a field force of qualified sales representatives to satisfy the Regeneron Commitment Level. In each Co-Commercialization Country, Sanofi shall perform the anticipated total FTE effort above the Regeneron Commitment Level.

- (ii) <u>Ophthalmology</u>. In the event that a Licensed Product receives Marketing Approval for an Indication related to ophthalmology, then, at Regeneron's option, Regeneron shall have the lead in the promotion of such Licensed Product in such Indication, provided, however, that the limitations set forth in Section 6.5(e)(i) shall apply.
- (f) <u>Training</u>. The Parties will coordinate sales force training efforts in Co-Commercialization Countries and will share training materials (and conduct joint training, where appropriate) to facilitate joint sales force training efforts.
- (g) <u>Samples</u>. Sanofi shall provide Regeneron with Licensed Product samples for use in Co-Commercialization Countries as required in the applicable Country/Region Commercialization Plan. Sanofi and Regeneron (and their respective Affiliates) shall use samples strictly in accordance with the then-applicable approved Country/Region Commercialization Plan and shall store and distribute samples in compliance with applicable Laws. Each Party (and its local Affiliates) will maintain those records required by all applicable Laws and shall allow representatives of the other Party to inspect such records and storage facilities for the Licensed Product samples on request.

 - 6.7 Sales and Licensed Product Distribution in the Territory; Other Responsibilities.
- (a) Sanofi (or its Affiliate) shall invoice and book, and appropriately record, all sales of the Licensed Products in the Field in the Territory. Sanofi (or its Affiliate) also shall be responsible for (i) the distribution of Licensed Products in the Field in the Territory and for paying all governmental rebates which are due and owing with respect to the Licensed Products in the Field in the Territory, (ii) handling all returns of Licensed Product sold under this Agreement and (iii) handling all aspects of ordering, processing, invoicing, collection, distribution and receivables with respect to Licensed Products in the Field in the Territory.
- (b) Sanofi (through its local Affiliates where appropriate), and with respect to the Co-Commercialization Countries, Regeneron (through its local Affiliates where appropriate), shall maintain records relating to its sales representative FTEs for the Licensed Products in the Field in the countries in a manner sufficient to permit the

determination of Sales Force Cost and Medical Post-Approval Cost and the incentive compensation requirements set forth in the Marketing Guidelines.

6.9 Promotional Materials.

- (a) Except as provided in and subject to Section 6.9(b): Sanofi will be responsible, consistent with the Marketing Guidelines, the Global Commercialization Plan and the Country/Region Commercialization Plans (as applicable) and the decisions of the JCC with respect to Promotional Materials as contemplated by Section 3.4(b)(vi), for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the Territory, except where Regeneron shall perform such responsibilities as the Lead Regulatory Party. Upon request, Regeneron will have the right to review and comment on all major Promotional Materials for use in any country in the Territory prior to their distribution by Sanofi for use in the Territory.
- (b) The Parties and their Affiliates shall only use the Promotional Materials and only conduct marketing and promotional activities for the Licensed Products which, in each case, are approved by the JCC or the applicable Country/Region Commercialization Committee if so delegated by the JCC for the applicable Major Market Country. Sanofi shall ensure that Regeneron's sales representatives are provided with reasonable quantities of Promotional Materials for use in a Co-Commercialization Country consistent with the Regeneron Commitment Level for such Co-Commercialization Country in accordance with the applicable approved Country/Region Commercialization Plan. All Promotional Materials generated for a Co-Commercialization Country shall be maintained in confidence and shall not be disclosed or distributed to Third Parties, until such time as they have been reviewed and approved as set forth in this Section.
 - (c) Sanofi shall own all rights to all Promotional Materials, including all copyrights thereto, in the Major Market Countries.

- 6.10 <u>Promotional Claims/Compliance</u>. Neither Party nor any of its Affiliates shall make any medical or promotional claims for any Licensed Product in the Field other than as permitted by applicable Laws. When distributing information related to any Licensed Product or its use in the Field in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), each Party and its Affiliates shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country.
- 6.11 <u>Restriction on Bundling in the Territory</u>. If Sanofi or its Affiliates or Sublicensees sell a Licensed Product in the Field in the Territory to a customer who also purchases other products or services from any such entity, Sanofi agrees not to, and to require its Affiliates and Sublicensees not to, bundle or include any Licensed Product as part of any multiple product offering or discount or price the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by a Party or its Affiliates to such customer, (b) is inconsistent with the Collaboration Purpose or (c) would result in pricing and discounting inconsistent with the applicable Marketing Guidelines.
- 6.12 <u>Inventory Management</u>. Sanofi shall use Commercially Reasonable Efforts to manage Licensed Product inventory on hand at wholesalers and Sublicensees so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.
- 6.13 <u>Medical and Consumer Inquiries</u>. The JCC shall establish guidelines to handle medical questions or inquiries from consumers relative to Licensed Products.
- 6.14 <u>Market Exclusivity Extensions</u>. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) a Party(ies) has the exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to Commercialize a Licensed Product in the Field in such country and (b) no generic equivalent of a Licensed Product in the Field may be marketed in such country.
- 6.15 <u>Post Marketing Clinical Trials</u>. Subject to the provision of this Agreement, the Parties shall comply with any clinical trials obligations with respect to a Marketing Approval with respect to any Licensed Product use in the Field in any country in the Territory, imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

ARTICLE VII CLINICAL AND REGULATORY AFFAIRS

- 7.1 Ownership of Approvals and Registration Filings.
- (a) Unless otherwise agreed to by the Parties, the Post-POC Principal Party shall be the Lead Regulatory Party and shall own (i) all Approvals with respect to Licensed Product in the Territory and (ii) the IND for Licensed Products during such time

as it is the Post-POC Principal Party and shall have the rights and obligations set forth in Sections 7.2 to 7.4 (inclusive) with respect thereto.

- (b) The Lead Regulatory Party shall license, transfer, provide a letter of reference with respect to, or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.
- (c) The non-Lead Regulatory Party shall provide such assistance with respect to regulatory matters as is reasonably requested by the Lead Regulatory Party and consistent with the terms of this Agreement.

7.2 Regulatory Coordination.

- (a) The Lead Regulatory Party shall oversee, monitor and coordinate applicable regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to each Licensed Product in the Field in each jurisdiction as to which it is the Lead Regulatory Party; provided that it shall adhere to the obligations in this Article VII. Without limiting the foregoing, the Lead Regulatory Party will be responsible for, and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for each Licensed Product in the Field for which it has responsibility as the Lead Regulatory Party. To the extent applicable, the Lead Regulatory Party shall perform all such activities in accordance with the Plans and all applicable Laws.
- (b) The Parties shall establish procedures, through the JDC or the JCC, to ensure that the Parties exchange on a timely basis all necessary information to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field, including, without limitation, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities and (ii) to comply with Laws in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field anywhere in the Territory. The Parties shall provide to each other prompt written notice of any Approval of a Licensed Product in the Field anywhere in the world. The Parties shall work together cooperatively through the JDC in the preparation of regulatory strategies and with respect to all material regulatory actions, communications and Regulatory Filings for Licensed Products in the Field in the Territory.
- (c) The Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party as promptly as practicable with written notice and copies of any material (i) draft filings with, (ii) submissions to and (iii) correspondence (including Approvals) with, Regulatory Authorities pertaining to the Development and/or Commercialization of a Licensed Product in the Field under the Plans, and shall use reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such material filings and submissions (including,

without limitation, all annual and periodic safety reports for Licensed Products in the Field), and consistent with applicable laws, to have up to two (2) representatives from the other Party attend and actively participate in all material, pre-scheduled meetings, telephone conferences and/or discussions with Regulatory Authorities to the extent such material meetings, telephone conferences and/or discussions pertain to the Development and/or Commercialization of any Licensed Product in the Field. Without limiting the foregoing, the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party on a timely basis with all material information, data and materials reasonably necessary for the other Party to participate in the preparation of the material filings and submissions referred to in this paragraph (c), said items to be provided to the other Party in a timely manner. The Parties will discuss in good faith any disputes on the contents of filings or submissions referred to in this paragraph (c) to the Regulatory Authorities and disputes shall be submitted to the JDC for timely resolution.

- (d) For each Licensed Product, the JDC shall develop and the JSC shall approve proposed target Licensed Product labeling ("<u>Target</u> Labeling") for use in the Territory.
- 7.3 <u>Regulatory Events</u>. Each Party shall keep the other Party informed, commencing within forty-eight (48) hours after notification (or other time period specified below), of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority, which:
 - (a) raises any material concerns regarding the safety or efficacy of any Licensed Product in the Field;
 - (b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of a Licensed Product in the Field under the Plans; provided, however, that each Party shall inform the other Party of the foregoing no later than twenty-four (24) hours after receipt of a notification referred to in this clause (b); or
 - (c) is reasonably likely to lead to a recall or market withdrawal of any Licensed Product in the Field anywhere in the Territory.

Information that shall be disclosed pursuant to this Section 7.3 shall include, but not be limited to the following matters with respet to Licensed Products:

- (i) Governmental Authority inspections of Manufacturing, Development, distribution or other facilities;
- (ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities, in each case, to the extent involving matters described in clauses (a), (b) or (c) of this Section 7.3;

- (iii) receipt of a warning letter issued by a Regulatory Authority;
- (iv) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction; and
- (v) receipt of product complaints concerning actual or suspected Licensed Product tampering, contamination, or mix-up (<u>e.g.</u>, wrong ingredients).
- 7.4 <u>Pharmacovigilance and Product Complaints</u>. While the Lead Regulatory Party shall be responsible for managing pharmacovigilance and product complaints and for formulating and implementing any related strategies, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning pharmacovigilence and risk management plans and product complaint reporting in all countries in which any Licensed Product is being developed, manufactured, or commercialized anywhere in the Territory. Without limitation to the foregoing, the Parties shall execute a Safety Data Exchange Agreement ("<u>SDEA</u>") setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse events/adverse drug reactions and Licensed Product complaints to ensure timely communication to Regulatory Authorities and compliance with Laws.
- 7.5 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a Licensed Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit to the extent it relates to the Development, Manufacture or Commercialization of a Licensed Product for use in the Field under this Agreement. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will promptly provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses; provided that the other Party, to the extent practicable, shall have the right to review and comment on such responses to the extent they cover or may be reasonably expected to adversely impact the Licensed Products in the Field in the Territory, and the Party that received the observations shall consider in good faith the comments made by such other Party. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within forty-eight (48) hours of receipt of a notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities used or proposed to be used for the Manufacture of Licensed Products for use in the Field under this Agreement; provided that such notification shall be given no later than twenty-four (24) hours prior to any such Regulatory Authority audit or inspection.
- 7.6 <u>Recalls and Other Corrective Actions</u>. Decisions with respect to any recall, market withdrawal or other corrective action related to any Licensed Product in the Field in the Territory shall be made only upon mutual agreement of the Parties, which agreement shall not be unreasonably withheld or delayed; provided, however, that nothing herein shall prohibit either

Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or Law. The Party that determines that a recall or market withdrawal of a Licensed Product in the Field in the Territory may be required shall, within twenty-four (24) hours, notify the other Party and, without limitation of and subject to the proviso in the immediately preceding sentence, the Parties shall decide whether such a recall or market withdrawal is required. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal. Expenses associated with such recalls will be treated as Other Shared Expenses.

ARTICLE VIII MANUFACTURING AND SUPPLY

- 8.1 Manufacture and Supply of Clinical Supply Requirements of Formulated Bulk Product. Until such time as Commercial Supply Requirements are being Manufactured, Regeneron will use Commercially Reasonable Efforts to provide an adequate and timely supply of Formulated Bulk Product for Clinical Supply Requirements of Licensed Products in the Field in the Territory in accordance with the Manufacturing Plan. Regeneron may use its Manufacturing facilities or, subject to Sanofi's prior written approval, such approval not to be unreasonably withheld or delayed, Sanofi or Third Parties to Manufacture such Formulated Bulk Product. If an entity other than Regeneron is to be used to Manufacture Formulated Bulk Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to Manufacture the applicable Licensed Product in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Party Manufacturers. The Formulated Bulk Product Manufactured by or on behalf of Regeneron for Clinical Supply Requirements will be billed to Sanofi by Regeneron at the Manufacturing Cost per Part I of Schedule 1 as a Development Cost. To the extent that Regeneron maintains manufacturing capacity available for the Manufacture of Clinical Supply Requirements, the cost of maintaining such capacity shall be included as a Development Cost to the extent it is not included as a Manufacturing Cost.
- 8.2 Finished Product Supply of Clinical Supply Requirements. Regeneron will timely identify, and enter into an agreement with, a Third Party or Third Parties or Sanofi (or use its own facilities, if Regeneron has such capabilities) to perform the filling, packaging, labeling and testing of the Formulated Bulk Product and supply Finished Product for Clinical Supply Requirements for Licensed Products for use under this Agreement. If an entity other than Regeneron is to be used to perform filling, packaging, labeling or testing services related to Finished Product for Clinical Supply Requirements, preference shall be given to Sanofi or an Affiliate of Sanofi that is qualified to perform such services in accordance with applicable Good Practices and where the estimated Manufacturing Cost is comparable to that of Third Parties. Such Finished Product for Clinical Supply Requirements Manufactured on behalf of Regeneron will be billed to Sanofi at the Manufacturing Cost as a Development Cost, in accordance with Part I of Schedule 1.
 - 8.3 Manufacture and Supply of Commercial Supply Requirements.
 - (a) The Parties, through the JMC and JSC, will determine whether a Party, or a Third Party on behalf of a Party, will be responsible for Manufacturing and

- (b) Once Manufacture of Commercial Supply Requirements of a Licensed Product begins, or is scheduled to begin, Manufacture of Clinical Supply Requirements of such Licensed Product shall be coordinated with Manufacture of Commercial Supply Requirements of such Licensed Product. Formulated Bulk Product and/or Finished Product Manufactured by or on behalf of a Party for Commercial Supply Requirements, and for Clinical Supply Requirements that are Manufactured in coordination with the Commercial Supply Requirements, will be billed at the Manufacturing Cost described in Part II of Schedule 1 as a Commercial Supply Cost and Clinical Supply Cost, respectively. If a Party has commercial scale capacity available in anticipation of beginning to Manufacture Commercial Supply Requirements, the JMC shall decide if such Party shall Manufacture any Clinical Supply Requirements even before it begins to Manufacture Commercial Supply Requirements.
- (c) Any Third Party manufacturer of Commercial Supply Requirements or Clinical Supply Requirements will be required to enter into a separate confidentiality agreement with Regeneron prior to the transfer of the manufacturing operations from Regeneron to such Third Party. All of Regeneron's costs and expenses associated with the transfer of the manufacturing operations and related Know-How to the Third Party manufacturer (or Sanofi, to the extent that Sanofi manufactures all or part of the Commercial Supply Requirements or Clinical Supply Requirements) will be billed as a Development Cost.

agreement containing terms and conditions regarding quality assurance and Good Practices and provide for terms for forecasting, ordering, delivery, payment and supply consistent with the terms of this Agreement.

- 8.6 <u>Manufacturing Shortfall</u>. Each Party is required to provide prompt written notice to the other Party if it reasonably determines that it will not, despite its using Commercially Reasonable Efforts, be able to supply the agreed upon demand forecast for the Licensed Products set forth in the Manufacturing Plan. Upon such notification, the matter will be referred to the JMC and JSC to determine what, if any (and identify and establish, as quickly as possible, if applicable) alternative supply source of Licensed Product (including the other Party) should be utilized.
- 8.7 Manufacturing Compliance. Each Party will use diligent efforts to Manufacture the Formulated Bulk Product and Finished Product supplied under this Article VIII or, as applicable, to ensure that the same is Manufactured by Third Parties in conformity with Good Practices and applicable Laws. Each Party will timely notify and seek the approval of the other Party, which approval shall not be unreasonably withheld or delayed, for any Manufacturing changes for the Formulated Bulk Product or Finished Product that are reasonably likely to have an adverse impact on (a) the quality of the Licensed Products supplied under this Agreement or (b) the regulatory status of the Licensed Products in the Territory, including requirements to support or maintain any Approvals. Each Party shall have the right to conduct inspections and audits of the other Party's facilities involved in the Manufacture of Licensed Products in the Field pursuant to this Agreement at reasonable times and on reasonable prior notice on terms to be agreed upon by the Parties. Moreover, each Party will use diligent efforts to negotiate agreements that would allow the other Party to audit the facilities of Third Party contractors (including Sanofi, if applicable) involved in the Manufacture of Licensed Products for use in the Field under this Agreement.

ARTICLE IX PERIODIC REPORTS; PAYMENTS

- 9.2 <u>Milestone Payments</u>. In addition to the other payments contemplated herein, Sanofi shall be obligated to pay the non-refundable, non-creditable milestone payments listed in Schedule 3 to Regeneron upon the occurrence of the applicable milestone event. Sanofi shall have thirty (30) Business Days after the achievement of any such milestones to pay the corresponding amount to Regeneron, in each case, which shall not be reduced by any withholding or similar taxes.
- 9.4 <u>Sharing of Profits from Licensed Products</u>. Commencing on the Effective Date and continuing during the Term, the Parties shall share the U.S. Profit Split in the United States, and (ii) the Rest of World Profit Split in the Rest of World Countries, in each case, as described in Schedule 2.
 - 9.5 <u>Periodic Reports</u>. Sanofi and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:
 - (a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Section 5.4;
 - (b) Within twenty (20) days following the end of each month, commencing with the month in which First Commercial Sale occurs, Sanofi shall deliver electronically to Regeneron a monthly detailed Net Sales report with monthly and year-to-date sales for each Licensed Product in the Field in the Territory by country in United States Dollars;
 - (c) Within forty-five (45) days following the end of each Quarter, commencing with the Quarter in which First Commercial Sale occurs, Sanofi shall

deliver electronically to Regeneron a written report setting forth, on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each Licensed Product in local currency and in United States Dollars, (ii) Licensed Product quantities sold in the Field by dosage form and unit size and (iii) gross Licensed Product sales in the Field and an accounting of the deductions from gross sales permitted by the definition of Net Sales:

- (d) Within forty-five (45) days following the end of each Quarter, each Party that has incurred any Other Shared Expenses or Shared Commercial Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses and/or Shared Commercial Expenses incurred by such Party in such Quarter on a country-by-country and Licensed Product-by-Licensed Product basis, including whether any such expenses are also included in the reports delivered pursuant to clause (e) below;
- (e) Within forty-five (45) days after the end of each Quarter, commencing with the Quarter in which First Commercial Sale in a Reporting Country/Region occurs (or such earlier agreed upon calendar Quarter, if appropriate), Sanofi shall provide to Regeneron, in electronic form, for each Reporting Country/Region, and Regeneron shall provide to Sanofi, in electronic form, for each Co-Commercialization Country, a report summarizing in reasonable detail the marketing, detailing, selling and promotional activities undertaken by a Party (or its Affiliates) during the previous Quarter in such Reporting/Country Region and/or Co-Commercialization Country; and
- (f) Within sixty (60) days following the end of each Quarter, Sanofi shall deliver electronically to Regeneron a Consolidated Payment Report in respect of such Quarter, combining the information reported by each Party pursuant to this Article IX and showing its calculations in accordance with Schedule 2 of the amount of any payments to be made by the Parties hereunder for such Quarterly period as contemplated by Section 9.5 (including, as applicable, showing the calculation of the U.S. Profit Split and Rest of World Profit Split) and, if applicable, providing for the netting of such payments.

All reports referred to in this Section 9.5 shall be in such form, format and level of detail as may be approved by the JFC. Unless otherwise agreed by the JCC, the financial data in the reports will include calculations in local currency and United States Dollars.

9.6 Funds Flow. The Parties shall make Quarterly True-Up payments as set forth in Schedule 2. If Sanofi is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report, it shall, subject to Section 9.12, make such payment to Regeneron within fifteen (15) days after its delivery to Regeneron of such Consolidated Payment Report. If Regeneron is the Party owing the Quarterly True-Up payment based on the calculations in the applicable Consolidated Payment Report, it shall, subject to Section 9.12, make such payment to Sanofi within fifteen (15) days after its receipt of such Consolidated Payment Report from Sanofi. Notwithstanding the foregoing, no later than fifty-five (55) days after the end of each Quarter, Sanofi shall pay Regeneron fifty percent (50%) of the amount of royalties or other amounts payable under any License (to the extent attributable to

the Manufacture, Development and/or Commercialization of Licensed Products under the Plans for the Territory) to which Regeneron is a party on account of the Commercialization of Licensed Products in the Field in the Territory and provide such supporting documentation required by such License, as the case may be.

- 9.7 <u>Invoices and Documentation</u>. The JFC shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder.
- 9.8 Payment Method and Currency. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars using the average of the buying and selling exchange rates for conversion of the applicable foreign currency into United States Dollars, using the spot rates (the "Closing Mid-Point Rates" found in the "Dollar spot forward against the Dollar" table published by *The Financial Times*, or any other publication as agreed to by the Parties) from the last Business Day of the preceding month.
- 9.9 <u>Late Payments</u>. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. All late payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in *The Wall Street Journal* (Eastern Edition) effective for the date on which the payment was due, plus ********* (such sum being referred to as the "<u>Default Interest Rate</u>").
- 9.10 <u>Taxes</u>. Except as set forth in Section 9.2, any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall promptly furnish to the other Party proper evidence or other reasonable documentation of the taxes so paid. Each Party shall cooperate with the other and furnish to the other Party appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). Without limiting the foregoing, each Party agrees to make all lawful and reasonable efforts to minimize any such taxes, assessments and fees and will claim on the other Party's behalf the benefit of any available treaty on the avoidance of double taxation that applies to any payments hereunder to such other Party.
- 9.11 <u>Adjustments to FTE Rates</u>. Notwithstanding anything herein to the contrary, upon the request of either Party, the Parties shall meet to review the accuracy of an applicable FTE rate in any country (<u>e.g.</u>, Sales Force FTE Rate, Medical Post-Approval FTE Rate, Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents

and materials in connection with an assessment of the applicable FTE rate and to determine in good faith whether to adjust the rate(s) in any country.

9.12 <u>Resolution of Payment Disputes</u>. In the event there is a dispute relating to any of the payment obligations or reports under this Article IX, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. In the event that no resolution is reached by the JFC, the matter shall be referred to the JSC in accordance with Section 3.11(a). Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder, provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

ARTICLE X DISPUTE RESOLUTION

- 10.1 <u>Resolution of Disputes</u>. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement and to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.
- 10.2 <u>Governance Disputes</u>. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article III ("<u>Governance Disputes</u>") shall be resolved pursuant to Article III and, to the extent such matters constitute Technical Development Matters, a dispute referred to in Section 14.2(b) or a Budget Dispute, Section 10.4, except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply. For the purposes of this Agreement, the term "<u>Technical Development Matter</u>" shall mean any dispute concerning a Party's refusal to approve a clinical trial proposed pursuant to Section 2.6(b).
- 10.3 <u>Legal Disputes</u>. The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the Effective Date by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute within five (5) Business Days of receipt by a Party of notice of such Legal Dispute, either Party may submit the Legal Dispute to the Executive Officers for resolution. In the event the Executive Officers are unable to resolve any such Legal Dispute within the time period set forth in Section 3.11(b), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1 and Section 20.15.
 - 10.4 Expert Panel.
 - (a) In the event of a dispute between the Parties concerning a Technical Development Matter, any Budget Dispute or a dispute referred to in Section

- 14.2(b) that cannot be resolved by the Executive Officers pursuant to Section 3.11(b) (other than a Legal Dispute), either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts ("Expert Panel") in accordance with this Section 10.4 (for the avoidance of doubt, it is understood that, subject to Section 10.4(e), in the case of a Budget Dispute first submitted to the Expert Panel, the specific issue shall be limited to the overall commercial reasonableness of the Disputed Budget). Such notice shall contain a statement of the issue forming the basis of the dispute, the position of the moving Party as to the proper resolution of that issue and the basis for such position. Within fifteen (15) days after receipt of such notice, the responding Party shall submit to the moving Party a statement of its conception of the specific issue in question, its position as to the proper resolution of that issue and the basis for such position.
 - (b) Within fifteen (15) days of the responding Party's response, each Party shall appoint to the Expert Panel an individual who (i) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue (or, in the case of a dispute regarding an audit as referred to in Section 14.2(b), expertise in accounting and auditing with respect to the development and commercialization of pharmaceutical products), (ii) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past five (5) years and (iii) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (i) through (iii) above, disclosing any potential conflict or bias and certifying that, as a member of the Expert Panel, such individual is able to render an independent decision.
 - (c) Within fifteen (15) days of the appointment of the second (2nd) expert, the two (2) appointed experts shall agree on an additional expert who meets the same criteria as described above, and shall appoint such expert as chair of the Expert Panel. If the Party-appointed experts fail to timely agree on a third (3rd) expert, then upon the written request of either Party, each Party-appointed expert shall, within ten (10) days of such request, nominate one expert candidate and the CPR Institute for Dispute Resolution shall, within ten (10) days of receiving the names of the Parties' respective nominees, select one of those experts to serve as the chair of the Expert Panel. Each expert shall agree, prior to his or her appointment, to render a decision as soon as practicable after the appointment of the full Expert Panel.
 - (d) Within seven (7) days of the appointment of the third (3rd) expert, the Expert Panel shall hold a preliminary meeting or teleconference with the Parties or their representatives and shall designate a time and place for a hearing of the Parties on the dispute and the procedures to be utilized at the hearing. The Parties may agree in writing to waive the hearing and have the Expert Panel reach a decision on the basis of written submissions alone. The Expert Panel may order the Parties to produce any documents or

documents or information which are relevant to the dispute. All such documents or information shall be provided to the other Party and the Expert Panel as expeditiously as possible but no later than one (1) week prior to the hearing (if any), along with the names of all witnesses who will testify at the hearing and a brief summary of their testimony. The hearing shall be held in New York, NY, unless otherwise agreed by the Parties, and shall take place as soon as possible but no more than forty-five (45) days after the appointment of the third expert, unless the Parties otherwise agree in writing or the Expert Panel agrees to extend such time period for good cause shown. The hearing shall last no more than one (1) day, unless otherwise agreed by the Parties or the Expert Panel agrees to extend such time period for good cause shown. After the conclusion of all testimony (or if no hearing is held after all submissions have been received from the Parties), at a time designated by the Expert Panel no later than seven (7) days after the close of the hearing or the receipt of all submissions, each Party shall simultaneously submit to the Expert Panel and exchange with the other Party its final proposed resolution (which, in the case of a Budget Dispute first submitted to the Expert Panel shall be a Party's proposed resolution that the Disputed Budget either is or is not overall commercially reasonable).

(e) In rendering the final decision with respect to a Budget Dispute first submitted to the Expert Panel, the Expert Panel shall be limited to determining the overall commercial reasonableness of the Disputed Budget. If the Expert Panel determines that such Disputed Budget is overall commercially reasonable, then such Budget Dispute shall be deemed finally resolved and such resolution shall be binding on the Parties. However, if the Expert Panel determines that such Disputed Budget is not overall commercially reasonable, then the Expert Panel shall, within fifteen (15) days after such determination, render a final decision as to what modifications could be made to such Disputed Budget in order for it to be overall commercially reasonable (a "Budget Modification Decision"). In connection with reaching a Budget Modification Decision, the Expert Panel shall order the Parties to produce any documents or other information which are relevant to such final decision, and the Parties shall submit such documents or other information, together with their respective proposed resolutions which shall consist of their respective proposed modifications to the Disputed Budget in order for it to be overall commercially reasonable, at least seven days prior to the date a Budget Modification Decision is required to be rendered as provided above. In rendering the final decision (which, for other than a Budget Modification Decision, shall be rendered no later than fifteen (15) days after receipt by the Expert Panel of the Parties' respective proposed resolutions, and for a Budget Modification Decision, shall be rendered no later than seven days after receipt by the Expert Panel of the Parties' respective proposed resolutions), the Expert Panel shall be limited to choosing a resolution proposed by a Party without modification; provided, however, that in no event shall the Expert Panel render a decision that is inconsistent with the Collaboration Purpose and the Parties' intentions as set forth in this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.

(f) The decision of the Expert Panel shall be final and binding on the Parties and may be entered and enforced in any court having jurisdiction. Each Party

shall bear the cost of its appointee to the Expert Panel and the Parties shall share equally the costs of the third expert.

10.5 <u>No Waiver</u>. Nothing in this Article X or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

ARTICLE XI TRADEMARKS AND CORPORATE LOGOS

- 11.1 <u>Corporate Names</u>. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.
- 11.2 Selection of Product Trademarks. For each Licensed Product, the JCC shall select one Product Trademark for use in the Field throughout the Territory, unless such Product Trademark is prohibited by law in any country in the Territory or the JCC determines that a different Product Trademark should be used in particular countries or Regions to maximize the commercial potential of such Licensed Product. Once a Product Trademark has been selected by the JCC, the Parties shall enter into an agreement or, in the alternative, shall amend this Agreement as the Parties may agree, in order to address the Parties' respective rights and obligations with respect to such Product Trademark. Each Licensed Product in the Field shall be promoted and sold in the Territory under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.
- 11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, and subject to Sections 11.4 and 11.5, Sanofi (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s), together with all associated domain names and all goodwill related thereto in all countries in the Territory.
- 11.4 <u>Prosecution and Maintenance of Product Trademark(s)</u>. Sanofi will use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark(s) in all countries in the Territory. Notwithstanding the foregoing, in the event Sanofi elects not to prosecute or maintain any Product Trademark(s) in any country in the Territory, Sanofi shall provide reasonable prior written notice to Regeneron of its intention not to prosecute or maintain any such Product Trademark in such country in the Territory, and Regeneron shall have the right to do so on behalf of Sanofi for use with Licensed Products, subject to consultation and cooperation with Sanofi. All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of Product Trademarks as provided in this Section 11.4 shall be shared by the Parties as part of Shared Commercial Expenses.
- 11.5 <u>License to the Product Trademark(s)</u>. Sanofi hereby grants to Regeneron a co-exclusive license (non-exclusive only with respect to Regeneron) to use the Product Trademark(s) for the Licensed Products solely for the purposes of Regeneron's Development, Manufacturing, and, if applicable, Co-Promotion of Licensed Products, or other Regeneron Commercialization activities with respect to Licensed Products if agreed to by Sanofi or set forth

in any Plans, subject to the terms and conditions of this Agreement. Consistent with Section 4.4 of this Agreement, neither Party shall license (or in the case of Regeneron, sublicense) rights to use, or otherwise transfer ownership of the Product Trademark(s) without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Sanofi shall only utilize the Product Trademark(s) on approved Promotional Materials, on the Licensed Products as needed and on or other approved product-related materials for the Licensed Products in the Field in the Territory for the purposes contemplated herein, and all use by Sanofi or its Affiliates or Sublicensees of the Product Trademark(s) shall be in accordance with (a) rules established by the JCC and (b) quality standards established by the JCC which are reasonably necessary in order to preserve the validity and enforceability of the Product Trademark(s). Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the Product Trademark(s) in relation to a product that is a Licensed Product, or take any other action which damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or a recordable version thereof, referred to above in this Section 11.5.

11.6 <u>Use of Corporate Names</u>. Sanofi (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include Regeneron's name with equal prominence on materials related to each Licensed Product in the Field (including, without limitation, package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with such Licensed Product), unless to do so would be prohibited under applicable Laws; provided, however, in the case of multi-product materials that refer to a Licensed Product in the Field as well as other pharmaceutical products, the prominence of Regeneron's name shall be commensurate with the relative prominence of the Licensed Product in such materials. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with the applicable Licensed Product in the Field in the Territory during the Term and thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging and samples, only for the time period and solely to the extent necessary to exhaust the existing inventory of Licensed Product (including packaging materials for such Licensed Product) and Promotional Materials containing such name or logo. During the Term, each Party shall submit samples of each such package inserts, packaging, trade packaging, etc. to such other Party for its prior approval, which approval shall not be unreasonably withheld or delayed, at least thirty (30) days before dissemination of such materials. Failure of the receiving Party to object within such thirty (30) day period shall constitute approval of the submitting Party's package inserts, packaging, trade packaging, etc.

ARTICLE XII NEWLY CREATED INVENTIONS AND KNOW-HOW

12.1 Ownership of Newly Created Intellectual Property.

(a) Subject to Section 12.1(e), each Party (and each Party's respective Affiliates) shall exclusively own all intellectual property (including, without limitation,

Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created in connection with the Collaboration solely by such Party, its Affiliates, employees, agents and consultants ("Sole Inventions"). Sole Inventions made solely by Sanofi, its Affiliates, employees, agents and consultants are referred to herein as "Sanofi Sole Inventions". Sole Inventions made solely by Regeneron, its Affiliates, employees, agents and consultants are referred to herein as "Regeneron Sole Inventions". The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder. Any remuneration payable under applicable law to an inventor and costs associated with determining such remuneration shall be treated as Other Shared Expenses.

- (b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Collaboration during the Term that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Sanofi or its Affiliate (or for which ownership vests in Sanofi or its Affiliate by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron or its Affiliate (or for which ownership vests in Regeneron or its Affiliate by operation of Law), on the other hand, on the basis of each Party (or its Affiliate) having an undivided interest in the whole ("Joint Inventions").
- (c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Sanofi Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.
- (d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under the Collaboration during the Term vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.
- (e) Subject to the other terms and conditions of this Agreement (other than Section 12.1(a)), to the extent permitted under any relevant Third Party agreement, each Party agrees that all Know-How, other than Excluded Know-How Rights, discovered, invented, authored or otherwise created by it (or its Affiliate) after the

Effective Date directly in connection with the performance of the research and clinical activities approved by the JDC, in each case, as included in the Global Development Plans shall be Joint Inventions. Each Party agrees to execute all necessary documentation to reflect the foregoing. As used above, the term "Excluded Know-How Rights" shall mean any Know-How claiming or covering composition (including any formulation) of a Licensed Product, including, for the avoidance of doubt, any manufacturing and/or cell line related intellectual property. For further clarity, nothing in this Section 12.1(e) shall be construed to grant either Party any rights to Patents or Know-How of the other Party discovered, invented, authored or otherwise created by it outside the performance of the research activities approved by the JDC and/or the clinical development activities approved by the JDC, in each case, as included in Global Development Plans.

(f) The Parties hereby agree that each Party's use of the Joint Inventions is governed by the terms and conditions of this Agreement shall be governed as follows: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as may be expressly set forth in Article IV, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 12.1(e) and (iii) nothing in this Article XII shall relieve a Party or its Affiliates of their obligations under Article XVI with respect to confidential Party Information provided by the other Party or such other Party's Affiliates. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. Neither Party hereto shall have the obligation to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Collaboration. The provisions governing Joint Inventions set forth in this Section 12.1(e) shall survive the expiration or termination of this Agreement.

12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights in the Territory. Regeneron shall undertake such activities using outside counsel reasonably acceptable to Sanofi except that all provisionals, the priority application based thereon and the corresponding PCT may be prepared and filed by Regeneron's in-house counsel. Regeneron shall confer with and keep Sanofi reasonably informed regarding the status of such activities. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of Regeneron Patent Rights: (i) Regeneron shall provide to Sanofi for review and comment a substantially completed draft of any

priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Regeneron and incorporate any reasonable comment from Sanofi within such thirty (30) day period unless Regeneron reasonably believes that such comments will adversely affect the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Regeneron shall provide Sanofi promptly with copies of all material communications received from or filed in patent offices in the Territory with respect to such filings; (iii) Regeneron shall consult with Sanofi promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications, provided, however, applications shall be filed in at least

(b) Sanofi shall prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Sanofi Patent Rights in the Territory and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Sanofi shall have the following obligations with respect to the filing, prosecution and maintenance of Sanofi Patent Rights: (i) Sanofi shall provide to Regeneron for review and comment a copy of a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Sanofi and incorporate any reasonable comment from Regeneron unless Sanofi reasonably believes that such comments will adversely affect the Patent Application or resulting Patent (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period); (ii) Sanofi shall provide Regeneron promptly with copies of all material communications received from or filed in patent offices with respect to such filings; (iii) Sanofi shall consult with Regeneron promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications, provided, however, applications shall be filed in at least the Patent Jurisdictions unless otherwise agreed in writing; and (iv) Sanofi shall

consult with Regeneron a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Sanofi desires to abandon any Patent included in the Sanofi Patent Rights in the Territory, Sanofi shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Sanofi Patent with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Sanofi's name, unless, with respect to any such Patent Applications that are unpublished, Sanofi notifies Regeneron that Sanofi would prefer to maintain the subject matter of such Patent Application as a trade secret and Regeneron agrees in writing.

(c) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners through outside counsel reasonably acceptable to the non-Controlling Party, except that the Controlling Party may prepare and file all provisional applications, priority applications based thereon and the corresponding PCTs using in-house counsel. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents under any such Joint Patent Rights: (i) the Controlling Party shall provide the non-Controlling Party with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by the Controlling Party and incorporate any reasonable comment provided by the non-Controlling Party within such thirty (30) day period (it being understood that the Parties will discuss any points of disagreement and work to resolve disagreements during this thirty (30) day period; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent Application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications provided, however, applications shall be filed in at least the Patent Jurisdictions unless otherwise agreed in writing; (iv) the Controlling Party shall provide the non-Controlling Party promptly with copies of all material communications received from or filed in patent offices with respect to such filings and the Parties use all reasonable efforts to reach agreement in a timely manner with respect to all material responses and amendments; and (v) the Controlling Party shall provide the non-Controlling Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office (including but not limited to substantially narrowing or canceling any claim without reserving the

right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Controlling Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the non-Controlling Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof. Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Patent or Patent Application relating to any Joint Patent Rights on thirty (30) days' prior written notice to the other Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the non-Controlling Party a free-of-charge option to assume the prosecution or maintenance thereof.

- (d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patents and Patent Applications pursuant to this Section 12.2, including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The JCC, with the approval of the JSC, will determine which of the Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights for which to seek an extension of term and the applicable Party will file for said patent term extension.
- (e) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Sanofi Patent Rights, Regeneron Patent Rights and Joint Patent Rights in the Territory for use in the Field, and any extensions thereof, shall be treated as Other Shared Expenses.

12.3 Interference, Opposition and Reissue.

(a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition or reexamination relating to Regeneron Patent Rights, Sanofi Patent Rights or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. The Parties will reasonably consult with one another in an effort to agree with respect to decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms,

provided that if such agreement cannot be reached promptly, such decisions will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron and (iii) with respect to Joint Patent Rights, jointly by the Parties.

(b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Regeneron Patent Rights, Sanofi Patent Rights and/or Joint Patent Rights in the Territory for use in the Field shall be treated as Other Shared Expenses.

ARTICLE XIII INTELLECTUAL PROPERTY LITIGATION AND LICENSES

13.1 Third Party Infringement Suits

(a) In the event that either Party or any of its Affiliates becomes aware of an actual, potential or suspected infringement of a Sanofi Patent Right, a Regeneron Patent Right, a Joint Patent Right, Product Trademark or any other intellectual property right jointly owned or licensed under this Agreement, by a Third Party's activities in the Field in the Territory, the Party that became aware of the infringement shall promptly notify the other Party in writing of this claim or assertion and shall provide such other Party with all available evidence supporting such known, potential or suspected infringement or unauthorized use. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the JSC to meet and consider the appropriate course of action with respect to such infringement. The Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution and/or settlement of any such claim.

(b) With respect to any such actual, suspected or potential infringement by virtue of a generic or potential generic competitor's activities in the Field in the Territory, including but not limited to, any ANDA filing, Paragraph IV Certification (or the equivalent for biologics) or other actual or potential infringement by a generic or potential generic competitor anywhere in the Territory, the Parties will consult and cooperate fully to determine a course of action. Final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made by Sanofi with active assistance from and in consultation with Regeneron. Regeneron will provide reasonable assistance to Sanofi in prosecuting any suit, and if required by Law, will join in the suit. Although Sanofi has the right to select counsel of its own choice, it shall first consult with Regeneron and consider in good faith the recommendations of Regeneron. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs, including attorneys' fees, relating to such legal proceedings and then shared equally by the Parties or according to the U.S. Profit Split and Rest of World Profit Split if and as applicable.

- (c) With respect to all other such actual, potential or suspected infringement by virtue of a Third Party's activities in the Field in the Territory, the Parties will consult and cooperate fully in an effort to determine a mutually agreeable course of action, provided if such agreement cannot be reached promptly, final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Sanofi, (ii) with respect to Sanofi Patent Rights, by Sanofi in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties. Any disagreement between the Parties concerning the enforcement of Joint Patent Rights shall be referred to the Executive Officers for resolution. The Party initiating the litigations shall be referred to as the "Lead Litigation Party." The non-Lead Litigation Party will provide reasonable assistance to the Lead Litigation Party in prosecuting any suit, and if required by Law, will join in the suit. Although the Lead Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall first be used to pay reasonable costs, including attorneys' fees, relating to such legal proceedings and then shared equally by the Parties.
- (d) All Out-of-Pocket Costs incurred in connection with any litigation under Section 13.1(b) or (c) related to activities in the Field in the Territory shall be treated as Other Shared Expenses.
- (e) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 13.1 that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent. Furthermore, no Party shall enter into any Third Party intellectual property license requiring the payment of royalties or other amounts based on the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory under this Agreement without the other Party's prior written consent.
- 13.2 <u>Patent Marking</u>. Each Party shall comply with the patent marking statutes in each country in which a Licensed Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates and/or Sublicensees.
 - 13.3 Third Party Infringement Claims; New Licenses.
 - (a) If either Party or its Affiliates shall learn of an allegation that the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this allegation. As soon as reasonably practicable after the receipt of such notice and at all times thereafter, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement. In any such instance, each Party shall have the right to defend any action naming it using its own

counsel; however, the Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense and/or settlement of any such claim. The rights and obligations in this Section 13.3 shall apply even if only one Party defends any claimed infringement action commenced by a Third Party in the Territory claiming that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes or otherwise violates any intellectual property rights of any Third Party.

- (b) Except as otherwise set forth in this Agreement, all Out-of-Pocket Costs (except for the expenses of the non-controlling Party's counsel, if only one Party defends a claim) incurred in connection with any litigation referred to in this Section 13.3 shall be treated as Other Shared Expenses.
- (d) License fees, royalties and other payments under Licenses to the extent attributable to, and based on, the discovery, Development and Manufacture of Commercial Supply Requirements or the Commercialization of Licensed Products in the Field in the Territory shall be treated as Other Shared Expenses.

ARTICLE XIV BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

14.1 <u>Books and Records</u>. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with GAAP or IAS/IFRS) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

14.2 Audits and Adjustments.

(a) Each Party shall have the right (at its own cost), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during

any Contract Year, to have the books and records of the other Party and its Affiliates to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.

- (b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to dispute resolution in accordance with Article X. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than seven and one-half percent (7.5%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article XVI.
- (c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then unless the result of the audit is to be contested pursuant to Section 14.2(b) above, the Party owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section.
- 14.3 <u>GAAP/IAS/IFRS</u>. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with, at a Party's election, GAAP or IAS/IFRS.

ARTICLE XV REPRESENTATIONS, WARRANTIES AND COVENANTS

15.1 <u>Due Organization</u>, Valid Existence and <u>Due Authorization</u>; Financial <u>Capability</u>. Each Party hereby represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate (or, in the case of Sanofi Amerique, partnership) power and authority and has taken all corporate (or, in the case of Sanofi Amerique, partnership) action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement by which it is bound or any requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in

accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under Article IV hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Each Party hereby represents and warrants to the other Party that such Party has, and will continue to have, sufficient liquid assets to promptly and timely pay and perform all of the payments and obligations required by such Party or its Affiliates to be paid and performed by them hereunder.

- 15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any Governmental Authority or arbitrator that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.
- 15.3 <u>Additional Regeneron Representations</u>, Warranties and Covenants. Regeneron additionally represents and warrants to Sanofi that, as of the Effective Date:
 - (a) Regeneron owns all right, title and interest in and to all Regeneron Patent Rights in existence as of the Effective Date;
 - (b) Regeneron has the right and authority to grant the rights granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted any rights that would be inconsistent with or in conflict with or in derogation of the rights granted herein;
 - (c) there is no pending litigation that alleges that any of Regeneron's activities relating to the Regeneron Intellectual Property have violated, or would violate, the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation);
 - (d) to Regeneron's knowledge, no litigation has been otherwise threatened which alleges that any of its activities relating to the Regeneron Intellectual Property have violated or would violate, any intellectual property rights of any Third Party;
 - (e) the conception, development and reduction to practice of any Regeneron Intellectual Property existing as of the Effective Date has not constituted or involved the misappropriation of trade secrets or other rights of any Person;
 - (f) to Regeneron's knowledge, the issued Patents included in the Regeneron Intellectual Property existing as of the Effective Date are not invalid or unenforceable, in whole or part;

- (g) Regeneron has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Regeneron Patent Rights or Regeneron's rights therein, and, to Regeneron's knowledge, none of the Regeneron Patent Rights are subject to any pending re-examination, opposition, interference or litigation proceedings; and
- (h) Regeneron has enforceable written agreements with all of its employees and contractors who may participate in the conduct of the Collaboration or receive Confidential Information hereunder assigning to Regeneron ownership of all intellectual property rights created in the course of their employment or provision of services, as applicable.
- 15.4 <u>Disclaimer of Wartanties</u>. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT IN THE FIELD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.
- 15.5 Mutual Covenants. Each Party hereby covenants to the other Party as of the Effective Date as follows: (a) it will not during the Term grant any right or license to any Third Party in the Territory which would be inconsistent with or in conflict with or in derogation of the rights granted to the other Party under this Agreement, and will not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement; (b) neither Party will use the Patent Rights or Know-How of the other Party outside the scope of the licenses and rights granted to it under this Agreement; and (c) in the course of the Development or Commercialization of a Licensed Product in the Field under this Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

ARTICLE XVI CONFIDENTIALITY

16.1 Confidential Information.

(a) Each of Sanofi and Regeneron acknowledges (subject to the further provisions of this Article XVI and the provisions of Article XIX) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement (or, in the case of Sanofi, Party Information provided to it under the Confidentiality Agreements is confidential and proprietary to such other Party. Furthermore, each of Sanofi and Regeneron acknowledges (subject to the further provisions of this Article XVI) that all New

Information is confidential and proprietary to both Parties. Subject to the further provisions of this Article XVI, each of Sanofi and Regeneron agrees to (i) maintain such Party Information of the other Party (or its Affiliates) and all New Information in confidence during the Term and for a period of ten (10) years thereafter and (ii) use such Party Information of the other Party (or its Affiliate) and New Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Sanofi and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such Party Information of the other Party (or its Affiliate) or New Information to any Third Party except (A) to its employees, agents, consultants or any other Person under its authorization; provided such employees, agents, consultants or Persons are subject in writing to substantially the same confidentiality obligations as the Parties, (B) as approved by both Parties hereunder or (C) as set forth elsewhere in this Agreement.

(b) Notwithstanding anything provided above, the restrictions provided in this Article XVI shall not apply to information that was or is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information; (iv) similar in nature to the purported Party Information or New Information but has been independently created, as evidenced by written or electronic documentation, without any aid, application or use of the Party Information or New Information; (v) necessary to file, prosecute or defend Patents and Patent Applications for which the Party has the right to assume filing, prosecution, defense or maintenance pursuant to this Agreement; or (vi) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded), or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable, and provided, further, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information which is required by Governmental Authority, applicable Law (including the rules or regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded) or court order to be disclosed. Moreover, either Party may use Party Information and New Information to enforce the terms of this Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information.

- (c) Notwithstanding anything provided above or elsewhere in this Agreement, Regeneron and its Affiliates shall have the right to use and disclose any New Information directly related to any Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law.
- (d) Notwithstanding anything provided above or elsewhere in this Agreement, Sanofi and its Affiliates shall have the right to use and disclose any New Information directly related to any Licensed Product (including the Manufacture or use thereof) to Governmental Authorities or Regulatory Authorities as required by Law.
- 16.2 <u>Injunctive Relief</u>. The Parties hereby acknowledge and agree that the rights of the Parties hereunder are special, unique and of extraordinary character, and that if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the other Party, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any Party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged Party at law or in equity, such damaged Party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.
- 16.3 <u>Publication of New Information</u>. During the Term, if either Sanofi or Regeneron (the "<u>Publishing Party</u>") desires to disclose any New Information in scientific journals, publications or scientific presentations, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it or the Licensed Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material adverse effect) to which the Publishing Party shall give due consideration. Disputes concerning publication shall be resolved by the JDC (other than Legal Disputes).
- 16.4 <u>Disclosures Concerning this Agreement</u>. The Parties will mutually agree upon the contents of their respective press releases with respect to the execution of this Agreement and any Ancillary Agreement which shall be issued simultaneously by both Parties on the Effective Date. Sanofi and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement, any Ancillary Agreement or any actions or activities contemplated hereunder or thereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable

cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement, any Ancillary Agreement or any actions or activities contemplated hereunder or thereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding the Collaboration. Except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article XVI without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. The Parties, through the Committees, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the Licensed Products in the Field. Sanofi acknowledges that Regeneron as a publicly traded company may be legally obligated to make timely disclosures of material events relating to Licensed Products. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement and each Ancillary Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the nonfiling Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE XVII INDEMNITY

17.1 Indemnity and Insurance.

(a) Sanofi will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees, licensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Sanofi, its Affiliates or their respective directors, officers, employees, agents or Sublicensees, including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad

faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee; or

- (ii) material breach by Sanofi of the terms of, or the inaccuracy when made of any representation or warranty made by it in, this Agreement.
- (b) Regeneron will defend, indemnify and hold harmless Sanofi, its Affiliates and their respective officers, directors, employees, Sublicensees and agents ("Sanofi Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Sanofi Indemnitee that is due to or based upon:
 - (i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Regeneron, its Affiliates or their respective directors, officers, employees, licensees or agents including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions or violations of Law committed by Sanofi or any other Sanofi Indemnitee; or
 - (ii) material breach by Regeneron of the terms of, or the inaccuracy when made of any representation or warranty made by it in, this Agreement.
- (c) In the event of any Third Party claim alleging that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes a Patent Right of a Third Party for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other Party for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.
- (d) In the event of any Third Party product liability claim alleging that the Development or Commercialization of any Licensed Product in the Field causes damages for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.

- (f) Notwithstanding anything to the contrary in this Section 17.1, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Sanofi Indemnitees, as the case may be) from Third Party claims resulting from, and to the extent allocable to, the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Third Parties contracted to Manufacture any part of the Clinical Supply Requirements or Commercial Supply Requirements pursuant to Article VIII; provided, however, that nothing in this Section 17.1(f) limits either Party's indemnification obligations to the extent any Third Party claims arise from the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed directly by the Party that is responsible for contracting with such Third Party Manufacturer(s) pursuant to Article VIII.
- 17.2 <u>Indemnity Procedure</u>. The Party entitled to indemnification under this Article XVII (an "<u>Indemnified Party</u>") shall notify the Party potentially responsible for such indemnification (the "<u>Indemnifying Party</u>") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder. For the avoidance of doubt, the indemnification procedures in this Section 17.2 shall not apply to claims for which each Party indemnifies the other Party for fifty percent (50%) of all Damages, under the terms of Section 17.1(c).
 - (a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; and (ii) such compromise or settlement does not (A) include any admission of legal wrongdoing by the Indemnified Party, (B) require any payment by the Indemnified Party that is not indemnified hereunder or (C) result in the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed); provided that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnifying Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such

litigation. The Indemnified Party may not compromise or settle such litigation without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld or delayed.

- (b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party.
- (c) The amount of any Damages for which indemnification is provided under this Article XVII will be reduced by the insurance proceeds received, and any other amount recovered if any, by the Indemnified Party in respect of any such Damages.
- (d) If an Indemnified Party receives an indemnification payment pursuant to this Article XVII and subsequently receives insurance proceeds from its insurer with respect to the Damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article XVII and (ii) the amount necessary to fully and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article XVII.

ARTICLE XVIII FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

ARTICLE XIX
TERM AND TERMINATION

19.1 Term/Expiration of Term.

- (a) The "Term" of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated in its entirety in accordance with this Article XIX, shall expire upon the later to occur of (i) the expiration of the Discovery Program, and (ii) such time as neither Party, nor either Party's Affiliates or Sublicensees, is Developing or Commercializing any Licensed Product in the Field in the Territory under this Agreement and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent.
- (b) Upon expiration of the Term pursuant to Section 19.1(a) above, except as set forth in this Agreement, all licenses and rights with respect to Licensed Products shall automatically terminate and revert to the granting Party.

19.2 Termination Without Cause.

(a) By Sanofi. (i) Sanofi may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the Discovery Program in accordance with the terms of the Discovery Agreement, or may terminate this Agreement in the entire Territory for a particular Licensed Product or particular Licensed Products in the Field, in any such case on twelve (12) months' prior written notice to Regeneron. Except as otherwise provided below in this Section 19.2(a), in the event of such termination by Sanofi of this Agreement in its entirety or with respect to one or more Licensed Product(s) pursuant to this Section 19.2, this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the "Sanofi Termination Notice Period") and the terms of Schedule 4 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(a) or Schedule 4, during the Sanofi Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products (including the Opt-Out Products(s)) in the Field in accordance with Plans. During the Sanofi Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Sanofi hereunder and in any event upon the expiration of the Sanofi Termination Notice Period, whether or not any such notice is given by Regeneron, (i) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Opt-Out Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Sanofi Termination Notice Period), (ii) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Opt-Out Product(s) shall terminate, and (iii) Sanofi will promptly take the actions required by Schedule 4 and Regeneron will reasonably cooperate with Sanofi (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron's (or its nominee's) expeditious assumption during the Sanofi Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Opt-Out Product(s) in the Field in the Territory. In addition, during the Sanofi Termination Notice Period, neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or

change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Sanofi Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

- (ii) In addition to Sanofi's termination rights set forth in Section 19.2(a)(i), from and after the twelfth (12th) anniversary of the First Commercial Sale of a Licensed Product in a country, Sanofi may, upon twenty-four (24) months' prior written notice to Regeneron, terminate this Agreement with respect to such Licensed Product in such country. If Sanofi exercises such right, the provisions of Section 19.2(a)(i) (except that the Sanofi Termination Notice Period referred to therein shall be twenty-four (24) months rather than twelve (12) months), and Sections 19.7(a) and 19.8 shall apply with respect to such Terminated Licensed Product in such country.
- (b) By Regeneron, Regeneron may terminate this Agreement in its entirety, but only after the expiration or earlier termination of the Discovery Program in accordance with its terms, or may terminate this Agreement in the entire Territory for a particular Licensed Product or particular Licensed Products in the Field, in any such case, on twelve (12) months' prior written notice to Sanofi. Except as otherwise provided below in this Section 19.2(b), in the event of such termination by Regeneron of this Agreement in its entirety or with respect to one or more Licensed Product(s) pursuant to this Section 19.2(b), this Agreement (including, without limitation, all payment obligations hereunder) shall continue in full force and effect through the notice period set forth above (the "Regeneron Termination Notice Period") and the terms of Schedule 5 (including the grant of rights and licenses set forth in paragraph 2 thereof) shall automatically apply. Except as set forth in this Section 19.2(b) or Schedule 5, during the Regeneron Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products (including the Opt-Out Products(s)) in the Field in accordance with Plans. During the Regeneron Termination Notice Period, to the extent set forth or requested in one or more written notices from Sanofi to Regeneron hereunder and in any event upon the expiration of the Regeneron Termination Notice Period, whether or not any such notice is given by Sanofi, (i) the licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Opt-Out Product(s) shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the Regeneron Termination Notice Period), (ii) the licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Opt-Out Products(s) shall terminate, and (iii) Regeneron will promptly take the actions required by Schedule 5 and Sanofi will reasonably cooperate with Regeneron (for avoidance of doubt, such cooperation shall not require Sanofi to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Sanofi) to facilitate Sanofi's (or its nominee's) expeditious assumption during the Regeneron Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of the Opt-Out Product(s) in the Field in the Territory. In addition, during the Regeneron Termination

Notice Period, neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Regeneron Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s).

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety or for a particular Licensed Product or particular Licensed Products in the Field in the entire Territory, upon written notice to the other Party, if such other Party commits a material breach of its obligations under this Agreement with respect to such Licensed Product(s) as to which such notice of termination is given (or all Licensed Products if such notice of termination is with respect to this Agreement is in its entirety). Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach bit such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days so long as the breaching party is using Commercially Reasonable Efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use Commercially Reasonable Efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall not apply). For purposes of this Section 19.3, the term "material breach" shall mean an intentional, continuing (and uncured within the time period described above) material breach by a Party, as determined by a court of competent jurisdiction.

19.4 <u>Termination for Insolvency</u>. Either Party shall have the right to terminate this Agreement in its entirety, by and effective immediately, upon written notice to the other Party, if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, (b) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within ninety (90) days after the filing thereof or (c) if the other Party shall make a general assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties agree

that all intellectual property rights licensed hereunder, including, without limitation, any patents or patent applications in any country of a party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

19.5 Termination for Breach of Standstill or Lock-Up. Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have breached their obligations under any of Sections 3, 4 or 5 of the Investor Agreement (to the extent such sections of the Investor Agreement is then in effect). Furthermore, Regeneron shall have the unilateral right to terminate this Agreement in its entirety, effective immediately upon written notice to Sanofi, if Sanofi or any of its Affiliates shall have (a) breached their obligations under Section 20.16 of the Aventis Collaboration Agreement, to the extent that such Section 20.16 remains in effect after the Effective Date, or (b) breached its obligations under Section 5.3 of the Aventis Stock Purchase Agreement, to the extent that such Section 5.3 remains in effect after the Effective Date. Any such breach of the Investor Agreement, the Aventis Stock Purchase Agreement or the Aventis Collaboration Agreement, as the case may be, shall be treated as a breach of this Agreement. Notwithstanding the foregoing and for the avoidance of doubt, Regeneron shall not have the right to terminate this Agreement as a result of (i) a de minimus breach of Section 3.1(a) of the Investor Agreement (to the extent such Section 3.1(a) is in effect after the Effective Date) or of Section 20.16(a) of the Aventis Collaboration Agreement (to the extent such Section 3.1(g) is in effect after the Effective Date) or an inadvertent breach of Section 20.16(g) of the Investor Agreement (to the extent such Section 3.1(g) is in effect after the Effective Date) or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement (to the extent such Section 20.16(g) remains in effect after the Effective Date), arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in par

19.6 Termination of Discovery Agreement.

- (a) By Regeneron. Regeneron may terminate this Agreement in its entirety, effective upon written notice to Sanofi, if the Discovery Agreement has been terminated by Regeneron pursuant to Section 12.2, 12.3 or 12.5 thereof.
- (b) By Sanofi May terminate this Agreement in its entirety effective upon written notice to Regeneron, if the Discovery Agreement has been terminated by Sanofi pursuant to Section 12.2 or 12.3 thereof.
- (c) <u>Automatic</u>. This Agreement shall automatically terminate in its entirety if, at the time the Discovery Agreement terminates for any reason pursuant to Article 12 thereof, Sanofi has not exercised its Opt-In Right pursuant to Section 5.3 of the Discovery Agreement with respect to any Product Candidate.

19.7 Effect of Termination.

- (a) Except as provided in Section 19.2(b), and in Section 19.7(b) below, upon termination of this Agreement with respect to all Licensed Products in the Field, or for a particular Licensed Product or particular Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the provisions of Schedule 4 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated Licensed Product(s), and except to the extent required by Sanofi to fulfill its obligations pursuant to Schedule 4, (i) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate, and revert to Regeneron, (ii) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate and (iii) the license from Sanofi and its Affiliates to Regeneron referred to in Schedule 4 shall automatically come into full force and effect with respect to the Terminated Licensed Product(s). If Regeneron terminates this Agreement pursuant to Section 19.3, 19.4 or 19.5, or pursuant to Section 19.6(a) then Sanofi shall pay to Regeneron, in addition to any other amount payable by Sanofi to Regeneron under this Agreement, under Law, or pursuant to any contractual remedies available to Regeneron, an amount equal to one hundred percent (100%) of the Development Costs incurred by Regeneron under the Global Development Plan during the period commencing on the effective date of such termination of this Agreement pursuant to any of such Sections and ending on the twelve (12) month anniversary of such date.
- (b) Upon termination of this Agreement by Regeneron pursuant to Section 19.2(b) or by Sanofi pursuant to Section 19.3 or 19.4, in its entirety, or for a particular Licensed Product or particular Licensed Products in the Field, the provisions of Schedule 5 shall apply (including during any applicable Termination Notice Period) with respect to the Terminated Licensed Product(s) and, except to the extent required by Regeneron to fulfill its obligations pursuant to Schedule 5, (i) all licenses and rights granted by Sanofi to Regeneron hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate, and revert to Sanofi, (ii) all licenses and rights granted by Regeneron to Sanofi hereunder with respect to the Terminated Licensed Product(s) shall automatically terminate and (iii) the license from Regeneron referred to in Schedule 5 shall come into full force and effect with respect to the Terminated Licensed Product(s)
- 19.8 <u>Survival of Obligations</u>. Except as otherwise provided in this Article XIX, or Schedule 4 or Schedule 5, upon expiration, or upon termination of this Agreement with respect to all Licensed Products in the Field, or for a particular Licensed Product or particular Licensed Products in the Field in the Territory or, if applicable pursuant to Section 19.2(a)(ii), in one or more countries, the rights and obligations of the Parties hereunder with respect to the Terminated Licensed Product(s), in the applicable country or countries if such termination is pursuant to Section 19.2(a)(ii), shall terminate, and this Agreement shall cease to be of further force or effect to the extent of such termination, provided that notwithstanding any expiration or termination of this Agreement:

- (a) neither Sanofi nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that Regeneron's obligations with respect to the Global Development Balance payments provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero:
- (b) subject to the provisions of this Article XIX, including Schedule 4 and Schedule 5 to the extent applicable, the obligations of the Parties with respect to the protection and nondisclosure of Party Information and New Information in accordance with Article XVI, as well as other provisions (including, without limitation, Sections 7.4, 9.8, 9.9, 9.12, 10.3 and 10.4, the second sentence of Section 12.1(e) and Articles XII (with respect to Joint Inventions), XVI, XVII, XIX and XX) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable; and
- (c) such expiration or termination and this Article XIX shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

ARTICLE XX MISCELLANEOUS

- 20.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. Except as set forth in Article X, the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.
- 20.2 <u>Waiver</u>. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.
- 20.3 <u>Notices</u>. All notices, instructions and other communications required or permitted hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 6 attached hereto and shall be (a) delivered personally, (b) sent via a reputable

nationwide overnight courier service, or (c) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, one (2) Business Days after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.

- 20.4 Entire Agreement. This Agreement, together with the Discovery Agreement and, solely to the extent referred to herein, the Ancillary Agreements contain the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof, provided that the last sentence of Section 1.41 of the Discovery Agreement shall apply with respect to any conflict or inconsistency between this Agreement and the Discovery Agreement.
- 20.5 <u>Amendments</u>. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Sanofi and Regeneron.
- 20.6 <u>Interpretation</u>. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation" or like expression; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine and neuter pronouns and expressions shall be interchangeable; and (d) the words "herein" or "hereunder" relate to this Agreement.
- 20.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.
- 20.8 <u>Registration and Filing of the Agreement</u>. To the extent that a Party concludes in good faith that it is or may be required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.
- 20.9 <u>Assignment</u>. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Sanofi or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by

Sanofi or (b) the prior written consent of Sanofi in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.10 <u>Successors and Assigns</u>. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Sanofi Indemnitees to the extent provided in the last sentence of Section 20.13.

20.11 Affiliates. Each Party may, and to the extent it is in the best interests of the Licensed Products in the Field in the Territory shall, perform its obligations hereunder through one or more of its Affiliates. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party the prompt and timely performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Sanofi Amerique guarantees to Regeneron the prompt and timely payment of amounts payable by Sanofi to Regeneron hereunder once those amounts have become legally due and payable. Without limiting the foregoing, no Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of a Licensed Product under this Agreement, then such Party shall enter into a separate agreement with such Affiliate pursuant to which the obligations of such Party hereunder shall be binding on such Affiliate and which shall provide that the other Party is a third-party beneficiary of such agreement entitled to enforce such agreement and this Agreement against such Affiliate. Each Party represents and warrants to the other Party that it has licensed or will license from its Affiliates the Patents and Know-How owned by its Affiliates that are to be licensed (or sublicensed) to the other Party under this Agreement.

20.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

20.13 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the foregoing, Article XVII is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Sanofi Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

- 20.14 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as provided for in this Agreement. Neither Sanofi nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Sanofi, and Sanofi's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.
- 20.15 Limitation of Damages. IN NO EVENT SHALL REGENERON OR SANOFI BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 20.15 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD-PARTY CLAIMS.
- 20.16 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the Development, Manufacture or Commercialization of any Licensed Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.
 - 20.17 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.

[Remainder of page intentionally left blank; signature page follows]

IN WITNESS WHEREOF, Sanofi, Sanofi Amerique and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

AVENTIS PHARMACEUTICALS INC.

By: /s/ Karen Linehan

Name: Karen Linehan Title: Authorized Signatory

By: /s/ Robin White

Name: Robin White

Title: Authorized Signatory

SANOFI-AVENTIS AMERIQUE DU NORD (solely for purposes of Section 15.1, 15.2 and 20.11).

By: /s/ Jean-Luc Renard

Name: Jean-Luc Renard Title: Authorized Signatory

By: /s/ Karen Linehan

Name: Karen Linehan Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard Schleifer

Name: Leonard Schleifer Title: President & CEO

EXHIBIT A

Royalties For Opt-Out Products

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EXHIBIT B

Summary Outline of Initial Development Plan For REGN88 (IL-6RmAb)

Manufacturing Cost

Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the "Quarterly True-Up") equal to (a) the U.S. Profit Split for such Quarter payable to Regeneron (as set forth in Part I), plus (b) the Rest of World Profit Split for such Quarter payable to Regeneron (as set forth in Part II), minus (c) the Development Compensation Payment for such Quarter payable to Sanofi (as set forth in Part III), plus or minus (d) the Regeneron Reimbursement Amount for such Quarter payable to either Regeneron or Sanofi (as set forth in Part IV).

In the event that the Quarterly True-Up is an amount greater than zero, such amount shall be payable by Sanofi to Regeneron in accordance with the terms set forth in Article 9. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Sanofi in accordance with the terms set forth in Article 9. An example of the Quarterly True-Up is shown in Part V.

I. U.S. PROFIT SPLIT

The "<u>U.S. Profit Split</u>" shall mean fifty percent (50%) of U.S. Profits in a Quarter. "<u>U.S. Profits</u>" in a Quarter shall mean aggregate Net Sales of all Licensed Products in the U.S. in the Quarter less the sum of (a) aggregate COGS in the U.S. in the Quarter, (b) aggregate Shared Commercial Expenses incurred by both Parties and allocable to the U.S. in the Quarter, and (c) aggregate Other Shared Expenses incurred by both Parties and allocable to, the U.S. in the Quarter.

An example of a calculation of the U.S. Profit Split in a Quarter would be:

II. REST OF WORLD PROFIT SPLIT

The Parties intend to share profits from Net Sales of Licensed Products in the Rest of World (or ROW) in each Contract Year (the "Rest of World Profit Split," defined below) based on the aggregate amount of such Net Sales in accordance with the Target ROW Profit Split (defined below). Since the full calculation cannot be done until aggregate Net Sales for the full Contract Year are known, each Quarter, the Parties will calculate an estimated profit split for the Quarter based on Net Sales for the Quarter in ROW and the Applicable ROW Percentages (defined below). Following the end of each Contract Year, the Parties will true-up the quarterly estimates of the Rest of World Profit Split to the Target ROW Profit Split through the ROW Profit Split Annual True-Up calculation (defined below).

The "<u>Target ROW Profit Split</u>" for any Contract Year shall mean a profit split whereby ROW Profits from ROW Net Sales of all Licensed Products up to ****** in the Contract Year are split 65% Sanofi/35% Regeneron, and ROW Profits from ROW Net Sales of all Licensed Products from ******* up to \$750 million in the Contract Year are split 60% Sanofi/40% Regeneron, and ROW Profits from ROW Net Sales of all Licensed Products greater than \$750 million in the Contract Year are split 55% Sanofi/45% Regeneron, with all profit splits calculated using the assumption that the ratio of ROW Profits to ROW Net Sales is the same on each dollar of ROW Net Sales in the Contract Year.

The "Rest of World Profit Split" (or "ROW Profit Split") for a Quarter shall mean ********

The "Applicable ROW Percentages" for the Quarter for each of Sanofi and Regeneron shall mean the percentages to be used to calculate each Party's Rest of World Profit Split for the Quarter, as illustrated in the example below. At the end of each Contract Year, as part of the calculation of the fourth Quarter Rest of World Profit Split, a "ROW Profit Split Annual True-Up" shall also be calculated to make each Party's Rest of World Profit Split for the Contract Year equal to the Target ROW Profit Split. Calculation of the Applicable ROW Percentages and Rest of World Profit Splits for a Quarter and ROW Profit Split Annual True-Up for a Contract Year are illustrated in the example below.

Notwithstanding the method of calculation shown above, in any Quarter (or for any full Contract Year) in which the ROW Profits are negative, the Applicable ROW Percentages for such Quarter

(or for such Contract Year after calculation of the ROW Profit Split Annual True-Up) shall be fifty-five percent (55%) for Sanofi and forty-five percent (45%) for Regeneron.

An example of a calculation of the Rest of World Profit Split in a Quarter would be:

Net Sales in the ROW	Aggregate ******	Sanofi *****	Regeneron *****
COGS	*****	*****	*****
Shared Commercial Expenses	******	*****	****
Other Shared Expenses	*****	*****	****
ROW Profits	*****	*****	*****
Applicable ROW Percentages		***	***
ROW Profit Split		***	***

III. DEVELOPMENT COMPENSATION PAYMENT

The "Regeneron Profit Split" in a Quarter shall mean the sum of (a) the U.S. Profit Split for such Quarter payable to Regeneron plus (b) the Rest of World Profit Split for such Quarter payable to Regeneron.

The "Development Balance" as of the end of a Quarter shall mean ********

An example of a calculation of the Development Compensation Payment in a Quarter would be:	
Development Balance at the end of the Quarter	**
U.S. Profit Split payable to Regeneron Rest of World Profit Split payable to Regeneron Regeneron Profit Split *****	**: ** **:
Development Compensation Payment	**
For the avoidance of doubt, the Development Costs for and Opt-Out Product until the time such Opt-Out Product becomincluded in the calculation of the Development Balance.	nes an Opt-Out Product are
IV. REGENERON REIMBURSEMENT AMOUNT	
The "Regeneron Reimbursement Amount" for a Quarter shall mean ******	
An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:	
Regeneron Shared Commercial Expenses in the U.S.	**** ****
Regeneron Shared Commercial Expenses in ROW Regeneron Other Shared Expenses in the U.S.	****
Regeneron Other Shared Expenses in ROW Regeneron Development Costs under a Global Development Plan Shared Phase 3 Trial Costs Balance	**** **** ****
Regeneron Reimbursement Amount	****

V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-Up in a Quarter would be:

U.S. Profit Split Payable to Regeneron

ROW Profit Split Payable to Regeneron

ROW Profit Split Payable to Regeneron

Development Compensation Payment

Regeneron Reimbursement Amount

Quarterly True-Up

In this example, Sanofi would pay Regeneron *** in accordance with the terms set forth in Article 9.

Sales Milestones

Aggregate annual Net Sales of all Licensed Products in Post of World Countries

in Rest of World Countries	Sales Milestone
US\$1 billion	******
******	*****
******	******
*****	******
*****	****

For purposes of clarification, each of the foregoing milestone payments shall be made only once and only upon the first occurrence of each milestone. Aggregate annual Net Sales of Licensed Products shall be determined based on the aggregate Net Sales of all Licensed Products in Rest of World Countries in any rolling twelve (12) month period.

Termination Arrangements

The rights and obligations set forth in this Schedule 4 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated Licensed Product(s) as to which, and, if applicable pursuant to Section 19.2(a)(ii), only in the country or countries in which, this Agreement has been terminated.

- 1. Sanofi shall promptly collect and return, and cause its Affiliates and Sublicensees to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing New Information or Party Information directly related to any Terminated Licensed Product(s), and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to any Terminated Licensed Product(s). In addition, at Regeneron's request, Sanofi shall collect and transfer to Regeneron any remaining inventory of Promotional Materials, sales training materials, samples, and product inventory. Notwithstanding the foregoing, Sanofi may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.
- 2. Regeneron and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than any royalties due for any Royalty Products under the Discovery Agreement and any amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or Collaboration by Sanofi), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Sanofi Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing and Commercializing Terminated Licensed Product(s) in the Field in the Territory (and solely to the extent such Sanofi Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Sanofi Intellectual Property retained by Sanofi).
- 3. Sanofi shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture, and Commercialization of the Terminated Licensed Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:
- (a) Sanofi shall transfer and assign to Regeneron (or its nominee) all Marketing Approvals, Pricing Approvals, and other regulatory filings (including Registration Filings) made or obtained by Sanofi or its Affiliates or any of its Sublicensees to the extent specifically relating to the Terminated Licensed Product(s).

- (b) Sanofi shall assign and transfer to Regeneron (or its nominee) Sanofi's entire right, title and interest in and to all Product Trademarks for any Terminated Licensed and Promotional Materials relating to the Terminated Licensed Product(s); provided that nothing herein is intended to convey any rights in or to Sanofi's corporate name and logos or any trade names except for the limited rights set forth herein.
- (c) Sanofi shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to the Terminated Licensed Product(s) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Sanofi, or such other format as may be reasonably requested by Regeneron.
- (d) Sanofi shall use Commercially Reasonable Efforts to assign to Regeneron any applicable sublicenses to the extent related to the Terminated Licensed Product(s) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory, as reasonably requested by Regeneron.
- (e) Without limitation of Sanofi's other obligations under this Schedule 4, to the extent Sanofi or its Affiliate is Manufacturing (in whole or in part) the Terminated Licensed Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Sanofi (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of such Terminated Licensed Product(s), and Regeneron shall purchase such Terminated Licensed Product(s), at the same price, and on such other terms and conditions on which Sanofi was supplying, or in the absence of termination would have been required to supply, such Terminated Licensed Product(s), through the second anniversary of the effective date of termination of this Agreement with respect to such Terminated Licensed Product(s) or such shorter period if Regeneron notifies Sanofi that Regeneron is able to Manufacture or have Manufactured such Terminated Licensed Product(s) on comparable financial terms.
- 4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the development, manufacture, and commercialization of the Terminated Licensed Product(s) in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.
- 5. For the avoidance of doubt, except as expressly provided in the Discovery Agreement or this Agreement, Regeneron shall not be required to provide Sanofi any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 4; provided, however, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Sanofi may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights.

Termination Arrangements

The rights and obligations set forth in this Schedule 5 shall apply only to the extent of the applicable termination of this Agreement, and accordingly such rights and obligations shall apply only with respect to the applicable Terminated Licensed Product(s) as to which this Agreement has been terminated.

- 1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Sanofi or, at Sanofi's request, destroy, all documents containing New Information or Party Information of Sanofi and its Affiliates directly related to any Opt-Out Products, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any such New Information or Party Information with respect to the Terminated Licensed Product(s). In addition, at Sanofi's request, Regeneron shall collect and transfer to Sanofi any remaining inventory of Promotional Materials, sales training materials, product samples and product inventory. Notwithstanding the foregoing, Regeneron may retain copies of any Party Information or New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.
- 2. Sanofi and its Affiliates shall have a worldwide, fully paid-up, royalty-free (other than for amounts payable to Third Parties for any intellectual property or technology contributed to the Discovery Program or Collaboration by Regeneron), exclusive right and license, with the right to sublicense unless otherwise restricted by any License, under the Regeneron Intellectual Property existing at the time notice of termination was given or at the effective date of termination solely for the purpose of Developing, Manufacturing, and Commercializing the Terminated Licensed Product(s) in the Field in the Territory (and solely to the extent such Regeneron Intellectual Property has, as of the date notice of termination was given, actually been incorporated into such Licensed Product(s) or otherwise claims or covers its use), with all other rights to such Regeneron Intellectual Property retained by Regeneron.
- 3. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Sanofi to enable Sanofi (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture and Commercialization of the Terminated Licensed Product(s) in the Field in the Territory. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:
- (a) Regeneron shall transfer and assign to Sanofi (or its nominee) all Marketing Approvals, Pricing Approvals and other regulatory filings (including Registration Filings) made or obtained by Regeneron or its Affiliates or any of its sublicensees to the extent specifically relating to the Terminated Licensed Product(s).

- (b) Regeneron shall assign and transfer to Sanofi (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks for the Terminated Licensed Product(s) and Promotional Materials relating to the Terminated Licensed Product(s); provided that nothing herein is intended to convey any rights in or to Regeneron's corporate name and logos or any trade names except for the limited rights set forth herein.
- (c) Regeneron shall provide to Sanofi (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory) of all information (including any New Information) in its possession or under its control to the extent directly relating to the Terminated Licensed Product(s) in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Regeneron, or such other format as may be reasonably requested by Sanofi.
- (d) Regeneron shall use Commercially Reasonable Efforts to assign to Sanofi any applicable sublicenses to the extent related to the Terminated Licensed Product(s) and/or contracts relating to significant services to be performed by Third Parties to the extent related to the Development, Manufacture or Commercialization of the Terminated Licensed Product(s) in the Field in the Territory, as reasonably requested by Sanofi.
- (e) Without limitation of Regeneron's other obligations under this Schedule 5, to the extent Regeneron or its Affiliate is Manufacturing (in whole or in part) the Terminated Licensed Product(s) for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Regeneron (or its Affiliate) will perform such Manufacturing responsibilities and supply Sanofi with Clinical Supply Requirements and/or Commercial Supply Requirements of such Terminated Licensed Product(s), and Sanofi shall purchase such Terminated Licensed Product(s), at the same price, and on such other terms and conditions on which Regeneron was supplying, or in the absence of termination would have been required to supply, such Terminated Licensed Product(s), through the second anniversary of the effective date of termination of this Agreement with respect to such Terminated Licensed Product(s) or such shorter period if Sanofi notifies Regeneron that Sanofi is able to Manufacture or have Manufactured such Terminated Licensed Product(s) on comparable financial terms.
- 4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Terminated Licensed Product(s) in the Field hereunder to Sanofi (or its Sublicensee or Third Party designee) as soon as is reasonably possible.
- 5. For the avoidance of doubt, Sanofi shall not be required to provide Regeneron any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 5; provided, however, that Sanofi shall be solely responsible for paying any royalties, fees or other consideration that Regeneron may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Sanofi of such licenses or other rights.

Notices

If to Sanofi or Sanofi Amerique: (a)

Aventis Pharmaceuticals Inc 200 Crossing Boulevard Bridgewater New Jersey 08807 USA Attention: President R&D Copy: General Counsel

With a copy to:

sanofi-aventis 174 Avenue de France Paris, France 75017 Attention: General Counsel

(b) If to Regeneron:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 U.S.A. Attention: President Copy: General Counsel

With a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP One Beacon Street, 31st Floor Boston, Massachusetts 02108 Attention: Kent A. Coit

STOCK PURCHASE AGREEMENT By and Among

SANOFI-AVENTIS AMÉRIQUE DU NORD, SANOFI-AVENTIS US LLC

AND REGENERON PHARMACEUTICALS, INC.

Dated as of November 28, 2007

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Exhibit A – Form of Cross Receipt
Exhibit B – Form of Investor Agreement
Exhibit C – Conduct of the Business Pending Closing
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STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "Agreement"), dated as of November 28, 2007, by and among sanofi-aventis Amérique du Nord (the "Investor"), a société en nom collectif organized under the laws of France and wholly owned by sanofi-aventis, a company organized under the laws of France ("sanofi-aventis"), with its principal headquarters at 174, avenue de France, 75013 Paris, France, sanofi-aventis US LLC (solely for purposes of Sections 5.11, 8.2, 8.3, 11.2 and 12.13), a Delaware limited liability company indirectly wholly owned by the Investor ("Sanofi US") and the successor in interest to Aventis Pharmaceuticals Inc., a Delaware corporation indirectly wholly owned by the Investor ("Aventis"), with respect to the Aventis Collaboration Agreement, with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 00807, and Regeneron Pharmaceuticals, Inc. (the "Company"), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

WHEREAS, pursuant to the terms and subject to the conditions set forth in this Agreement, the Company desires to issue and sell to the Investor, and the Investor desires to subscribe for and purchase from the Company, certain shares of common stock, par value \$0.001 per share, of the Company (the "Common Stock").

NOW, THEREFORE, in consideration of the following mutual promises and obligations, and for good and valuable consideration, the adequacy and sufficiency of which are hereby acknowledged, the Investor, Sanofi US and the Company agree as follows:

1. Definitions.

1.1 Defined Terms. When used in this Agreement, the following terms shall have the respective meanings specified therefor below:

"Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside of the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the

Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates of the Investor or any of its Affiliates.

- "Agreement" shall have the meaning set forth in the Preamble, including all Exhibits attached hereto.
- "Aventis Collaboration Agreement" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Sanofi US (as successor in interest to Aventis) and the Company, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, Section 11.2 of this Agreement, and as further amended from time to time.
 - "Business Day" shall mean a day on which commercial banking institutions in New York, New York are open for business.
- "Collaboration Agreements" means, collectively, the Aventis Collaboration Agreement, the Discovery Agreement and the Sanofi License and Collaboration Agreement.
- "Cross Receipt" shall mean an executed document signed by each of the Company and the Investor, in substantially the form of Exhibit A attached hereto.
- "<u>Discovery Agreement</u>" shall mean that certain Discovery and Preclinical Development Agreement between the Company and Aventis dated as of the date hereof, as the same may be amended from time to time.
 - "Effect" shall have the meaning set forth in the definition of "Material Adverse Effect."
- "Governmental Authority" shall mean any court, agency, authority, department or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.
- "Intellectual Property" shall mean shall mean trademarks, trade names, trade dress, service marks, copyrights, and similar rights (including registrations and applications to register or renew the registration of any of the foregoing), patents and patent applications, trade secrets, and any other similar intellectual property rights.
- "Intellectual Property License" shall mean any license, permit, authorization, approval, contract or consent granted, issued by or with any Person relating to the use of Intellectual Property.
- "Investor Agreement" shall mean that certain Investor Agreement among sanofi-aventis, Sanofi US, Aventis, the Investor and the Company, to be dated as of the Closing Date, in substantially the form of Exhibit B attached hereto, as the same may be amended from time to time.

"<u>Law</u>" or "<u>Laws</u>" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.

"Material Adverse Effect" shall mean any change, event or occurrence (each, an "Effect") that, individually or when taken together with all other Effects, has (i) a material adverse effect on the business, financial condition, results of operations or prospects of the Company and its subsidiaries, taken as a whole, or (ii) a material adverse effect on the Company's ability to perform its obligations, or consummate the Transaction, in accordance with the terms of this Agreement, except in the case of (i) or (ii) to the extent that any such Effect results from or arises out of: (A) changes in conditions in the United States or global economy or capital or financial markets generally, including changes in interest or exchange rates, (B) changes in general legal, regulatory, political, economic or business conditions or changes in generally accepted accounting principles in the United States or interpretations thereof that, in each case, generally affect the biotechnology or biopharmaceutical industries, (C) the announcement, pendency or performance of this Agreement, the Discovery Agreement or the Sanofi License and Collaboration Agreement, or the consummation of the Transaction or the identity of the Investor, (D) any change in the trading prices or trading volume of the Common Stock (it being understood that the facts giving rise to or contributing to any such change may be deemed to constitute, or be taken into account when determining whether there has been or will be, a Material Adverse Effect, except to the extent any of such facts is an Effect referred in clauses (A) through (J) of this definition), (E) acts of war, sabotage or terrorism, or any escalation or worsening of any such acts of war, sabotage or terrorism, (F) earthquakes, hurricanes, floods or other natural disasters, (G) any action taken by the Company contemplated by this Agreement or in accordance with any of the Collaboration Agreements or with the Investor's written consent, (H) any breach, violation or non-performance by the Investor or any of its Affiliates under any of the Collaboration Agreements, or (I) shareholder litigation arising out of or in connection with the execution, delivery or performance of the Transaction Agreements, the Discovery Agreement or the Sanofi License and Collaboration Agreement; provided, that with respect to clauses (A), (B), (E) and (F) such Effect does not have a materially disproportionate and adverse effect on the Company relative to most other comparable companies and their respective subsidiaries, taken as a whole, in the biotechnology or biopharmaceutical industries.

"Organizational Documents" shall mean (i) the Restated Certificate of Incorporation of the Company as of June 21, 1991, as amended through the date of this Agreement and (ii) the By-Laws of the Company, as amended through the date of this Agreement.

"Person" shall mean any individual, partnership, limited liability company, firm, corporation, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.

"Sanofi License and Collaboration Agreement" shall mean that certain License and Collaboration Agreement between the Company, the Investor and Aventis dated as of the date hereof.

"Third Party" shall mean any Person (other than a Governmental Authority) other than the Investor, the Company or any Affiliate of the Investor or the Company.

"<u>Transaction</u>" means the issuance and sale of the Shares by the Company, and the purchase of the Shares by the Investor, in accordance with the terms hereof.

"Transaction Agreements" shall mean this Agreement and the Investor Agreement.

1.2 Additional Defined Terms. In addition to the terms defined in Section 1.1, the following terms shall have the respective meanings assigned thereto in the sections indicated below:

Defined Term	Section	
Aggregate Purchase Price	Section 2	
Aventis	Preamble	
Class A Stock	Section 4.2(a).	
Closing	Section 3.1	
Closing Date	Section 3.1	
Common Stock	Preamble	
Company	Preamble	
Company SEC Documents	Section 4.11(a)	
Exchange Act	Section 4.11(a)	
Final Termination Date	Section 10.1(b)	
HSR Act	Section 4.7	
Investor	Preamble	
LAS	Section 4.7	
Modified Clause	Section 12.7	
Permits	Section 4.10	
Original Termination Date	Section 10.1(b)	
Sanofi US	Preamble	
sanofi-aventis	Preamble	
SEC	Section 4.7	
Securities Act	Section 4.11(a)	
Share Amount	Section 2	
Shares	Section 2	

2. Purchase and Sale of Common Stock. Subject to the terms and conditions of this Agreement, at the Closing, the Company shall issue and sell to the Investor, free and clear of all liens, other than any liens arising as a result of any action by the Investor, and the Investor shall purchase from the Company, a number of shares of Common Stock equal to the Share Amount (the "Shares"), for an aggregate purchase price of US \$312,000,000.00. (the "Aggregate Purchase Price"). The "Share Amount" shall equal 12,000,000; provided, however, that in the event of any stock dividend, stock split, combination of shares, recapitalization or other similar change in the capital structure of the Company after the date hereof and on or prior to the Closing which affects or relates to the Common Stock, the Share Amount shall be adjusted proportionately.

3. Closing Date; Deliveries.

3.1 Closing Date. Subject to the satisfaction or waiver of all the conditions to the Closing set forth in Sections 7, 8 and 9 hereof, the closing of the purchase and sale of the Shares hereunder (the "Closing") shall be held on the third (3rd) Business Day after the satisfaction of the conditions to Closing set forth in Sections 7, 8 and 9 (other than those conditions that by their nature are to be satisfied at the Closing), at 10:00 a.m. New York City time, at the offices of Skadden, Arps, Slate, Meagher & Flom LLP, 4 Times Square, New York, New York 10036, or at such other time, date and location as the parties may agree in writing. The date the Closing occurs is hereinafter referred to as the "Closing Date."

3.2 Deliveries.

- (a) <u>Deliveries by the Company</u>. At the Closing, the Company shall deliver to the Investor a stock certificate, registered in the name of the Investor, representing the Shares, and the Company shall instruct its transfer agent to register such issuance at the time of such issuance. The Company shall also deliver at the Closing: (i) a duly executed Cross Receipt; (ii) a certificate in form and substance reasonably satisfactory to the Investor and duly executed on behalf of the Company by an authorized executive officer of the Company, certifying that the conditions to Closing set forth in Sections 7 and 9.3(b) of this Agreement have been fulfilled; (iii) a duly executed Investor Agreement; and (iv) a certificate of the secretary of the Company dated as of the Closing Date certifying (A) that attached thereto is a true and complete copy of the By-Laws of the Company as in effect on the Closing Date; (B) that attached thereto is a true and complete copy of all resolutions adopted by the Board of Directors of the Company authorizing the execution, delivery and performance of the Transaction Agreements and the Transaction and that all such resolutions are in full force and effect and are all the resolutions adopted in connection with the transactions contemplated hereby as of the Closing Date; (C) that attached thereto is a true and complete copy of the Company's Restated Certificate of Incorporation as in effect on the Closing Date; and (D) as to the incumbency and specimen signature of any officer of the Company executing a Transaction Agreement on behalf of the Company.
- (b) <u>Deliveries by the Investor</u>. At the Closing, the Investor shall deliver to the Company the Aggregate Purchase Price by wire transfer of immediately available United States funds to an account designated by the Company. The Company shall notify the Investor in writing of the wiring instructions for such account not less than three (3) Business Days before the Closing Date. The Investor shall also deliver, or cause to be delivered, at the Closing: (i) a duly executed Cross Receipt; (ii) a certificate in form and substance reasonably satisfactory to the Company duly executed by an authorized executive officer of the Investor certifying that the conditions to Closing set forth in Section 8 of this Agreement have been fulfilled; (iii) an Investor Agreement, duly executed by sanofi-aventis, Sanofi US, Aventis and the Investor; and (iv) a certificate of the secretaries of sanofi-aventis, Sanofi US, Aventis and the Investor dated as of the Closing Date certifying (A) that attached thereto are true and complete copies of any and all organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents) of each of sanofi-aventis, Sanofi US, Aventis and the Investor, as applicable, as in effect on the Closing Date; and (B) as to the incumbency and specimen signature of any officer executing a Transaction Agreement on behalf of sanofi-aventis, Sanofi US, Aventis or the Investor, as applicable.

4. Representations and Warranties of the Company. The Company hereby represents and warrants to the Investor that:

4.1 Organization, Good Standing and Qualification.

- (a) The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of New York. The Company has all requisite corporate power and corporate authority to own, lease and operate its properties and assets, to carry on its business as now conducted, and as proposed to be conducted as described in the Company SEC Documents, to enter into the Transaction Agreements to issue and sell the Shares and to carry out the other transactions contemplated by the Transaction Agreements.
- (b) The Company is qualified to transact business and is in good standing in each jurisdiction in which the character of the properties owned, leased or operated by the Company or the nature of the business conducted by the Company makes such qualification necessary, except where the failure to be so qualified would not have a Material Adverse Effect.

4.2 Capitalization and Voting Rights.

- (a) The authorized capital of the Company as of the date hereof consists of: (i) 160,000,000 shares of Common Stock of which, as of the date of this Agreement, (w) 63,932,731 shares are issued and outstanding, (x) 2,260,266 shares are reserved for issuance upon conversion of the Company's Class A Stock, par value \$0.001 per share (the "Class A Stock"), each share of Class A Stock being convertible into one (1) share of Common Stock, (y) 18,843,943 shares are reserved for issuance pursuant to the Company's 2000 Long-Term Incentive Plan, of which 15,244,146 shares are issuable upon the exercise of stock options outstanding on the date hereof, and (z) 6,611,300 shares are reserved for issuance upon conversion of the Company's 5½% Convertible Senior Subordinated Notes due 2008; (ii) 40,000,000 shares of Class A Stock of which, as of the date of this Agreement, 2,260,266 shares are issued and outstanding and 44,246 shares are reserved for issuance pursuant to the Company's 1989 Executive Stock Purchase Plan; and (iii) 30,000,000 shares of preferred stock, par value \$0.01 per share, of which no shares are issued and outstanding as of the date of this Agreement. All of the issued and outstanding shares of Common Stock and Class A Stock (A) have been duly authorized and validly issued, (B) are fully paid and non-assessable and (C) were issued in compliance with all applicable federal and state securities Laws and not in violation of any preemptive rights.
- (b) All of the authorized shares of Common Stock are entitled to one (1) vote per share. All of the authorized shares of Class A Stock are entitled to ten (10) votes per share.
- (c) Except as described or referred to in Section 4.2(a) above, as of the date hereof, there are not: (i) any outstanding equity securities, options, warrants, rights (including conversion or preemptive rights) or other agreements pursuant to which the Company is or may become obligated to issue, sell or repurchase any shares of its capital stock or any other securities of the Company or (ii) except as set forth in the Investor Agreement, any restrictions on the transfer of capital stock of the Company other than pursuant to state and federal securities Laws.

- (d) Except as provided in the Investor Agreement, the Company is not a party to or subject to any agreement or understanding relating to the voting of shares of capital stock of the Company or the giving of written consents by a stockholder or director of the Company.
- **4.3 Subsidiaries.** The Company does not have any subsidiaries required to be disclosed in an exhibit to its Annual Report on Form 10-K pursuant to Item 601(b)(21) of Regulation S-K.

4.4 Authorization.

- (a) All requisite corporate action on the part of the Company, its directors and stockholders required by applicable Law or, assuming the accuracy of the Investor's representation in Section 5.8, The NASDAQ Stock Market LLC for the authorization, execution and delivery by the Company of the Transaction Agreements and the performance of all obligations of the Company hereunder and thereunder, including the authorization, issuance and delivery of the Shares, has been taken.
- (b) This Agreement has been, and upon the execution and delivery of the Investor Agreement by the Company at the Closing, the Investor Agreement will be, duly executed and delivered by the Company, and upon the due execution and delivery of this Agreement by the Investor and Sanofi US, this Agreement will constitute, and upon the due execution and delivery of the Investor Agreement by sanofi-aventis, Sanofi US, Aventis and the Investor, the Investor Agreement will constitute, valid and legally binding obligations of the Company, enforceable against the Company in accordance with their respective terms (except as such enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (ii) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).
- **4.5 No Defaults.** The Company is not in default under or in violation of (a) its Organizational Documents, (b) any provision of applicable Law or any ruling, writ, injunction, order, Permit, judgment or decree of any Governmental Authority or (c) any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound, except, in the case of subsections (b) and (c), as would not have a Material Adverse Effect. To the knowledge of the Company, there exists no condition, event or act which after notice, lapse of time, or both, would constitute a default or violation by the Company under any of the foregoing, except, in the case of subsections (b) and (c), as would not have a Material Adverse Effect.
- **4.6 No Conflicts.** The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Company do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Company or any of its assets are bound or (c)

violate or conflict with any of the provisions of the Company's Organizational Documents, except, in the case of subsections (a) and (b), as would not have a Material Adverse Effect.

- **4.7 No Governmental Authority or Third Party Consents.** No consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by the Company in connection with the authorization, execution and delivery by the Company of any of the Transaction Agreements or with the authorization, issue and sale by the Company of the Shares, except (i) such filings as may be required to be made with the Securities and Exchange Commission (the "SEC") and with any state blue sky or securities regulatory authority, which filings shall be made in a timely manner in accordance with all applicable Laws, (ii) as required pursuant to the Hart-Scott-Rodino Antitrust Improvements Act, as amended (the "HSR Act") and (iii) with respect to the Shares, the filing with The NASDAQ Stock Market LLC of, and the absence of unresolved issues with respect to, a Notification Form: Listing of Additional Shares (the "LAS").
- **4.8 Valid Issuance of Shares.** When issued, sold and delivered at the Closing in accordance with the terms hereof for the Aggregate Purchase Price, the Shares shall be duly authorized, validly issued, fully paid and nonassessable, free from any liens, encumbrances or restrictions on transfer, including preemptive rights, rights of first refusal or other similar rights, other than as arising pursuant to the Transaction Agreements, as a result of any action by the Investor or under federal or state securities Laws.
- **4.9 Litigation.** Except as set forth in the Company SEC Documents filed prior to the date of this Agreement, there is no action, suit, proceeding or investigation pending (of which the Company has received notice or otherwise has knowledge) or, to the Company's knowledge, threatened, against the Company or which the Company intends to initiate which has had or is reasonably likely to have a Material Adverse Effect.
- **4.10 Licenses and Other Rights; Compliance with Laws.** The Company has all franchises, permits, licenses and other rights and privileges ("Permits") necessary to permit it to own its properties and to conduct its business as presently conducted and is in compliance thereunder, except where the failure to be in compliance does not and would not have a Material Adverse Effect. To the Company's knowledge, it has not taken any action that would interfere with the Company's ability to renew all such Permit(s), except where the failure to renew such Permit(s) would not have a Material Adverse Effect. The Company is and has been in compliance with all Laws applicable to its business, properties and assets, and to the products and services sold by it, except where the failure to be in compliance does not and would not have a Material Adverse Effect.

4.11 Company SEC Documents; Financial Statements; Nasdaq Stock Market.

(a) Since December 31, 2006, the Company has timely filed all required reports, schedules, forms, statements and other documents (including exhibits and all other information incorporated therein), and any required amendments to any of the foregoing, with the SEC (the "Company SEC Documents"). As of their respective filing dates, each of the Company SEC Documents complied in all material respects with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the Securities Exchange Act of

1934, as amended (the "Exchange Act"), and the rules and regulations of the SEC promulgated thereunder applicable to such Company SEC Documents, and no Company SEC Documents when filed, declared effective or mailed, as applicable, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

- (b) The financial statements of the Company included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2006 and in its quarterly reports on Form 10-Q for the quarterly periods ended September 30, 2007, June 30, 2007, and March 31, 2007 comply as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto, have been prepared in accordance with United States generally accepted accounting principles applied on a consistent basis during the periods involved (except as may be indicated in the notes thereto) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended. Except (i) as set forth in the Company SEC Documents or (ii) for liabilities incurred in the ordinary course of business subsequent to the date of the most recent balance sheet contained in the Company SEC Documents, the Company has no liabilities, whether absolute or accrued, contingent or otherwise, other than those that would not, individually or in the aggregate, have a Material Adverse Effect.
- (c) As of the date of this Agreement, the Common Stock is listed on The Nasdaq Global Market, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from The Nasdaq Global Market. As of the date of this Agreement, the Company has not received any notification that, and has no knowledge that, the SEC or The NASDAQ Stock Market LLC is contemplating terminating such listing or registration.
- **4.12 Absence of Certain Changes.** Except as disclosed in the Company SEC Documents, since December 31, 2006, there has not occurred any event that has caused or would reasonably be expected to cause a Material Adverse Effect.
- **4.13 Internal Controls; Disclosure Controls and Procedures.** The Company maintains internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. The Company has implemented the "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) required in order for the Chief Executive Officer and Chief Financial Officer of the Company to engage in the review and evaluation process mandated by the Exchange Act, and is in compliance with such disclosure controls and procedures in all material respects. Each of the Chief Executive Officer and the Chief Financial Officer of the Company (or each former Chief Executive Officer of the Company and each former Chief Financial Officer of the Company, as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act of 2002 with respect to all reports, schedules, forms, statements and other documents required to be filed by the Company with the SEC.

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- **4.14 Intellectual Property.** The Intellectual Property that is owned by the Company is owned free from any liens or restrictions, and all of the Company's material Intellectual Property Licenses are in full force and effect in accordance with their terms, and are free of any liens or restrictions, except (a) where the failure to be free from such liens or restrictions would not have a Material Adverse Effect or (b) as set forth in any such Intellectual Property License. Except as set forth in the Company SEC Documents, there is no legal claim or demand of any Person pertaining to, or any proceeding which is pending (of which the Company has received notice or otherwise has knowledge) or, to the knowledge of the Company, threatened, (i) challenging the right of the Company in respect of any Company Intellectual Property, or (ii) that claims that any default exists under any Intellectual Property License, except, in the case of (i) and (ii) above, where any such claim, demand or proceeding would not have a Material Adverse Effect.
- **4.15 Offering.** Subject to the accuracy of the Investor's representations set forth in Sections 5.5, 5.6, 5.7, 5.9 and 5.10, the offer, sale and issuance of the Shares to be issued in conformity with the terms of this Agreement constitute transactions which are exempt from the registration requirements of the Securities Act and from all applicable state registration or qualification requirements. Neither the Company nor any Person acting on its behalf will take any action that would cause the loss of such exemption.
- **4.16 No Integration.** The Company has not, directly or through any agent, sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of, any security (as defined in the Securities Act) which is or will be integrated with the Shares sold pursuant to this Agreement in a manner that would require the registration of the Shares under the Securities Act.
- **4.17 Brokers' or Finders' Fees.** No broker, finder, investment banker or other Person is entitled to any brokerage, finder's or other fee or commission from the Company in connection with the transactions contemplated by the Transaction Agreements.
- **4.18 Not Investment Company.** The Company is not, and solely after receipt of the Aggregate Purchase Price and application of such proceeds in substantially the manner described under "Use of Proceeds" in the Company's prospectus supplement filed November 15, 2006 with the SEC, will not be, an "investment company" as defined in the Investment Company Act of 1940, as amended.
- **5. Representations and Warranties of the Investor.** The Investor hereby represents and warrants to the Company as set forth in Sections 5.1 through 5.10 (on behalf of itself, Sanofi US, Aventis and sanofi-aventis), and the Investor and Sanofi US hereby jointly and severally represent and warrant to the Company as set forth in Section 5.11, that:
- **5.1 Organization; Good Standing.** The Investor is a partnership duly organized, validly existing and in good standing under the laws of France. Sanofi US is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware. Aventis is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. sanofi-aventis is a company duly organized, validly existing and in good standing under the laws of France. Each of the Investor and Sanofi US has, and Aventis and sanofi-aventis will have, all requisite power and authority to enter into the

Transaction Agreements to which it is or will be a party, in the case of the Investor to purchase the Shares and, in the case of the Investor, Sanofi US, Aventis and sanofi-aventis, to perform its respective obligations under and to carry out the other transactions contemplated by the Transaction Agreements to which it is or will be a party.

- **5.2 Authorization.** All requisite action on the part of the Investor, Sanofi US, Aventis, sanofi-aventis and their respective directors and stockholders, required by applicable Law for the authorization, execution and delivery by the Investor, Sanofi US, Aventis and sanofi-aventis of the Transaction Agreements to which they are a party, and the performance of all of their respective obligations thereunder, including the subscription for and purchase of the Shares, has been taken or, in the case of Aventis and sanofi-aventis, will be taken prior to the Closing. This Agreement, and upon the execution and delivery of the Investor Agreement at the Closing by the Investor, Sanofi US, Aventis and sanofi-aventis, the Investor Agreement will be, duly executed and delivered by, as applicable, the Investor, Sanofi US, Aventis and sanofi-aventis and upon the due execution and delivery thereof by the Company, will constitute valid and legally binding obligations of, as applicable, the Investor, Sanofi US, Aventis and sanofi-aventis in accordance with their respective terms (except as such enforceable against, as applicable, the Investor, Sanofi US, Aventis and sanofi-aventis in accordance with their respective terms (except as such enforceability may be limited by (a) applicable bankruptcy, insolvency, reorganization, moratorium or other Laws of general application relating to or affecting enforcement of creditors' rights and (b) rules of Law governing specific performance, injunctive relief or other equitable remedies and limitations of public policy).
- 5.3 No Conflicts. The execution, delivery and performance of the Transaction Agreements and compliance with the provisions thereof by the Investor, Sanofi US, Aventis and sanofi-aventis, do not and shall not: (a) violate any provision of applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, any agreement, arrangement or instrument, whether written or oral, by which the Investor, Sanofi US, Aventis or sanofi-aventis or any of their respective assets, are bound, or (c) violate or conflict with any of the provisions of the Investor's, Sanofi US', Aventis' or sanofi-aventis' organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents), except as would not impair or adversely affect the ability of the Investor, Sanofi US, Aventis or sanofi-aventis, as applicable, to consummate the Transactions and perform their respective obligations under the Transaction Agreements and except, in the case of subsections (a) and (b) as would not have a material adverse effect on the Investor, Sanofi US, Aventis or sanofi-aventis.
- **5.4 No Governmental Authority or Third Party Consents.** No consent, approval, authorization or other order of any Governmental Authority or other Third Party is required to be obtained by the Investor, Sanofi US, Aventis or sanofi-aventis in connection with the authorization, execution and delivery of any of the Transaction Agreements or with the subscription for and purchase of the Shares, except as required pursuant to the HSR Act.
- 5.5 Purchase Entirely for Own Account. The Shares shall be acquired for investment for the Investor's own account, not as a nominee or agent, and not with a view to the

resale or distribution of any part thereof, and the Investor has no present intention of selling, granting any participation or otherwise distributing the Shares. The Investor does not have and will not have as of the Closing any contract, undertaking, agreement or arrangement with any Person to sell, transfer or grant participation to a Person any of the Shares.

- **5.6 Disclosure of Information.** The Investor has received all the information from the Company and its management that the Investor considers necessary or appropriate for deciding whether to purchase the Shares hereunder. The Investor further represents that it has had an opportunity to ask questions and receive answers from the Company regarding the Company, its financial condition, results of operations and prospects and the terms and conditions of the offering of the Shares sufficient to enable it to evaluate its investment.
- **5.7 Investment Experience and Accredited Investor Status.** The Investor is an "accredited investor" (as defined in Regulation D under the Securities Act). The Investor has such knowledge and experience in financial or business matters that it is capable of evaluating the merits and risks of the investment in the Shares to be purchased hereunder.
- **5.8 Acquiring Person.** As of the date of this Agreement and immediately prior to the Closing, (a) sanofi-aventis together with its Affiliates, beneficially own and will beneficially own (as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership) 2,799,552 shares of Common Stock, and (b) neither sanofi-aventis nor any of its Affiliates beneficially owns, or will beneficially own (as determined pursuant to Rule 13d-3 under the Exchange Act without regard for the number of days in which a Person has the right to acquire such beneficial ownership), any other securities of the Company.
- **5.9 Restricted Securities.** The Investor understands that the Shares, when issued, shall be "restricted securities" under the federal securities Laws inasmuch as they are being acquired from the Company in a transaction not involving a public offering and that under such Laws the Shares may be resold without registration under the Securities Act only in certain limited circumstances. In this connection, the Investor represents that it is familiar with Rule 144 of the Securities Act, as presently in effect.
 - **5.10 Legends.** The Investor understands that the certificates representing the Shares shall bear the following legends:
- (a) "These securities have not been registered under the Securities Act of 1933. They may not be sold, offered for sale, pledged or hypothecated in the absence of a registration statement in effect with respect to the securities under the Securities Act or an opinion of counsel (which counsel shall be reasonably satisfactory to Regeneron Pharmaceuticals, Inc.) that such registration is not required or unless sold pursuant to Rule 144 of the Securities Act.";
 - (b) any legend required by applicable state securities Laws; and
- (c) "The securities represented by this certificate are subject to and shall be transferable only upon the terms and conditions of an Investor Agreement dated as of [], 2007,

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by and among Regeneron Pharmaceuticals, Inc. and the other parties signatory thereto, a copy of which is on file with the Secretary of Regeneron Pharmaceuticals. Inc."

5.11 Financial Assurances. As of the date hereof and as of the Closing Date, the Investor has and will have access to cash in an amount sufficient to pay to the Company the Aggregate Purchase Price.

6. Covenants of the Company.

- 6.1 Conduct of the Business Pending Closing. During the period from the date hereof until the Closing, except as (a) set forth on Exhibit C attached hereto, (b) consented to in writing by the Investor (which consent shall not be unreasonably withheld, conditioned or delayed) or (c) otherwise contemplated by this Agreement or any of the Collaboration Agreements, the Company shall (i) operate its business only in the ordinary course, (ii) maintain its existence under applicable Law, (iii) use commercially reasonable efforts to maintain and enforce its material Intellectual Property, (iv) pay all applicable material taxes when due and payable and (v) (A) not declare, set aside or pay any dividend or make any other distribution or payment (whether in cash, stock or property or any combination thereof) in respect of its capital stock, (B) not make any other actual, constructive or deemed distribution in respect of any shares of its capital stock or otherwise make any payments to stockholders in their capacity as such and (C) not redeem, repurchase or otherwise acquire any securities of the Company or any of its subsidiaries.
- **6.2 Use of Proceeds.** From and after the Closing Date, the Company shall use the Aggregate Purchase Price in substantially the manner described under "Use of Proceeds" in the Company's prospectus supplement filed November 15, 2006 with the SEC.
- 7. Investor's Conditions to Closing. The Investor's obligation to purchase the Shares at the Closing is subject to the fulfillment as of such Closing of the following conditions (unless waived in writing by the Investor):
- **7.1 Representations and Warranties.** (a) The representations and warranties made by the Company in Section 4 hereof shall be true and correct as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date; (b) the representations and warranties made by the Company in Article 8 of the Discovery Agreement (other than Section 8.1(a) thereof) shall be true and correct as of the date of the Discovery Agreement and as of the Closing Date as though made on and as of such Closing Date; and (c) the representations and warranties made by the Company in Article XV of the Sanofi License and Collaboration Agreement (other than Section 15.1(a) thereof) shall be true and correct as of the date of the Sanofi License and Collaboration Agreement and as of the Closing Date as though made on and as of such Closing Date, except in the case of subsections (a), (b) and (c) to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date; provided, however, that for purposes of this Section 7.1, all such representations and warranties of the Company (other than Sections 4.1(a), 4.2, 4.3, 4.4(a) and 4.8 of this Agreement, Section 8.1(b) of the Discovery Agreement and Section 15.1(b) of the Sanofi License and Collaboration Agreement) shall be deemed to be true and correct for purposes of this Section 7.1 unless the

failure or failures of such representations and warranties to be so true and correct, without regard to any "material," "materiality" or "Material Adverse Effect" qualifiers set forth therein (other than any reference to "material" in Sections 4.11(a) and 4.11(b)), individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

- **7.2** Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Company on or prior to the Closing Date shall have been performed or complied with in all material respects.
- **7.3 Investor Agreement.** The Company shall have duly executed and delivered to the Investor, pursuant to Section 3.2(a) of this Agreement, the Investor Agreement, and (subject to execution by sanofi-aventis, Sanofi US, Aventis and the Investor) such agreement shall be in full force and effect.
- **7.4 Discovery Agreement; Sanofi License and Collaboration Agreement.** The Company shall have duly executed and delivered to the Investor the Discovery Agreement and the Sanofi License and Collaboration Agreement, and there shall have been no termination of either of the Discovery Agreement or the Sanofi License and Collaboration Agreement that, as of the Closing, is effective.
- **7.5 No Material Adverse Effect.** From and after the date of this Agreement until the Closing Date, there shall have occurred no event that has caused or would reasonably be expected to cause a Material Adverse Effect.
- **8.** Company's Conditions to Closing. The Company's obligation to issue and sell the Shares at the Closing is subject to the fulfillment as of such Closing of the following conditions (unless waived in writing by the Company):
- **8.1 Representations and Warranties.** The representations and warranties made by the Investor (on its own behalf and on behalf of Sanofi US, Aventis and sanofi-aventis) and by Sanofi US (a) in Section 5 hereof (other than Sections 5.4 and 5.6 hereof) shall be true and correct and (b) in Sections 5.4 and 5.6 hereof shall be true and correct in all material respects, in each case as of the date of this Agreement and as of the Closing Date as though made on and as of such Closing Date (except to the extent such representations and warranties are specifically made as of a particular date, in which case such representations and warranties shall be true and correct as of such date).
- **8.2** Covenants. All covenants and agreements contained in this Agreement to be performed or complied with by the Investor or Sanofi US as applicable, on or prior to the Closing Date shall have been performed or complied with in all material respects.
- **8.3 Investor Agreement**, sanofi-aventis, Sanofi US, Aventis and Investor shall have duly executed and delivered to the Company, pursuant to Section 4.2(b) of this Agreement, the Investor Agreement, and (subject to execution by the Company) such agreement shall be in full force and effect.
- **8.4** Discovery Agreement; Sanofi License and Collaboration Agreement. Sanofi US, Aventis and the Investor, as applicable, shall have duly executed and delivered to the

Company the Discovery Agreement and the Sanofi License and Collaboration Agreement, and there shall have been no termination of either of the Discovery Agreement or the Sanofi License and Collaboration Agreement that, as of the Closing, is effective. The Company shall have received from Aventis the payment required by Section 4.1 of the Discovery Agreement.

- **9. Mutual Conditions to Closing.** The obligations of the Investor and the Company to consummate the Closing is subject to the fulfillment as of the Closing Date of the following conditions:
- **9.1 HSR Act and Other Qualifications.** The filings required under the HSR Act in connection with this Agreement shall have been made and the required waiting period shall have expired or been terminated as of the Closing Date, and all other authorizations, consents, waivers, permits, approvals, qualifications and registrations to be obtained or effected with any Governmental Authority, including, without limitation, necessary blue sky permits and qualifications required by any state for the offer and sale to the Investor of the Shares, shall have been duly obtained and shall be in effect as of the Closing Date.
- 9.2 Absence of Litigation. There shall be no action, suit, proceeding or investigation by a Governmental Authority pending or currently threatened in writing against the Company, the Investor, Sanofi US, Aventis or sanofi-aventis which questions the validity of any of the Transaction Agreements, the right of the Company, the Investor, Sanofi US, Aventis or sanofi-aventis to enter into any Transaction Agreement or to consummate the transactions contemplated hereby or thereby or which, if determined adversely, would impose substantial monetary damages on the Company, the Investor, Sanofi US, Aventis or sanofi-aventis as a result of the consummation of the transactions contemplated by any Transaction Agreement.
- **9.3 No Prohibition.** (a) No provision of any applicable Law and no judgment, injunction (preliminary or permanent), order or decree that prohibits, makes illegal or enjoins the consummation of the Transaction shall be in effect; and (b) there shall be no unresolved issues with The NASDAQ Stock Market LLC with respect to the LAS.

10. Termination.

- 10.1 Ability to Terminate. This Agreement may be terminated at any time prior to the Closing by:
 - (a) mutual written consent of the Company and the Investor;
- (b) either the Company or the Investor, upon written notice to the other no earlier than three (3) Business Days after January 31, 2008 (the "Original Termination Date"), if the Original Termination Date cannot be or has not been validly extended pursuant to this Section 10.1(b), and if the Transaction shall not have been consummated by the Original Termination Date; provided, however, that the Original Termination Date may be extended to March 31, 2008 (the "Final Termination Date") by either the Company or the Investor, upon written notice to the other on or within two (2) Business Days after the Original Termination Date, if the Transaction shall not have been consummated by the Original Termination Date solely as the result of a failure to satisfy the condition set forth in Section 9.1 as of the Original Termination Date; provided further, however, that the right to terminate this Agreement under

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this Section 10.1(b) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Original Termination Date or the Final Termination Date, as applicable:

- (c) either the Company or the Investor, upon written notice to the other, if any of the mutual conditions to the Closing set forth in Section 9 shall have become incapable of fulfillment by the Original Termination Date or, if the Original Termination Date has been validly extended pursuant to Section 10.1(b), the Final Termination Date, and shall not have been waived in writing by the other party; provided, however, that the right to terminate this Agreement under this Section 10.1(c) shall not be available to any party whose failure to fulfill any obligation under this Agreement has been the cause of, or resulted in, the failure to consummate the transactions contemplated hereby prior to the Original Termination Date or the Final Termination Date, as applicable;
- (d) the Company, upon written notice to the Investor, so long as the Company is not then in breach of its representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 7.1 or 7.2, as applicable, could not be satisfied by the Closing Date, (i) upon a breach of any covenant or agreement on the part of the Investor set forth in this Agreement, or (ii) if any representation or warranty of the Investor or Sanofi US shall have been or become untrue, in each case such that any of the conditions set forth in Section 8.1, 8.2, 8.3 or 8.4, as applicable, could not be satisfied by the Closing Date;
- (e) the Company, upon written notice to the Investor, if the Investor or any of its Affiliates has breached Section 20.16 of the Aventis Collaboration Agreement (for avoidance of doubt, the Company shall not have the right to terminate this Agreement as a result of a de minimis breach of Section 20.16(a) of the Aventis Collaboration Agreement or an inadvertent breach of Section 20.16(g) of the Aventis Collaboration Agreement arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 20.16 of the Aventis Collaboration Agreement); provided that any action taken in connection with the Transaction shall not be deemed to be a violation of Section 20.16 of the Aventis Collaboration Agreement; and
- (f) the Investor, upon written notice to the Company, so long as the Investor and Sanofi US are not then in breach of their representations, warranties, covenants or agreements under this Agreement such that any of the conditions set forth in Section 8.1 or 8.2, as applicable, could not be satisfied by the Closing Date, upon a breach of any covenant or agreement on the part of the Company set forth in this Agreement, or if any representation or warranty of the Company shall have been or become untrue, in each case such that any of the conditions set forth in Section 7.1, 7.2, 7.3 or 7.4, as applicable, could not be satisfied by the Closing Date.
- 10.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 10.1 hereof, (a) this Agreement (except for this Section 10.2 and Article XII (other than Section 12.13), and any definitions set forth in this Agreement and used in such sections) shall forthwith become void and have no effect, without any liability on the part of any

party hereto or its Affiliates, and (b) all filings, applications and other submissions made pursuant to this Agreement, to the extent practicable, shall be withdrawn from the agency or other Person to which they were made or appropriately amended to reflect the termination of the transactions contemplated hereby; <u>provided</u>, <u>however</u>, that nothing contained in this Section 10.2 shall relieve any party from liability for fraud or any intentional or willful breach of this Agreement.

11. Additional Covenants and Agreements.

- 11.1 Legending of Existing Shares. At the Closing, the Investor shall cause Aventis to deliver to the Company the certificate(s) representing 2,799,552 shares of Common Stock issued to Aventis, and the Company shall (or shall cause its transfer agent to) promptly cancel such certificate and issue to Aventis a replacement certificate representing 2,799,552 shares of Common Stock and containing the legends set forth in Section 5.10 hereof.
- 11.2 Amendment of Aventis Agreement. Effective as of the date of this Agreement, the Investor hereby acknowledges and agrees that it shall be bound by (and shall cause its Affiliates to comply with) the restrictions applicable to Sanofi US (as successor to Aventis) under Section 20.16 of the Aventis Collaboration Agreement, and the Investor, Sanofi US and the Company acknowledge and agree that for purposes of Section 19.5 of the Aventis Collaboration Agreement, references to "Aventis" in such section include the Investor and its other Affiliates. The Investor, Sanofi US and the Company agree that, subject to clause (c) below, effective as of the date of this Agreement:
 - (a) The first clause of Section 20.16 of the Aventis Collaboration Agreement is hereby amended and restated in its entirety to read:
 - "From and after the Effective Date until the later of (A) the fifth (5th) anniversary of the expiration or earlier termination of the Term and (B) the fifth (5th) anniversary of the expiration or earlier termination of the "Term" (as such term is defined in the License and Collaboration Agreement among the Company, sanofi-aventis Amérique du Nord and Aventis dated as of November 28, 2007), neither Aventis nor any of its Affiliates (for purposes of this Section 20.16, Aventis, together with such Affiliates, being referred to as the "Investor") shall:"
 - (b) Section 20.16(a) of the Aventis Collaboration Agreement is hereby amended and restated in its entirety to read:
 - "(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Capital Stock and/or Common Stock Equivalents, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Capital Stock and/or Common Stock Equivalents, if after giving effect to such acquisition (and assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by the Investor), the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act) more than the Standstill Limit; provided, however, that notwithstanding the provisions of this Section 20.16, if the number of shares constituting Shares of Then Outstanding Capital Stock is reduced or if

the aggregate ownership of the Investor is increased as a result of a recapitalization of Regeneron, the Investor shall not be required to dispose of any of its holdings of Shares of Then Outstanding Capital Stock even though such action resulted in Investor's ownership totaling more than the Standstill Limit; as used in this Section 20.16(a):

- (i) "Common Stock Equivalents" shall mean any options, warrants or other securities or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Class A Stock or Common Stock; and
- (ii) "Standstill Limit" shall mean (i) from November 28, 2007 until December 31, 2011, the lesser of (A) twenty-one percent (21%) of the Shares of Then Outstanding Capital Stock, in the case of this clause (A) only, calculated on a fully diluted basis assuming the full conversion into, or exercise or exchange for, shares of Common Stock of all Common Stock Equivalents outstanding (as such Common Stock Equivalents outstanding are calculated from Regeneron's most recent Form 10-Q or Form 10-K, as applicable, filed with the SEC), and (B) twenty-five percent (25%) of the Shares of Then Outstanding Capital Stock, and (ii) from and after January 1, 2012, thirty percent (30%) of the Shares of Then Outstanding Capital Stock;"
- (c) Notwithstanding the foregoing, if this Agreement is terminated in accordance with Section 10 hereof, the amendments to Section 20.16 of the Aventis Collaboration Agreement set forth above shall be of no further force or effect, and the provisions of Section 20.16 of the Aventis Collaboration Agreement in effect immediately prior to the execution and delivery of this Agreement shall again be in full force and effect.
- 11.3 Market Listing. From the date hereof through the Closing Date, Company shall use all reasonable efforts to (a) maintain the listing and trading of the Common Stock on The NASDAQ Global Market and (b) effect the listing of the Shares on The NASDAQ Global Market, including submitting a notice of listing of additional shares with respect to the Shares to The NASDAQ Stock Market LLC no later than fifteen (15) calendar days prior to the Closing Date.
- 11.4 Notification under the HSR Act. The parties shall, as soon as practicable, and, in any event, no later than ten (10) days after the date of this Agreement, file or cause to be filed with the Federal Trade Commission and the Department of Justice the notifications required to be filed under the HSR Act and the rules and regulations promulgated thereunder with respect to the transactions contemplated by this Agreement. The parties will use all reasonable efforts to respond on a timely basis to any requests for additional information made by either of such agencies.
- 11.5 Assistance and Cooperation. Prior to the Closing, upon the terms and subject to the conditions set forth in this Agreement, each of the parties agrees to use all reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, and to assist and cooperate with the other party in doing, all things necessary, proper or advisable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement, including using all reasonable efforts to accomplish the following: (a) taking all

reasonable acts necessary to cause the conditions precedent set forth in Sections 7, 8 and 9 to be satisfied (including, in the case of the Company, promptly notifying the Investor of any notice from The NASDAQ Stock Market LLC with respect to the LAS); (b) obtaining all necessary actions or non-actions, waivers, consents, approvals, orders and authorizations from Governmental Authorities and the making of all necessary registrations, declarations and filings (including registrations, declarations and filings with Governmental Authorities, if any) and taking all reasonable steps as may be necessary to avoid any suit, claim, action, investigation or proceeding by any Governmental Authority; (c) obtaining all necessary consents, approvals or waivers from Third Parties; and (d) defending any suits, claims, actions, investigations or proceedings, whether judicial or administrative, challenging this Agreement or the consummation of the transactions contemplated hereby, including seeking to have any stay or temporary restraining order entered by any court or other Governmental Authority vacated or reversed. In addition, each of the Company and the Investor will promptly take any and all steps necessary to obtain any consent or to vacate or lift any order, writ, judgment, injunction, decree, stipulation, determination or award entered by or with any Governmental Authority relating to antitrust matters that would have the effect of making any of the transactions contemplated by this Agreement illegal or otherwise prohibiting or materially delaying their consummation. Notwithstanding anything to the contrary in this Section 11.5, nothing in this Section 11.5 will require the Investor to dispose of or hold separate any portion of its business or assets if such action, in the reasonable business judgment of the Investor, would impair, or be reasonably expected to impair, in any significant manner (i) the benefits to the Investor of the transactions contemplated by this Agreement, the Discovery Agreement or the Collaboration Agreements or (ii) the business, financial condition, results of operations or prospects of the Investor and its subsidiaries, taken as a whole.

11.6 Effect of Waiver of Condition to Closing. In the event that, as of the Closing, the Investor waives the condition regarding a Material Adverse Effect set forth in Section 7.5 of this Agreement, the Investor shall be deemed to have waived any right of recourse against the Company for, and agreed not to sue the Company in respect of, any and all events or inaccuracies in any representations or warranties of the Company (a) that, as of the Closing, have caused or would reasonably be expected to cause such Material Adverse Effect and (b) of which the Investor had notice in writing from the Company immediately prior to the Closing.

12. Miscellaneous.

- 12.1 Governing Law; Submission to Jurisdiction. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. The parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.
- **12.2 Waiver.** Waiver by a party of a breach hereunder by the other party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such party. No waiver

shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

- 12.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit D attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either party may change its address by giving notice to the other party in the manner provided above.
- 12.4 Entire Agreement. This Agreement and the Investor Agreement (once executed), contain the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.
- **12.5 Amendments.** No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the Investor and the Company.
- 12.6 Headings; Nouns and Pronouns; Section References. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.
- 12.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.
- **12.8 Assignment.** Neither this Agreement nor any of the rights or obligations hereunder may be assigned by either the Investor or the Company without (a) the prior written

consent of Company in the case of any assignment by the Investor or (b) the prior written consent of the Investor in the case of an assignment by the Company.

- 12.9 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.
- 12.10 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.
- **12.11 Third Party Beneficiaries.** None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.
 - 12.12 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either party.
- 12.13 Survival of Warranties. The representations and warranties of the Company and the Investor contained in this Agreement shall survive the Closing for eighteen (18) months, except for (a) the representations and warranties set forth in Sections 4.1, 4.2, 4.4, 4.8, 4.15, 4.16, 4.17, 4.18, 5.1, 5.2, 5.5, 5.7, 5.8, 5.9 and 5.10, which shall survive forever and (b) the representation and warranty of the Investor and Sanofi US in Section 5.11, which shall not survive the Closing. The parties hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Investor as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation.

 Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.
- **12.14 Remedies.** The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.
- 12.15 Expenses. Each party shall pay its own fees and expenses in connection with the preparation, negotiation, execution and delivery of the Transaction Agreements.

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

SANOFI-AVENTIS AMÉRIQUE DU NORD

By: /s/ Jean-Luc Renard

Name: Jean-Luc Renard Title: Authorized Signatory

By: /s/ Karen Linehan

Name: Karen Linehan Title: Authorized Signatory

SANOFI-AVENTIS US LLC (Solely for purposes of Sections 5.11, 8.2, 8.3, 11.2 and 12.13)

By: /s/ Karen Linehan

Name: Karen Linehan Title: Authorized Signatory

By: /s/ Robin White

Name: Robin White

Title: Authorized Signatory

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard Schleifer

Name: Leonard S. Schleifer, M.D., Ph.D.

Title: President & CEO

Signature Page to Stock Purchase Agreement,

EXHIBIT A

FORM OF CROSS RECEIPT

CROSS RECEIPT

US\$312,000,000.00, representing the purchase price for 12,000,000	from sanofi-aventis Amérique du Nord on [], 2007 of shares of Common Stock, par value \$0.001 per share, of Regeneron reement, dated as of November 28, 2007, by and among sanofi-aventis Amérique Inc.
	REGENERON PHARMACEUTICALS, INC.
	By: Name: Title:
shares of Common Stock, par value \$0.001 per share, of Regeneror	from Regeneron Pharmaceuticals, Inc. on [], 2007 of 12,000,000 in Pharmaceuticals, Inc., delivered pursuant to that certain Stock Purchase aventis Amérique du Nord, sanofi-aventis US LLC and Regeneron
	SANOFI-AVENTIS AMÉRIQUE DU NORD
	By: Name: Title:
	By: Name: Title:

EXHIBIT B FORM OF INVESTOR AGREEMENT

[See the Investor Agreement, dated as of December 20, 2007, filed as Exhibit 10.21]

EXHIBIT C

CONDUCT OF THE BUSINESS PENDING CLOSING

The Company may refinance its 51/2% Convertible Senior Subordinated Notes due 2008.

The Company, in its sole discretion, shall be entitled to make equity-based or phantom equity incentive and other compensation awards, pursuant to equity-based or phantom equity incentive and other compensation plans in effect on the date of this Agreement.

EXHIBIT D

NOTICES

(a) If to the Investor or Sanofi US:

sanofi-aventis 174, avenue de France 75013 Paris France Attention: General Counsel

with a copy to:

Jones Day 222 East 41st Street New York, New York 10017 Attention: Jere R. Thomson

(b) If to the Company:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 U.S.A. Attention: President Copy: General Counsel

with a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP One Beacon Street, 31st Floor Boston, MA 02108 Attention: Kent A. Coit INVESTOR AGREEMENT

By and Among

SANOFI-AVENTIS,

SANOFI-AVENTIS US LLC,

AVENTIS PHARMACEUTICALS INC.,

SANOFI-AVENTIS AMÉRIQUE DU NORD

AND

REGENERON PHARMACEUTICALS, INC.

Dated as of December 20, 2007

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INVESTOR AGREEMENT

THIS INVESTOR AGREEMENT (this "Agreement") is made as of December 20, 2007, by and among sanofi-aventis, a company organized under the laws of France, with its principal headquarters at 174, avenue de France, 75013 Paris, France ("sanofi-aventis"), sanofi-aventis US LLC, a Delaware limited liability company indirectly wholly owned by sanofi-aventis ("Sanofi US") and the successor-in-interest to Aventis Pharmaceuticals Inc. ("Aventis") with respect to the Aventis Collaboration Agreement, with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 00807, Aventis, a Delaware corporation and an indirect wholly owned subsidiary of the Investor with its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 00807, sanofi-aventis Amérique du Nord, a société en nom collectif organized under the laws of France wholly owned by sanofi-aventis with its principal headquarters at 174, avenue de France, 75013 Paris, France (the "Investor", and, together with sanofi-aventis, Sanofi US and Aventis, the "Purchaser Parties"), and Regeneron Pharmaceuticals, Inc. (the "Company"), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

WHEREAS, the Stock Purchase Agreement, dated as of November 28, 2007, by and among the Investor, sanofi-aventis US and the Company (the "<u>Purchase Agreement</u>") provides for the issuance and sale by the Company to the Investor, and the purchase by the Investor, of a number of shares of the Company's common stock, par value \$0.001 per share (the "<u>Common Stock</u>"), equal to the Share Amount (as defined in the Purchase Agreement) (the "Purchased Shares"); and

WHEREAS, as a condition to consummating the transactions contemplated by the Purchase Agreement, the Purchaser Parties and the Company have agreed upon certain rights and restrictions as set forth herein with respect to the Purchased Shares and other securities of the Company beneficially owned by the Purchaser Parties and their respective Affiliates, and it is a condition to the closing under the Purchase Agreement that this Agreement be executed and delivered by the Purchaser Parties and the Company.

NOW, THEREFORE, in consideration of the premises and mutual agreements hereinafter set forth, and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

- 1. **Definitions.** As used in this Agreement, the following terms shall have the following meanings:
 - (a) "Acquisition Proposal" shall have the meaning set forth in Section 3.1(c).
- (b) "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent

(50%) of the stock or shares having the right to vote for the election of directors, and (ii) in the case of non-corporate entities, direct or indirect ownership of more than fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The parties acknowledge that in the case of certain entities organized under the Laws of certain countries outside the United States, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity. For the purposes of this Agreement, in no event shall the Investor or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor shall the Company or any of its Affiliates be deemed Affiliates.

- (c) "Agreement" shall have the meaning set forth in the Preamble to this Agreement, including all Exhibits attached hereto.
- (d) "Aventis" shall have the meaning set forth in the Preamble to this Agreement.
- (e) "<u>Aventis Collaboration Agreement</u>" shall mean the Collaboration Agreement, dated as of September 5, 2003, by and between Sanofi US and the Company, as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, the Fourth Amendment, dated as of January 31, 2006, and Section 11.2 of the Purchase Agreement, as the same may be further amended from time to time.
- (f) "Aventis Stock Purchase Agreement" shall mean the Stock Purchase Agreement, dated as of September 5, 2003, by and between Aventis and the Company.
- (g) "beneficial owner," "beneficially owns," "beneficial ownership" and terms of similar import used in this Agreement shall, with respect to a Person, have the meaning set forth in Rule 13d-3 under the Exchange Act (i) assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents beneficially owned by such Person and (ii) determined without regard for the number of days in which such Person has the right to acquire such beneficial ownership.
 - (h) "Business Day" shall mean a day on which commercial banking institutions in New York, New York are open for business.
- (i) "Change of Control" shall mean, with respect to the Company, any of the following events: (i) any Person is or becomes the beneficial owner (except that a Person shall be deemed to have beneficial ownership of all shares that any such Person has the right to acquire, whether such right which may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all Shares of Then Outstanding Common Stock; (ii) the Company consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into the Company, other than (A) a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent

(either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of a majority of the total voting power of all Shares of Then Outstanding Common Stock or (iii) the Company conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly owned Affiliate of the Company.

- (j) "Class A Stock" shall mean the Class A Stock, par value \$0.001 per share, of the Company.
- (k) "Closing Date" shall have the meaning set forth in the Purchase Agreement.
- (I) "Common Stock" shall have the meaning set forth in the Preamble to this Agreement.
- (m) "Common Stock Equivalents" shall mean any options, warrants or other securities (including Class A Stock) or rights convertible into or exercisable or exchangeable for, whether directly or following conversion into or exercise or exchange for other options, warrants or other securities or rights, shares of Common Stock.
 - (n) "Company" shall have the meaning set forth in the Preamble to this Agreement.
 - (o) "Demand Request" shall have the meaning set forth in Section 2.1.
- (p) "Disposition" or "Dispose of" shall mean any (i) offer, pledge, sale, contract to sell, sale of any option or contract to purchase, purchase of any option or contract to sell, grant of any option, right or warrant for the sale of, or other disposition of or transfer of any shares of Class A Stock or Common Stock, or any Common Stock Equivalents, including, without limitation, any "short sale" or similar arrangement, or (ii) swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of shares of Class A Stock or Common Stock, whether any such swap or transaction is to be settled by delivery of securities, in cash or otherwise.
- (q) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended, and the rules and regulations of the SEC promulgated thereunder.
 - (r) "Extraordinary Matter" shall have the meaning set forth in Section 5.2.
- (s) "Filing Date" shall mean (i) with respect to any Registration Statement to be filed on Form S-1 (or any applicable successor form), ninety (90) days after receipt by the Company of a Demand Request for such Registration Statement and (ii) with respect to any Registration Statement to be filed on Form S-3 (or any applicable successor form), forty-five (45) days after receipt by the Company of a Demand Request for such Registration Statement.

- (t) "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.
- (u) "Holders" shall mean (but, in each case, only for so long as such Person remains an Affiliate of sanofi-aventis) the Investor, Aventis and any Permitted Transferee thereof, if any, in accordance with Section 2.12.
 - (v) "Initiating Holder" shall have the meaning set forth in Section 2.2.
 - (w) "Interference" shall have the meaning set forth in Section 2.5.
 - (x) "Investor" shall have the meaning set forth in the Preamble to this Agreement.
- (y) " \underline{Law} " or " \underline{Laws} " shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.
 - (z) "Lock-Up Term" shall have the meaning set forth in Section 4.1.
 - (aa) "Modified Clause" shall have the meaning set forth in Section 7.7. (bb) "Offeror" shall have the meaning set forth in Section 3.1(c).
 - (cc) "Other Holders" shall mean any Person having rights to participate in a registration of the Company's securities.
- (dd) "<u>Permitted Transferee</u>" shall mean a controlled Affiliate of sanofi-aventis that is wholly owned, directly or indirectly, by sanofi-aventis; it being understood that for purposes of this definition "wholly owned" shall mean an Affiliate in which sanofi-aventis owns, directly or indirectly, at least ninety-nine percent (99%) of the outstanding capital stock of such Affiliate.
- (ee) "Person" shall mean any individual, partnership, firm, corporation, association, trust, unincorporated organization, government or any department or agency thereof or other entity, as well as any syndicate or group that would be deemed to be a Person under Section 13(d)(3) of the Exchange Act.
- (ff) "Prospectus" shall mean the prospectus forming a part of any Registration Statement, as supplemented by any and all prospectus supplements and as amended by any and all amendments (including post-effective amendments) and including all material incorporated by reference or explicitly deemed to be incorporated by reference in such prospectus.
- (gg) "Purchase Agreement" shall have the meaning set forth in the Preamble to this Agreement, and shall include all Exhibits attached thereto.

- (hh) "Purchased Shares" shall have the meaning set forth in the Preamble to this Agreement, and shall be adjusted for (i) any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the Purchased Shares.
 - (ii) "Purchaser Parties" shall have the meaning set forth in the Preamble to this Agreement.
- (jj) "registers," "registered," and "registration" refer to a registration effected by preparing and filing a Registration Statement or similar document in compliance with the Securities Act, and the declaration or ordering of effectiveness of such Registration Statement or document by the SEC.
- (kk) "Registrable Securities" shall mean (i) the Purchased Shares and any shares of Common Stock owned of record by Aventis as of the date of this Agreement, together with any shares of Common Stock issued in respect thereof as a result of any stock split, stock dividend, share exchange, merger, consolidation or similar recapitalization and (ii) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (i) of this definition, excluding in all cases, however, (A) any Registrable Securities if and after they have been transferred to a Permitted Transferee in a transaction in connection with which registration rights granted hereunder are not assigned, (B) any Registrable Securities sold to or through a broker or dealer or underwriter in a public distribution or a public securities transaction or (C) Registrable Securities eligible for resale pursuant to Rule 144(k) under the Securities Act.
- (II) "Registration Expenses" shall mean all expenses incurred by the Company in connection with any Required Registration pursuant to Section 2.1 or the Company's compliance with Section 2.7 (excluding clauses (m), (n) and (r) thereof), including, without limitation, all registration and filing fees, fees and expenses of compliance with securities or blue sky Laws (including reasonable fees and disbursements of counsel in connection with blue sky qualifications of any Registrable Securities), expenses of printing (i) certificates for any Registrable Securities in a form eligible for deposit with the Depository Trust Company or (ii) Prospectuses if the printing of Prospectuses is requested by Holders, messenger and delivery expenses, fees and disbursements of counsel for the Company and its independent certified public accountants (including the expenses of any management review, cold comfort letters or any special audits required by or incident to such performance and compliance), Securities Act liability insurance (if the Company elects to obtain such insurance), the reasonable fees and expenses of any special experts retained by the Company in connection with such registration, fees and expenses of other Persons retained by the Company and the reasonable fees and expenses of one (1) counsel for the Holders of Registrable Securities in each Required Registration, selected by the Holders of a majority of the Registrable Securities to be included in such Required Registration. In addition, the Company will pay its internal expenses (including, without limitation, all salaries and expenses of its officers and employees performing legal or accounting duties), the expense of any annual audit and the fees and expenses incurred in connection with the listing of the Purchased Shares to be registered on each securities exchange,

if any, on which equity securities issued by the Company are then listed or the quotation of such securities on any national securities exchange on which equity securities issued by the Company are then quoted.

- (mm) "Registration Rights Term" shall have the meaning set forth in Section 2.1.
- (nn) "Registration Statement" shall mean any registration statement of the Company under the Securities Act that covers any of the Registrable Securities pursuant to the provisions of this Agreement, including the related Prospectus, all amendments and supplements to such registration statement (including post-effective amendments), and all exhibits and all materials incorporated by reference or explicitly deemed to be incorporated by reference in such Registration Statement.
- (oo) "Required Period" with respect to a Required Registration shall mean the earlier of (i) the date on which all Registrable Securities covered by such Required Registration are sold pursuant thereto and (ii) one-hundred twenty (120) days following the first day of effectiveness of the Registration Statement for such Required Registration, in each case subject to extension as set forth herein; provided, however, that in no event will the Required Period expire prior to the expiration of the applicable period referred to in Section 4(3) of the Securities Act and Rule 174 promulgated thereunder.
 - (pp) "Required Registration" shall have the meaning set forth in Section 2.1.
- (qq) "<u>Sanofi License and Collaboration Agreement</u>" shall mean that certain License and Collaboration Agreement between the Company, the Investor and Aventis dated as of November 28, 2007, as the same may be amended from time to time.
 - (rr) "sanofi-aventis" shall have the meaning set forth in the Preamble to this Agreement.
 - (ss) "Sanofi US" shall have the meaning set forth in the Preamble to this Agreement.
 - (tt) "SEC" shall mean the United States Securities and Exchange Commission.
 - (uu) "Securities Act" shall mean the Securities Act of 1933, as amended, and the rules and regulations of the SEC promulgated thereunder.
- (vv) "Selling Expenses" shall mean all underwriting discounts and selling commissions applicable to the sale of Registrable Securities pursuant to this Agreement.
- (ww) "Shares of Then Outstanding Common Stock" shall mean, at any time, the issued and outstanding shares of Class A Stock and Common Stock at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend, or reclassification of Class A Stock or Common Stock distributable, on a pro rata basis, to all holders of Class A Stock and Common Stock, as applicable.

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- (xx) "Standstill Limit" shall mean (i) from the Closing Date until the fourth (4th) anniversary of the Closing Date, the lesser of (A) twenty-one percent (21%) of the Shares of Then Outstanding Common Stock, in the case of this clause (A) only, calculated on a fully diluted basis assuming the full conversion into, or exercise or exchange for, shares of Common Stock of all Common Stock Equivalents outstanding (as such Common Stock Equivalents outstanding are calculated from the Company's most recent Form 10-Q or Form 10-K, as applicable, filed with the SEC), and (B) twenty-five percent (25%) of the Shares of Then Outstanding Common Stock, and (ii) from the fourth (4th) anniversary of the Closing Date until the expiration of the Standstill Term, thirty percent (30%) of the Shares of Then Outstanding Common Stock.
 - (yy) "Standstill Parties" shall have the meaning set forth in Section 3.1. (zz) "Standstill Term" shall have the meaning set forth in Section 3.1.
 - (aaa) "Third Party" shall mean any Person other than the Purchaser Parties, the Company or any of their respective Affiliates.
- (bbb) "<u>Underwritten Registration</u>" or "<u>Underwritten Offering</u>" shall mean a registration in which Registrable Securities are sold to an underwriter for reoffering to the public.
 - (ccc) "Violation" shall have the meaning set forth in Section 2.10(a).

2. Registration Rights.

- **2.1 Required Registration.** If, at any time after the expiration of the Lock-Up Term but no later than the tenth (10th) anniversary of such expiration (the "Registration Rights Term"), the Company receives from any Holder or Holders a written request or requests (each, a "Demand Request") that the Company file a Registration Statement under the Securities Act to effect the registration (a "Required Registration") of Registrable Securities, the Company shall use all reasonable efforts to file a Registration Statement covering such Holders' Registrable Securities as soon as practicable (and by the applicable Filing Date) and shall use all reasonable efforts to, as soon as practicable thereafter, effect the registration of the Registrable Securities to permit or facilitate the sale and distribution in an Underwritten Offering of all or such portion of such Holder's or Holders' Registrable Securities as are specified in such Demand Request, subject however, to the conditions and limitations set forth herein; provided, however, that the Company shall not be obligated to effect any registration of Registrable Securities upon receipt of a Demand Request pursuant to this Section 2.1 if:
 - (i) the Company has already completed three (3) Required Registrations;
 - (ii) (A) in the event that the market value of all Registrable Securities outstanding is equal to or greater than \$50,000,000, the market value of the Registrable Securities proposed to be included in the registration, based on the average closing price during the ten (10) consecutive trading days period prior to the making of the Demand Request, is less than \$50,000,000 or (B) in the event that the market value of all Registrable Securities outstanding is less than

\$50,000,000, (i) less than all such Registrable Securities are proposed to be included in the registration, or (ii) the market value of all such Registrable Securities is less than \$25,000,000;

- (iii) the Company shall furnish to the Holders a certificate signed by an authorized officer of the Company stating that (A) within ninety (90) days of receipt of the Demand Request under this Section 2.1, the Company shall file a registration statement for the public offering of securities for the account of the Company (other than a registration of securities (x) issuable pursuant to an employee stock option, stock purchase or similar plan, (y) issuable pursuant to a merger, exchange offer or a transaction of the type specified in Rule 145(a) under the Securities Act or (z) in which the only securities being registered are securities issuable upon conversion of debt securities which are also being registered), or (B) the Company is engaged in a material transaction or has an undisclosed material corporate development, in either case, which would be required to be disclosed in the Registration Statement, and in the good faith judgment of the Company's Board of Directors, such disclosure would be seriously detrimental to the Company and its stockholders at such time (in which case, the Company shall disclose the matter as promptly as reasonably practicable and thereafter file the Registration Statement, and each Holder agrees not to disclose any information about such material transaction to Third Parties until such disclosure has occurred or such information has entered the public domain other than through breach of this provision by such Holder), provided, however, that the Company shall have the right to only defer the filing of the Registration Statement pursuant to this subsection once in any twelve (12) month period and, such deferral may not exceed a period of more than one-hundred twenty (120) days after receipt of a Demand Request;
- (iv) the Company has, within the twelve (12) month period preceding the date of the Demand Request, already effected one (1) Required Registration for any Holder pursuant to this Section 2.1; or
- (v) at any time during the period between the Company's receipt of the Demand Request and the completion of the Required Registration, any Holder is in breach of or has failed to cause its Affiliates to comply with the obligations and restrictions of Sections 3, 4 or 5 of this Agreement, and such breach or failure is ongoing and has not been remedied; it being understood that (A) a one-time, inadvertent and de minimis breach of Section 4 shall not be deemed to be a breach of the obligations and restrictions under Section 4 for purposes of this Section 2.1(v) and (B) a de minimis breach of Section 3.1(a) hereof, or an inadvertent breach of Section 3.1(g) hereof arising from informal discussions covering general corporate or other business matters the purpose of which is not intended to effectuate or lead to any of the actions referred to in paragraphs (a) through (e) of Section 3.1, shall not be deemed to be a breach of the obligations and restrictions under Section 3.1 for purposes of this Section 2.1(v).

2.2 Underwritten Required Registration Required; Priority in Underwritten Offering. The underwritter for any Underwritten Offering requested pursuant to Section 2.1 shall be selected by a majority in interest of the Holders initiating the Required Registration hereunder (such Holder(s) initiating the registration request, the "Initiating Holders") and shall be acceptable to the Company. The right of any Holder to include its Registrable Securities in the Underwritten Offering shall be conditioned upon such Holder's participation in such Underwritten Offering and the inclusion of such Holder's Registrable Securities to the extent provided herein. All Holders requesting the inclusion of their Registrable Securities in such Underwritten Offering shall (together with the Company as provided in Section 2.7(h)) enter into an underwriting agreement in customary form with the underwriter or underwriters selected for such Underwritten Offering. Notwithstanding any other provision of this Section 2, if the managing underwriter for the Underwritten Offering determines in good faith that marketing factors require a limitation of the number of shares of Registrable Securities to be included in such Underwritten Offering, then the Company shall so advise all Holders which requested inclusion of their Registrable Securities in such Underwritten Offering, and the number of shares of Registrable Securities that may be included in such Underwritten Offering shall be allocated among the Holders in proportion (as nearly as practicable) to the amount of Registrable Securities of the Company owned by each Holder, provided, however, that the number of shares of Registrable Securities to be included in such Underwritten Offering shall not be reduced unless all other securities are first entirely excluded from such Underwritten Offering. In the event the Company advises the Holders of its intent to decrease the total number of Registrable Securities that may be included by the Holders in such Required Registration such that the number of Registrable Securities included in such Required Registration would be less than seventy-five percent (75%) of all Registrable Securities which the Holders requested be included in such Required Registration, then Holders representing a majority of the Registrable Securities requested to be included in such Required Registration will have the right to withdraw, on behalf of all Holders of all Registrable Securities requested to be so included, such Required Registration, in which case, such Required Registration will not count as a Required Registration for the purposes of Section 2.1(i), and the Company shall bear all Registration Expenses in connection therewith; provided, that, the right to withdraw a registration and have it not count as a Required Registration may only be exercised once by the Holders (taken collectively).

2.3 Priority in Required Registration. With respect to any Required Registration of Registrable Securities requested pursuant to Section 2.1, the Company may also (i) propose to sell shares of Common Stock on its own behalf and (ii) provide written notice of such Required Registration to Other Holders and permit all such Other Holders who request to be included in the Required Registration to include any or all Company securities held by such Other Holders in such Required Registration on the same terms and conditions as the Registrable Securities. Notwithstanding the foregoing, if the managing underwriter or underwriters of the Underwritten Offering to which any Required Registration relates advise the Company and the Holders of Registrable Securities that, in its good faith determination, the total amount of securities that such Holders, Other Holders, and the Company intend to include in such Required Registration is in an amount in the aggregate which would adversely affect the success of such Underwritten Offering, then such Required Registration shall include (i) first, all Registrable Securities of the Holders allocated, if the amount is less than all the Registrable Securities requested to be sold, *pro rata* on the basis of the total number of Registrable Securities held by such Holders; and (ii) second, as many other securities proposed to be included in the Required Registration by the

Company and any Other Holders, allocated *pro rata* among the Company and such Other Holders, on the basis of the amount of securities requested to be included therein by the Company and each such Other Holder so that the total amount of securities to be included in such Underwritten Offering is the full amount that, in the written opinion of such managing underwriter, can be sold without materially and adversely affecting the success of such Underwritten Offering.

2.4 Revocation of Required Registration. With respect to one (1) Required Registration only, the Holders of at least a majority of the Registrable Securities to be included in a Registration Statement with respect to such Required Registration may, at any time prior to the effective date of such Registration Statement, on behalf of all Holders of all Registrable Securities requested to be included therein, revoke the request to have Registrable Securities included therein and revoke the request for such Required Registration by providing a written notice to the Company, in which case such Required Registration that has been revoked will be deemed not to have been effected and will not count as a Required Registration for purposes of Section 2.1(i) if, and only if, the Holders of Registrable Securities which had requested inclusion of Registrable Securities in such Required Registration promptly reimburse the Company for all Registration Expenses incurred by the Company in connection with such Required Registration. Notwithstanding the foregoing sentence, the parties agree and acknowledge that the Holders may revoke any Required Registration (without any obligation to reimburse the Company for Registration Expenses incurred in connection therewith) if such revocation is based on (i) a material adverse change in circumstances with respect to the Company and its subsidiaries, taken as a whole, caused by an act or failure to act by the Company or any of its subsidiaries and not known to any Holder at the time the Required Registration was first made or (ii) the Company's failure to comply in any material respect with its obligations hereunder, and any such revocation based on an event described in (i) or (ii) above shall be exercisable at any time and shall not be counted as the one (1) revocation of a Required Registration permitted by the first sentence of this Section 2.4.

2.5 Effective Required Registrations. A Required Registration will not be deemed to be effected for purposes of Section 2.1(i) if the Registration Statement for such Required Registration has not been declared effective by the SEC or become effective in accordance with the Securities Act and the rules and regulations thereunder and kept effective for the Required Period. In addition, if after such Registration Statement has been declared or becomes effective, (i) the offering of Registrable Securities pursuant to such Registration Statement is interfered with by any stop order, injunction, or other order or requirement of the SEC or other governmental agency or court such that the continued offer and sale of Registrable Securities being offered pursuant to such Registration Statement would violate applicable Law and such stop order, injunction or other order or requirement of the SEC or other governmental agency or court does not result from any act or omission of any Holder whose Registrable Securities are registered pursuant to such Registration Statement (an "Interference") and (ii) any such Interference is not cured within sixty (60) days thereof, such Required Registration will be deemed not to have been effected and will not count as a Required Registration. In the event such Interference occurs and is cured, the Required Period relating to such Registration Statement will be extended by the number of days of such Interference, including the date such Interference is cured.

- **2.6 Continuous Effectiveness of Registration Statement.** The Company will use all reasonable efforts to cause each Registration Statement filed pursuant to this Section 2 to be declared effective by the SEC or to become effective under the Securities Act as promptly as practicable and to keep each such Registration Statement that has been declared or becomes effective continuously effective for the Required Period.
- **2.7 Obligations of the Company.** Whenever required under Section 2.1 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:
- (a) prepare and file with the SEC a Registration Statement with respect to such Registrable Securities sought to be included therein; provided that at least five (5) Business Days prior to filing any Registration Statement or Prospectus or any amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and the managing underwriter copies of all such documents proposed to be filed, and any such Holder shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder or the managing underwriter with respect to such information prior to filing any such Registration Statement or amendment;
- (b) prepare and file with the SEC such amendments and post-effective amendments to any Registration Statement and any Prospectus used in connection therewith as may be necessary to keep such Registration Statement effective for the Required Period, and cause the Prospectus to be supplemented by any required prospectus supplement, and as so supplemented to be filed pursuant to Rule 424 under the Securities Act, to comply with the provisions of the Securities Act with respect to the disposition of all Registrable Securities covered by such registration statement for the Required Period; provided that at least five (5) Business Days prior to filing any such amendments and post effective amendments or supplements thereto, the Company shall furnish to the Holders of the Registrable Securities covered by such Registration Statement, their counsel and the managing underwriter copies of all such documents proposed to be filed, and any such Holder or managing underwriter shall have the opportunity to comment on any information pertaining solely to such Holder and its plan of distribution that is contained therein and the Company shall make the corrections reasonably requested by such Holder and the managing underwriter with respect to such information prior to filing any such Registration Statement or amendment;
- (c) furnish to the Holders of Registrable Securities covered by such Registration Statement and the managing underwriter such numbers of copies of such Registration Statement, each amendment and supplement thereto, the Prospectus included in such Registration Statement (including each preliminary prospectus or free writing prospectus) in conformity with the requirements of the Securities Act, and such other documents as they may reasonably request in order to facilitate the disposition of Registrable Securities owned by them;
- (d) notify the Holders of Registrable Securities covered by such Registration Statement, promptly after the Company shall receive notice thereof, of the time when such

Registration Statement becomes or is declared effective or when any amendment or supplement or any Prospectus forming a part of such Registration Statement has been filed;

- (e) notify the Holders of Registrable Securities covered by such Registration Statement promptly of any request by the SEC for the amending or supplementing of such Registration Statement or Prospectus or for additional information and promptly deliver to such Holders copies of any comments received from the SEC;
- (f) notify the Holders promptly of any stop order suspending the effectiveness of such Registration Statement or Prospectus or the initiation of any proceedings for that purpose, and use all reasonable efforts to obtain the withdrawal of any such order or the termination of such proceedings;
- (g) use all reasonable efforts to register and qualify the Registrable Securities covered by such Registration Statement under such other securities or blue sky Laws of such jurisdictions as shall be reasonably requested by the Holders, use all reasonable efforts to keep each such registration or qualification effective, including through new filings, or amendments or renewals, during the Required Period, and notify the Holders of Registrable Securities covered by such Registration Statement of the receipt of any written notification with respect to any suspension of any such qualification; provided, however, that the Company shall not be required in connection therewith or as a condition thereto to qualify to do business or to file a general consent to service of process in any such states or jurisdictions;
- (h) enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the managing underwriter of the Underwritten Offering pursuant to which such Registrable Securities are being offered;
- (i) use all reasonable efforts to obtain: (A) at the time of effectiveness of the Registration Statement covering such Registrable Securities, a "cold comfort letter" from the Company's independent certified public accountants covering such matters of the type customarily covered by "cold comfort letters" as the underwriters may reasonably request; and (B) at the time of any underwritten sale pursuant to such Registration Statement, a "bring-down comfort letter," dated as of the date of such sale, from the Company's independent certified public accountants covering such matters of the type customarily covered by "bring-down comfort letters" as the underwriters may reasonably request.
- (j) promptly notify each Holder of Registrable Securities covered by such Registration Statement at any time when a Prospectus relating thereto is required to be delivered under the Securities Act of the happening of any event as a result of which the Prospectus included in such Registration Statement or any offering memorandum or other offering document includes an untrue statement of a material fact or omits to state any material fact required to be stated therein or necessary to make the statements therein not misleading in the light of the circumstances then existing, and promptly prepare a supplement or amendment to such Prospectus or file any other required document so that, as thereafter delivered to the purchasers of such Registrable Securities, such Prospectus will not contain an untrue statement of material fact or omit to state any fact necessary to make the statements therein not misleading;

- (k) permit any Holder of Registrable Securities covered by such Registration Statement, which Holder in its reasonable judgment could reasonably be deemed to be an underwriter with respect to the Underwritten Offering pursuant to which such Registrable Securities are being offered, or to be a controlling Person of the Company, to reasonably participate in the preparation of such Registration Statement and to require the insertion therein of information to the extent concerning such Holder, furnished to the Company in writing, which in the reasonable judgment of such Holder and its counsel should be included:
- (l) in connection with any Underwritten Offering, use all reasonable efforts to obtain an opinion or opinions addressed to the underwriter or underwriters in customary form and scope from counsel for the Company;
- (m) upon reasonable notice and during normal business hours, subject to the Company receiving customary confidentiality undertakings or agreements from any Holder of Registrable Securities covered by such Registration Statement or other person obtaining access to Company records, documents, properties or other information pursuant to this subsection (m), make available for inspection by a representative of such Holder and any underwriter participating in any disposition of such Registrable Securities and any attorneys or accountants retained by any such Holder or underwriter, relevant financial and other records, pertinent corporate documents and properties of the Company, and use all reasonable efforts to cause the officers, directors and employees of the Company to supply all information reasonably requested by any such representative, underwriter, attorneys or accountants in connection with the Registration Statement;
- (n) with respect to one (1) Required Registration which includes Registrable Securities the market value of which is at least one hundred million United States dollars (\$100,000,000), participate, to the extent requested by the managing underwriter, in efforts extending for no more than five (5) days scheduled by such managing underwriter and reasonably acceptable to the Company's senior management, to sell the Registrable Securities being offered pursuant to such Required Registration (including participating during such period in customary "roadshow" meetings with prospective investors);
- (o) use all reasonable efforts to comply with all applicable rules and regulations of the SEC relating to such registration and make generally available to its security holders earning statements satisfying the provisions of Section 11(a) of the Securities Act, provided that the Company will be deemed to have complied with this Section 2.7(o) with respect to such earning statements if it has satisfied the provisions of Rule 158;
- (p) if requested by the managing underwriter or any selling Holder, promptly incorporate in a prospectus supplement or post-effective amendment such information as the managing underwriter or any selling Holder reasonably requests to be included therein, with respect to the Registrable Securities being sold by such selling Holder, including, without limitation, the purchase price being paid therefor by the underwriters and with respect to any other terms of the Underwritten Offering of Registrable Securities to be sold in such offering, and promptly make all required filings of such prospectus supplement or post-effective amendment;

- (q) cause the Registrable Securities covered by such Registration Statement to be listed on each securities exchange, if any, on which equity securities issued by the Company are then listed; and
- (r) reasonably cooperate with each selling Holder and each underwriter participating in the disposition of such Registrable Securities and their respective counsel in connection with filings required to be made with the Financial Industry Regulatory Authority, Inc., if any.
- **2.8 Furnish Information.** It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself and the Registrable Securities held by it as shall be reasonably necessary to effect the registration of such Holder's Registrable Securities.
- **2.9 Expenses.** Except as specifically provided herein, all Registration Expenses shall be borne by the Company. All Selling Expenses incurred in connection with any registration hereunder shall be borne by the Holders of Registrable Securities covered by a Registration Statement, pro rata on the basis of the number of Registrable Securities registered on their behalf in such Registration Statement.
 - 2.10 Indemnification. In the event any Registrable Securities are included in a Registration Statement under this Agreement:
- (a) The Company shall indemnify and hold harmless each Holder including Registrable Securities in any such Registration Statement, any underwriter (as defined in the Securities Act) for such Holder and each Person, if any, who controls such Holder or underwriter within the meaning of Section 15 of the Securities Act or Section 20 of Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, against any and all losses, claims, damages or liabilities (joint or several) to which they may become subject under any securities Laws including, without limitation, the Securities Act, the Exchange Act, or any other statute or common law of the United States or any other country or political subdivision thereof, or otherwise, including the amount paid in settlement of any litigation commenced or threatened (including any amounts paid pursuant to or in settlement of claims made under the indemnification or contribution provisions of any underwriting or similar agreement entered into by such Holder in connection with any offering or sale of securities covered by this Agreement), and shall promptly reimburse them, as and when incurred, for any legal or other expenses incurred by them in connection with investigating any claims and defending any actions, insofar as any such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon any of the following statements, omissions or violations (each, a "Violation"): (i) any untrue statement or alleged untrue statement of a material fact contained in or incorporated by reference into such Registration Statement, including any peliminary prospectus or final prospectus contained therein or any free writing prospectus or any amendments or supplements thereto, or in any offering memorandum or other offering document relating to the offering and sale of such securities or (ii) the omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statemen

damage, liability or action to the extent that it (A) arises out of or is based upon a Violation which occurs solely in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (B) is caused by such Holder's disposition of Registrable Shares during any period during which such Holder is obligated to discontinue any disposition of Registrable Shares as a result of any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities.

- (b) Each Holder including Registrable Securities in a registration statement shall indemnify and hold harmless the Company, each of its directors, each of its officers who has signed the registration statement, each Person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act and the officers, directors, owners, agents and employees of such controlling Persons, any underwriter, any other Holder selling securities in such registration statement and any controlling Person of any such underwriter or other Holder, against any losses, claims, damages or liabilities (joint or several) to which any of the foregoing Persons may become subject, under liabilities (or actions in respect thereto) which arise out of or are based upon any Violation, in each case to the extent (and only to the extent) that such Violation: (i) arises out of or is based upon a Violation which occurs solely in reliance upon and in conformity with written information furnished expressly for use in connection with such registration by such Holder; or (ii) is caused by such Holder's disposition of Registrable Shares during any period during which such Holder is obligated to discontinue any disposition of Registrable Shares as a result of any stop order suspending the effectiveness of any registration statement or prospectus with respect to Registrable Securities. Each such Holder shall pay, as incurred, any legal or other expenses reasonably incurred by any Person intended to be indemnified pursuant to this Section 2.10(b), in connection with investigating or defending any such loss, claim, damage, liability or action if such settlement contained in this Section 2.10(b) shall not apply to amounts paid in settlement of any such loss, claim, damage, liability or action if such settlement is effected without consent of the Holder, which consent shall not be unreasonably withheld.
- (c) Promptly after receipt by an indemnified party under this Section 2.10 of notice of the commencement of any action (including any action by a Governmental Authority), such indemnified party shall, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.10, deliver to the indemnifying party a written notice of the commencement thereof and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume the defense thereof with counsel mutually satisfactory to the parties; <u>provided</u>, <u>however</u>, that an indemnified party shall have the right to retain its own counsel, with the reasonable fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such proceeding. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such indemnifying party of any liability to the indemnified party under this Section 2.10, but the omission so to deliver written notice to the indemnifying party shall not relieve it of any liability that it may have to any indemnified party otherwise than under this Section 2.10.

- (d) In order to provide for just and equitable contribution to joint liability in any case in which a claim for indemnification is made pursuant to this Section 2.10 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case notwithstanding the fact that this Section 2.10 provided for indemnification in such case, the Company and each Holder of Registrable Securities shall contribute to the aggregate losses, claims, damages or liabilities to which they may be subject (after contribution from others) in proportion to the relative fault of the Company, on the one hand, and such Holder, severally, on the other hand; <u>provided</u>, <u>however</u>, that in any such case, no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; <u>provided further</u>, <u>however</u>, that in no event shall any contribution under this Section 2.10(d) on the part of any Holder exceed the net proceeds received by such Holder from the sale of Registrable Securities giving rise to such contribution obligation.
- (e) The obligations of the Company and the Holders under this Section 2.10 shall survive the completion of any offering of Registrable Securities in a registration statement under this Agreement and otherwise.
- **2.11 SEC Reports.** With a view to making available to the Holders the benefits of Rule 144 under the Securities Act and any other rule or regulation of the SEC that may at any time permit a Holder to sell Registrable Securities of the Company to the public without registration, the Company agrees to at any time that it is a reporting company under Section 13 or 15(d) of the Exchange Act:
 - (a) file with the SEC in a timely manner all reports and other documents required of the Company under the Exchange Act; and
- (b) furnish to any Holder, so long as such Holder owns any Registrable Securities, forthwith upon request (i) a written statement by the Company that it has complied with the reporting requirements of the Exchange Act, (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company, and (iii) such other information as may be reasonably requested in availing any Holder of any rule or regulation of the SEC (exclusive of Rule 144A) which permits the selling of any Registrable Securities without registration.
- 2.12 Assignment of Registration Rights. The rights to cause the Company to register any Registrable Securities pursuant to this Agreement may be assigned in whole or in part (but only with all restrictions and obligations set forth in this Agreement) by a Holder to a Permitted Transferee which acquires Registrable Securities from such Holder; provided, however, (a) such Holder shall, within five (5) days prior to such transfer, furnish to the Company written notice of the name and address of such Permitted Transferee, details of its status as a Permitted Transferee and details of the Registrable Securities with respect to which such registration rights are being assigned, (b) the Permitted Transferee, prior to or simultaneously with such transfer or assignment, shall agree in writing to be subject to and bound by all restrictions and obligations set forth in this Agreement, (c) the Purchaser Parties shall continue to be bound by all restrictions

and obligations set forth in this Agreement and (d) such transfer or assignment shall be effective only if immediately following such transfer or assignment the further disposition of such Registrable Securities by the Permitted Transferee is restricted under the Securities Act and other applicable securities Law.

3. Restrictions on Beneficial Ownership.

- **3.1 Standstill.** During the period (such period, the "<u>Standstill Term</u>") from and after the date of this Agreement until the later of (A) the fifth (5th) anniversary of the expiration or earlier termination of the "Term" (as such term is defined in the Aventis Collaboration Agreement) and (B) the fifth (5th) anniversary of the expiration or earlier termination of the "Term" (as such term is defined in the Sanofi License and Collaboration Agreement), neither the Purchaser Parties nor any of their respective Affiliates (collectively, the "<u>Standstill Parties</u>") shall (and the Purchaser Parties shall cause their respective Affiliates not to), except as expressly approved or invited in writing by the Company:
- (a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Common Stock and/or Common Stock Equivalents, if after giving effect to such acquisition, the Standstill Parties would beneficially own more than the Standstill Limit; provided, however, that notwithstanding the provisions of this Section 3.1(a), if the number of shares constituting Shares of Then Outstanding Common Stock is reduced or if the aggregate ownership of the Standstill Parties is increased as a result of a repurchase of Shares of Then Outstanding Common Stock, stock split, stock dividend or a recapitalization of the Company, the Standstill Parties shall not be required to dispose of any of their holdings of Shares of Then Outstanding Common Stock even though such action resulted in the Standstill Parties' beneficial ownership totaling more than the Standstill Limit;
- (b) directly or indirectly, seek to have called any meeting of the stockholders of the Company, propose or nominate for election to the Company's Board of Directors any person whose nomination has not been approved by a majority of the Company's Board of Directors or cause to be voted in favor of such person for election to the Company's Board of Directors any Shares of Then Outstanding Common Stock;
- (c) directly or indirectly, encourage or support a tender, exchange or other offer or proposal by any other Person or group (an "Offeror") the consummation of which would result in a Change of Control of the Company (an "Acquisition Proposal");
- (d) directly or indirectly, solicit proxies or consents or become a participant in a solicitation (as such terms are defined in Regulation 14A under the Exchange Act) in opposition to the recommendation of a majority of the Company's Board of Directors with respect to any matter, or seek to advise or influence any Person, with respect to voting of any Shares of Then Outstanding Common Stock of the Company;
- (e) deposit any Shares of Then Outstanding Common Stock in a voting trust or subject any Shares of Then Outstanding Common Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Common Stock;

- (f) act in concert with any Third Party to take any action in clauses (a) through (e) above, or form, join or in any way participate in a "partnership, limited partnership, syndicate, or other group" within the meaning of Section 13(d)(3) of the Exchange Act.
- (g) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in (a) through (e) above; or
- (h) request or propose in writing to the Company's Board of Directors, any member(s) thereof or any officer of the Company that the Company amend, waive, or consider the amendment or waiver of, any provisions set forth in this Section 3.1;

<u>provided</u>, <u>however</u>, that the mere voting in accordance with Section 5 hereof of any voting securities of the Company held by the Purchaser Parties or their Affiliates shall not constitute a violation of any of clauses (a) through (h) above.

3.2 Amendment to Aventis Collaboration Agreement. Sections 3.1 and 6.2 of this Agreement shall, effective as of the date of this Agreement, supersede and replace Sections 20.16 and 20.17 of the Aventis Collaboration Agreement. The foregoing sentence shall not impair the rights of the Company or constitute a waiver by the Company of any breach or default by Aventis, Sanofi US or any of their Affiliates under Sections 20.16 and 20.17 of the Aventis Collaboration Agreement. sanofi-aventis, the Investor, Sanofi US and the Company agree that Section 19.5 of the Aventis Collaboration Agreement is hereby amended and restated in its entirety to read:

4. Restrictions on Dispositions.

4.1 Lock-Up. From and after the date of this Agreement and until the earlier of (i) the fifth (5th) anniversary of the date of this Agreement and (ii) the expiration, or earlier valid termination by Aventis in its entirety pursuant to Section 19.3 or 19.4 thereof, of the Sanofi License and Collaboration Agreement (the "Lock-Up Term"), without the prior approval of a majority of the Company's Board of Directors, the Purchaser Parties shall not, and shall cause their respective Affiliates not to, Dispose of (x) any of the Purchased Shares or any shares of Common Stock beneficially owned by any Standstill Party as of the date of this Agreement, together with any shares of Common Stock issued in respect thereof as a result of any stock split,

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stock dividend, share exchange, merger, consolidation or similar recapitalization, and (y) any Common Stock issued as (or issuable upon the exercise of any warrant, right or other security that is issued as) a dividend or other distribution with respect to, or in exchange or in replacement of, the shares of Common Stock described in clause (x) of this sentence; <u>provided, however</u>, that the foregoing shall not prohibit the Investor or Aventis from (A) transferring Registrable Securities to a Permitted Transferee in accordance with and subject to the terms of Section 2.12, or (B) Disposing of any Shares of Then Outstanding Common Stock as they may hold from time to time in order to reduce the beneficial ownership of the Standstill Parties to 19.9% of the Shares of Then Outstanding Common Stock, provided that any such Disposition referred to in this clause (B), whether occurring before or after the expiration of the Lock-Up Term, shall be subject to the restrictions and requirements set forth in paragraphs (a), (b) and (c) of Section 4.2.

- **4.2 Limitations Following Lock-Up Term.** The Purchaser Parties agree that, except for any transfer of Registrable Securities by the Investor or Aventis to a Permitted Transferee in accordance with and subject to the terms of Sections 2.12 and 4.1, they shall not, and shall cause their respective Affiliates not to, Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents at any time after the expiration of the Lock-Up Term except (i) pursuant to a registered underwritten public offering in accordance with Section 2, (ii) pursuant to Rule 144 under the Securities Act or (iii) pursuant to privately negotiated sales in transactions exempt from the registration requirements under the Securities Act; provided, however, that:
- (a) In any Underwritten Offering in accordance with Section 2, the Holders whose Registrable Securities are included in such Underwritten Offering shall require that the underwriter for such Underwritten Offering, and shall require that the underwriter for such Underwritten Offering shall agree in writing to, use all reasonable efforts to make as broad a distribution as reasonably practical and to prevent any Person, or Affiliates of such Person, from purchasing in such offering Registrable Securities which would constitute, or result in such Person, together with such Person's Affiliates, having beneficial ownership of, five percent (5%) or more of the total shares of Common Stock then outstanding.
- (b) The Purchaser Parties shall not (and shall cause their respective Affiliates not to), without the prior approval of a majority of the Company's Board of Directors, Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents if such Disposition, together with any Disposition(s) by any Standstill Parties during the immediately preceding three (3) months, would exceed one million (1,000,000) Shares of Then Outstanding Common Stock of the Company (assuming the full conversion into, and exercise and exchange for, shares of Common Stock of all Common Stock Equivalents Disposed of by the Standstill Parties): provided, however, that, without limitation of Section 4.2(a), the foregoing limitations in this Section 4.2(b) shall not prohibit or limit any Disposition of Registrable Securities by a Holder as part of an Underwritten Offering with respect to such Registrable Securities in accordance with Section 2 hereof. This Section 4.2(b) shall, effective as of the date of this Agreement, supersede and replace Section 5.3(a) of the Aventis Stock Purchase Agreement. The foregoing sentence shall not impair the rights of the Company or constitute a waiver by the Company of any breach or default by Aventis or any of its Affiliates under such Section 5.3(a) with respect to events or circumstances occurring or existing prior to the date of this Agreement.

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- (c) The Purchasing Parties shall not (and shall cause their respective Affiliates not to), without the prior approval of a majority of the Company's Board of Directors, Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents to any Person if such Person is, or such Disposition would (in the case of a Disposition pursuant to Rule 144 under the Securities Act, to the knowledge of any Standstill Party) result in such Person becoming, after giving effect to such Disposition, the beneficial owner of five percent (5%) or more of the total shares of Common Stock then outstanding; <u>provided</u>, <u>however</u>, that, without limitation of Section 4.2(a), the foregoing limitation in this Section 4.2(c) shall not prohibit or limit any Disposition of Registrable Securities by a Holder as part of a registered offering with respect to such Registrable Securities in accordance with Section 2 hereof.
- **4.3 Certain Tender Offers.** Notwithstanding any other provision of this Section 4, this Section 4 shall not prohibit or restrict any Disposition of Shares of Then Outstanding Common Stock and/or Common Stock Equivalents by the Standstill Parties into (a) a tender offer by a Third Party which is not opposed by the Company's Board of Directors (but only after the Company's filing of a Schedule 14D-9, or any amendment thereto, with the SEC disclosing the recommendation of the Company's Board of Directors with respect to such tender offer) or (b) an issuer tender offer by the Company.
- **4.4 Offering Lock-Up.** The Holders shall, if requested by the Company and an underwriter of Common Stock of the Company, agree not to Dispose of any Shares of Then Outstanding Common Stock and/or Common Stock Equivalents for a specified period of time, such period of time not to exceed ninety (90) days. Such agreement shall be in writing in a form satisfactory to the Company and the underwriter(s) in such offering. The Company may impose stop transfer instructions with respect to the Shares of Then Outstanding Common Stock and/or Common Stock Equivalents subject to the foregoing restrictions until the end of the specified period of time. This Section 4.4 shall, effective as of the date of this Agreement, supersede and replace Section 5.3(c) of the Aventis Stock Purchase Agreement.

5. Voting Agreement.

5.1 Voting of Securities. From and after the date of this Agreement, other than as permitted by Section 5.2 with respect to Extraordinary Matters, in any vote or action by written consent of the stockholders of the Company (including, without limitation, with respect to the election of directors), the Purchaser Parties shall, and shall cause their respective Affiliates to, vote or execute a written consent with respect to all voting securities of the Company as to which they are entitled to vote or execute a written consent, in the sole discretion of the Purchaser Parties, either (a) in accordance with the recommendation of the Company's Board of Directors or (b) if such Purchaser Party or Affiliate of a Purchaser Party has delivered written notice to the Company at any time prior to the vote on any given matter or the effective time of an action to be taken by written consent, setting forth its intent to vote pursuant to this Section 5.1(b), in the same proportion as the votes cast by all other holders of all classes of voting securities of the Company (as estimated by the inspector of election immediately prior to the closing of the polls with respect to the vote on any given matter, subject to adjustment for the inspector of election's final tabulation of votes cast). In the event that a Purchaser Party or Affiliate of a Purchaser Party does not deliver written notice to the Company as provided in Section 5.1(b), such Person shall be deemed to have elected to vote all voting securities of the Company as to which it is

entitled to vote as provided in Section 5.1(a). In furtherance of this Section 5.1, the Purchaser Parties shall, and shall cause their respective Affiliates to, if and when requested by the Company from time to time, promptly execute and deliver to the Company an irrevocable proxy, substantially in the form of Exhibit A attached hereto, and irrevocably appoint the Company or its designees, with full power of substitution, its attorney, agent and proxy to vote (or cause to be voted) or to give consent with respect to, all of the voting securities of the Company as to which such Purchaser Party or Affiliate of a Purchaser Party is entitled to vote, in the manner and with respect to the matters set forth in this Section 5.1. The Purchaser Parties acknowledge, and shall cause their Affiliates to acknowledge, that any such proxy executed and delivered shall be coupled with an interest, shall constitute, among other things, an inducement for the Company to enter into this Agreement, shall be irrevocable and binding on any successor in interest of such Purchaser Party or Affiliate of such Purchaser Party, as applicable, and shall not be terminated by operation of Law upon the occurrence of any event. Such proxy shall operate to revoke and render void any prior proxy as to any voting securities of the Company heretofore granted by such Purchaser Party or Affiliate of such Purchaser Party, as applicable, to the extent it is inconsistent herewith. Such proxy shall terminate upon the earlier of the expiration or termination of this Section 5.1.

- **5.2** Certain Extraordinary Matters. The Purchaser Parties and their Affiliates may vote, or execute a written consent with respect to, any or all of the voting securities of the Company as to which they are entitled to vote or execute a written consent, as they may determine in their sole discretion, with respect to the following matters (each such matter being an "Extraordinary Matter"):
 - (a) any transaction which would result in a Change of Control;
- (b) any vote of the Company's stockholders with respect to any stock option or stock purchase plan, or any material amendment thereto, or other equity compensation arrangement or material amendment thereto, which has been approved by the Company's Compensation Committee and taken as a whole is not generally and materially consistent with the Company's equity compensation historical practices;
- (c) any other issuance of shares of Common Stock or Common Stock Equivalents voted upon by stockholders of the Company that equals or exceeds ten percent (10%) of, or ten percent (10%) of the voting power of, the Shares of Then Outstanding Common Stock, as of immediately prior to such issuance; and
 - (d) any liquidation or dissolution of the Company.
- **5.3 Quorum.** In furtherance of Section 5.1, the Purchaser Parties shall be, and shall cause each of their Affiliates to be, present in person or represented by proxy at all meetings of stockholders to the extent necessary so that all voting securities of the Company as to which they are entitled to vote shall be counted as present for the purpose of determining the presence of a quorum at such meeting.

6. Termination of Certain Rights and Obligations.

- **6.1 Termination of Registration Rights.** Except for Section 2.10, which shall survive until the expiration of any applicable statutes of limitation, Section 2 shall terminate automatically and have no further force or effect upon the earliest to occur of:
 - (a) the expiration of the Registration Rights Term;
 - (b) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and
 - (c) a liquidation or dissolution of the Company.
- **6.2 Termination of Standstill Agreement.** Provided that none of the Standstill Parties has violated Section 3.1(c), (d) or (f) with respect to the Offeror referred to in this Section 6.2, Section 3 (except for Section 3.2, but only to the extent such Section 3.2 amends Section 19.5 of the Aventis Collaboration Agreement) shall terminate and have no further force or effect, upon the earliest to occur of:
 - (a) the public announcement by an Offeror of an Acquisition Proposal for the Company;
 - (b) the public announcement by the Company or any Offeror of any definitive agreement providing for a Change of Control of the Company;
 - (c) the expiration of the Standstill Term;
- (d) the date of any issuance by the Company to a Third Party of shares of Common Stock, which, when combined with all other Shares of Then Outstanding Common Stock beneficially owned by such Third Party immediately prior to such issuance, represents more than ten percent (10%) of the voting power represented by all Shares of Then Outstanding Common Stock outstanding immediately after giving effect to such issuance, if the Company does not enter into a standstill agreement with such Third Party having material terms substantially similar (i) with respect to restrictions on such Third Party, to the restrictions on the Standstill Parties set forth in Section 3.1 of this Agreement and (ii) with respect to the termination of such restrictions, to the provisions of this Section 6.2; provided, however, that any collaborative or other commercial arrangements between the Company and such Third Party entered into connection with such issuance of Common Stock to such Third Party shall be taken into consideration in determining whether the terms of the standstill agreement entered into with such Third Party are materially similar to the terms of Section 3.1 of this Agreement;
 - (e) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act; and
 - (f) a liquidation or dissolution of the Company;

provided, however, that if any of the transactions referred to in (a) or (b) above terminates and the Company has not made a public announcement of its intent to solicit or engage in a

transaction (or has announced its decision to discontinue pursuing such a transaction) the consummation of which would result in a Change of Control of the Company, then the restrictions contained in Section 3 shall again be applicable, unless a Standstill Party has announced a bona-fide Acquisition Proposal for the Company prior to such termination.

- **6.3 Termination of Restrictions on Dispositions.** Section 4 shall terminate and have no further force or effect upon the earliest to occur of:
 - (a) the consummation by an Offeror of a Change of Control of the Company;
 - (b) a liquidation or dissolution of the Company; and
 - (c) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.
- **6.4 Termination of Voting Agreement.** Section 5 shall terminate and have no further force or effect upon the earliest to occur of:
 - (a) the consummation by an Offeror of a Change of Control of the Company;
 - (b) a liquidation or dissolution of the Company;
- (c) the date on which the Standstill Parties beneficially own voting securities representing less than five percent (5%) of the voting power of the Shares of Then Outstanding Common Stock; and
 - (d) the date on which the Common Stock ceases to be registered pursuant to Section 12 of the Exchange Act.
- **6.5 Effect of Termination.** No termination pursuant to any of Sections 6.1, 6.2 or 6.3 or 6.4 shall relieve any of the parties (or the Permitted Transferee, if any) for liability for breach of or default under any of their respective obligations or restrictions under any terminated provision of this Agreement, which breach or default arose out of events or circumstances occurring or existing prior to the date of such termination.

7. Miscellaneous.

- **7.1 Governing Law; Submission to Jurisdiction.** This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to the conflict of laws principles thereof that would require the application of the Law of any other jurisdiction. The parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.
- 7.2 Waiver. Waiver by a party of a breach hereunder by another party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a party in exercising or availing itself of any right, power or privilege hereunder

shall preclude the later exercise of any such right, power or privilege by such party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the party granting the waiver.

- 7.3 Notices. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant party set forth on Exhibit B attached hereto and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Any party may change its address by giving notice to the other parties in the manner provided above.
- **7.4 Entire Agreement.** This Agreement and the Purchase Agreement contain the entire agreement among the parties with respect to the subject matter hereof and thereof and supersede all prior and contemporaneous arrangements or understandings, whether written or oral, with respect hereto and thereto.
- **7.5 Amendments.** No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of the parties hereto.
- **7.6 Headings; Nouns and Pronouns; Section References.** Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement. Whenever the context may require, any pronouns used herein shall include the corresponding masculine, feminine or neuter forms, and the singular form of names and pronouns shall include the plural and vice-versa. References in this Agreement to a section or subsection shall be deemed to refer to a section or subsection of this Agreement unless otherwise expressly stated.
- 7.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.

- **7.8 Assignment.** Neither this Agreement nor any rights or duties of a party hereto may be assigned by such party, in whole or in part, without (a) the prior written consent of the Company in the case of any assignment by the Purchaser Parties, except as provided by Section 2.12 with respect to the Investor's or Aventis' assignment to a Permitted Transferee; or (b) the prior written consent of the Purchaser Parties in the case of an assignment by the Company.
- **7.9 Successors and Assigns.** This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.
- **7.10 Counterparts.** This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.
- **7.11 Third Party Beneficiaries.** None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any party hereto.
 - **7.12 No Strict Construction.** This Agreement has been prepared jointly and will not be construed against any party.
- **7.13 Remedies.** The rights, powers and remedies of the parties under this Agreement are cumulative and not exclusive of any other right, power or remedy which such parties may have under any other agreement or Law. No single or partial assertion or exercise of any right, power or remedy of a party hereunder shall preclude any other or further assertion or exercise thereof.
- **7.14 Specific Performance.** The Purchaser Parties hereby acknowledge and agree that the rights of the parties hereunder are special, unique and of extraordinary character, and that if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, such refusal or failure would result in irreparable injury to the Company or the Purchaser Parties, as the case may be, the exact amount of which would be difficult to ascertain or estimate and the remedies at law for which would not be reasonable or adequate compensation. Accordingly, if any party refuses or otherwise fails to act, or to cause its Affiliates to act, in accordance with the provisions of this Agreement, then, in addition to any other remedy which may be available to any damaged party at law or in equity, such damaged party will be entitled to seek specific performance and injunctive relief, without posting bond or other security, and without the necessity of proving actual or threatened damages, which remedy such damaged party will be entitled to seek in any court of competent jurisdiction.
- **7.15 No Conflicting Agreements.** Each of the Purchaser Parties hereby represents and warrants to the Company that neither it nor any of its Affiliates is, as of the date of this Agreement, a party to, and agrees that neither it nor any of its Affiliates shall, on or after the date of this Agreement, enter into any agreement that conflicts with the rights granted to the Company in this Agreement. The Company hereby represents and warrants to each Holder that it is not, as of the date of this Agreement, a party to, and agrees that it shall not, on or after the date of this Agreement, enter into, any agreement or approve any amendment to its Organizational Documents (as defined in the Purchase Agreement) with respect to its securities that conflicts

with the rights granted to the Holders in this Agreement. The Company further represents and warrants that the rights granted to the Holders hereunder do not in any way conflict with the rights granted to any other holder of the Company's securities under any other agreements.
(Signature Page Follows)
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IN WITNESS WHEREOF, the parties have executed and delivered this Agreement as of the date first above written.

SANOFI-AVENTIS

By: /s/ Jean-Michel Levy

Name: Jean-Michel Levy

Title: Senior Vice President, Business Development

By: /s/ Laurence Debroux

Name: Laurence Debroux

Title: Senior Vice President, Chief Financial Officer

SANOFI-AVENTIS US LLC

By: /s/ Karen Linehan

Name: Karen Linehan

Title: Authorized Representative

By: /s/ Robin White

Name: Robin White

Title: Authorized Representative

AVENTIS PHARMACEUTICALS INC.

By: /s/ Karen Linehan

Name: Karen Linehan

Title: Authorized Representative

By: /s/ Robin White

Name: Robin White

Title: Authorized Representative

SANOFI-AVENTIS AMÉRIQUE DU NORD

By: /s/ Karen Linehan

Name: Karen Linehan

Title: Authorized Representative

By: /s/ Jean-Luc Renard

Name: Jean-Luc Renard

Title: Authorized Representative

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard Schleifer

Name: Leonard Schleifer Title: President & CEO

EXHIBIT A — FORM OF IRREVOCABLE PROXY

(the "Agreement"), by and among sanofi-aventis, sanofi-aventis US LLC Regeneron Pharmaceuticals, Inc. (the "Company"), the undersigned here agents and proxies, with full power of substitution in each of them, for the vote (or cause to be voted) or, if applicable, to give consent, in such man sole discretion deem proper to record such vote (or consent) in the mans Agreement (but in any case, in accordance with any written instruction form of shares of Common Stock, par value \$0.001 per share, or other vote entitled to vote at any meeting of the Company held after the date hereo applicable, to give written consent with respect thereto. This proxy is co	by irrevocably appoints [] and [], and each of them, the attorneys, ne undersigned, and in the name, place and stead of the undersigned, to mers as each such attorney, agent and proxy or his substitute shall in his ners, and with respect to such matters as set forth in Section 5.1 of the from the undersigned, properly delivered under Section 5.1 of the The Agreement) with respect to all voting securities (whether taking the ing securities of the Company), which the undersigned is or may be f, whether annual or special and whether or not an adjourned meeting or, if upled with an interest, shall be irrevocable and binding on any successor f law upon the occurrence of any event. This proxy shall operate to revoked by the undersigned which is inconsistent herewith. This proxy shall
	Ву:
	Name:
	Title:

EXHIBIT B

NOTICES

(a) If to sanofi-aventis, the Investor, Aventis or Sanofi US:

sanofi-aventis 174, avenue de France 75013 Paris France

Attention: Chief Financial Officer

with a copy to:

sanofi-aventis 174, avenue de France 75013 Paris France Attention: General Counsel

(b) If to the Company:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 U.S.A. Attention: President

Copy: General Counsel

with a copy to:

Skadden, Arps, Slate, Meagher & Flom LLP One Beacon Street, 31st Floor Boston, MA 02108 Attention: Kent A. Coit

Regeneron Pharmaceuticals, Inc. Computation of Ratio of Earnings to Combined Fixed Charges

(Dollars in thousands)

	2003	2004	2005	2006	2007
Earnings:					
Income (loss) from continuing operations before	@(10 5 205)	0.41.565	0(05.456.)	0(102.150.)	E(105 (00)
income (loss) from equity investee	\$(107,395) 14.108	\$41,565 14.060	\$(95,456) 13.687	\$(103,150) 13.643	\$(105,600)
Fixed charges Amortization of capitalized interest	14,10 6 33	14,060 78	13,067 78	13,043	13,708 23
Interest capitalized	(276.)	70 	76 		
•					
Adjusted earnings	\$ (93,530)	\$55,703	\$(81,691)	\$ (89,434)	\$ (91,869)
Fixed charges					
Interest expense	\$ 11,932	\$12,175	\$ 12,046	\$ 12,043	\$ 12,043
Interest capitalized	276				
Assumed interest component of rental charges	1,900	1,885	1,641	1,600	1,665
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Total fixed charges	\$ 14,108	\$14,060	\$ 13,687	\$ 13,643	\$ 13,708
Ratio of earnings to fixed charges	(A)	3.96	(A)	(A)	(A)

⁽A) Due to the registrant's losses for the years ended December 31, 2003, 2005, 2006, and 2007 the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

	2003	2005	2006	2007
Coverage deficiency	\$107,638	\$95,378	\$103,077	\$105,577

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 33-50480, 33-85330, 33-97176, 333-33891, 333-80663, 333-61132, 333-97375, and 333-119257) and on Form S-3 (Nos. 333-74464 and 333-121225) of Regeneron Pharmaceuticals, Inc., of our report dated February 27, 2008 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP

New York, New York February 27, 2008

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

- 1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this annual report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the registrant, particularly during the period in which this annual report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles:
 - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions
 about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based
 on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting: and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2008 By: /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Murray A. Goldberg, certify that:
- 1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this annual report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and 15d-15(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within the registrant, particularly during the period in which this annual report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2008 By: /s/ Murray A. Goldberg

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ LEONARD S. SCHLEIFER

Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer February 27, 2008

/s/ MURRAY A. GOLDBERG

Murray A. Goldberg Chief Financial Officer February 27, 2008

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-K

Filing Date: 2/26/2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

FORM	10-K

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ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF

For the Fiscal Year Ended December 31, 2008

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF

Commission file number 0-19034

REGENERON PHARMACEUTICALS. INC.

(Exact name of registrant as specified in its charter,

New York

13-3444607

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No)

777 Old Saw Mill River Road, Tarrytown, New York

10591-6707

(Address of principal executive offices)

(Zip code)

(914) 347-7000 (Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Name of each exchange on which registered

Common Stock - par value \$.001 per share

Nasdag Global Select Market

Securities registered pursuant to section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes 💆 No 🗅

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes 🗆 No 🗹

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 🗵 No 🗆

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K ($\S229.405$ of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. \square

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Non-accelerated filer □

Large accelerated filer ■

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes 🔲 No 🗹

Accelerated filer □

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$1,081,564,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2008, the last trading day of the registrant's most recently completed second fiscal quarter

Smaller reporting company

The number of shares outstanding of each of the registrant's classes of common stock as of February 13, 2009:

Class of Common Stock

Number of Shares

Class A Stock, \$.001 par value Common Stock, \$.001 par value 2,246,698 77,730,064

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2009 Annual Meeting of Shareholders	are
incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 58 to 61 of this filing.	

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the commercial success of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is now available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We also have six clinical development programs, including three late-stage clinical programs. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis, REGN421, an antibody to Delta-like ligand -4 (Dll4), which is being developed in oncology, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed in collaboration with sanofi-aventis.

We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted primarily in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our $VelociSuite^{TM}$ technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology ($VelocImmune^{@}$) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Our first three antibody product candidates currently in clinical trials were developed using VelocImmune. Over the course of the next several years, we plan to advance an average of two to three new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Commercial Product:

ARCALYST® (rilonacept) - Cryopyrin-Associated Periodic Syndromes (CAPS)

In February 2008, we received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We shipped \$10.7 million of ARCALYST to our distributors in 2008. ARCALYST is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST is the only therapy approved in the United States for patients with CAPS, a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as CIASI) which encodes a protein named cryopyrin. In addition to FCAS and MWS, CAPS includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST has not been studied for the treatment of NOMID.

In March 2008, ARCALYST became available for prescription in the United States and we transitioned the patients who participated in the CAPS pivotal study from clinical study drug to commercial supplies. In 2009, we expect to ship \$20-24 million of ARCALYST to our U.S. distributors. In July 2008, we submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) for ARCALYST for the treatment of CAPS in the European Union.

Clinical Programs:

1. Aflibercept (VEGF Trap) - Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PIGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are enrolling patients in four Phase 3 trials that combine aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer (the VELOUR study) in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial is evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine (the VANILLA study). A third trial is evaluating aflibercept as a 1st line treatment for metastatic androgen independent prostate cancer in combination with docetaxel/prednisone (the VENICE study). The fourth trial is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel (the VITAL study). All four trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. As of February 2009, each of the four Phase 3 trials was over one-third enrolled, and initial data from the Phase 3 program is expected in 2010. In addition, a Phase 2 study of aflibercept in 1st-line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin (the AFFIRM study) began recruiting patients in January 2009.

Aflibercept is also being studied in a Phase 2 single-agent study in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA). This trial is now fully enrolled and we expect to have initial data from this trial by mid-2009. The FDA has granted Fast Track designation to aflibercept for the treatment of SMA.

In addition, multiple exploratory studies are being conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

Aflibercept Collaboration with the sanofi-aventis Group

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

2. VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare also initiated a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME) in late 2008. Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in \underline{W} et age-related macular degeneration), are comparing VEGF Trap-Eye and ranibizumab (Lucentis®, a registered trademark of Genentech, Inc.), an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating dosing intervals of four and eight weeks for VEGF Trap-Eye compared with ranibizumab dosed according to its U.S. label every four weeks over the first year. As needed dosing (PRN) with both agents will be evaluated in the second year of the studies. We and Bayer Healthcare expect to complete enrollment of the VIEW 1 and VIEW 2 trials in 2009 and initial data are expected in late 2010.

In August 2008, we and Bayer HealthCare AG announced the preliminary results of a Phase 2 study in wet AMD which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year. In September 2008, the complete results of this study, including additional data on reductions in the size of the active choroidal neovascularization membrane (CNV), the active lesion that is the underlying cause of vision loss in patients with wet AMD, were reported at the 2008 annual meeting of the Retina Society.

In this double-masked Phase 2 trial, patients were initially treated with either fixed monthly or quarterly dosing for 12 weeks and then continued to receive treatment for another 40 weeks on a PRN dosing schedule. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 milligrams (mg) for 12 weeks followed by PRN dosing achieved mean improvements in visual acuity versus baseline of 9.0 letters (p<0.0001 versus baseline) and 5.4 letters (p<0.085 versus baseline), respectively, at the end of one year. The proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) increased from 23% at baseline to 45% at week 52 in patients initially treated with 2.0 mg monthly and from 16% at baseline to 47% at week 52 in patients initially treated with 0.5 mg monthly. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg also achieved mean decreases in retinal thickness versus baseline of 143 microns (p<0.0001 versus baseline) and 125 microns (p<0.0001 versus baseline) at week 52, respectively.

During the week 12 to week 52 PRN dosing period, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 additional injections.

While PRN dosing following a fixed quarterly dosing regimen (with dosing at baseline and week 12) also yielded improvements in visual acuity and retinal thickness versus baseline at week 52, the results generally were not as robust as those obtained with initial fixed monthly dosing.

In this Phase 2 study, treatment with VEGF Trap-Eye was also associated with a reduction in the size of the CNV lesion. Patients initially receiving either a 2.0 mg or 0.5 mg monthly fixed dose of VEGF Trap-Eye for 12 weeks followed by PRN dosing experienced statistically significant 3.41 mm^2 and 1.42 mm^2 reductions in mean CNV size at 48 weeks (the final one-year analysis endpoint from the independent reading center) versus baseline, respectively. Patients in the 2.0 mg monthly cohort also achieved a statistically significant 1.75 mm^2 reduction in total lesion size. A reduction in total lesion size was not seen in the cohort initially dosed with 0.5 mg monthly.

In this Phase 2 study, VEGF Trap-Eye was generally well tolerated and there were no reported drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye, which was deemed not to be drug-related. The most commonly reported adverse events were those typically associated with intravitreal injections.

The recently initiated Phase 2 DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study will be enrolling approximately 200 patients in the U.S., Canada, European Union, and Australia. The patients in the study will be treated for 52 weeks followed by six additional months of safety evaluation. The primary efficacy endpoint is the change in best corrected visual acuity (BCVA) from baseline to week 24.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and other diseases and disorders. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare. In 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD, and can earn up to \$90 million in additional development and regulatory milestones related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

3. ARCALYST® (rilonacept) - Inflammatory Diseases

We are evaluating ARCALYST in certain diseases and disorders, in addition to CAPS, where IL-1 may play an important role. In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of ARCALYST versus placebo in the prevention of gout flares induced by the initiation of urate-lowering drug therapy that is used to control gout. In this 83-patient, double-blind, placebo-controlled study, the mean number of flares per patient over the first 12 weeks of urate-lowering therapy was 0.79 with placebo and 0.15 with ARCALYST (p=0.0011), an 81% reduction. This was the primary endpoint of the study. All secondary endpoints also were met with statistical significance. In the first 12 weeks of treatment, 45.2% of patients treated with placebo experienced a gout flare and, of those, 47.4% had more than one flare. Among patients treated with ARCALYST, only 14.6% experienced a gout flare (p=0.0037 versus placebo) and none had more than one flare. Injection-site reaction was the most commonly reported adverse event with ARCALYST and no serious drug-related adverse events were reported.

Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We are in the process of initiating a Phase 3 clinical development program with ARCALYST® (rilonacept) for the treatment of gout. Two Phase 3 clinical trials will evaluate ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. We plan to initiate a Phase 3 clinical trial of ARCALYST for acute gout that will evaluate treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The Phase 3 clinical development program will also include a separate safety study.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody, and to receive 45% of net profits on sales of the antibody product, in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe. Under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to ARCALYST.

4. Monoclonal Antibodies

We and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated using our *VelocImmune*® technology. The first therapeutic antibodies to enter clinical development under the collaboration are REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis, and REGN475, an antibody to Nerve Growth Factor (NGF) that is being developed for the treatment of pain. In addition, a Phase I trial is in the process of being initiated for REGN421, an antibody to Delta-like ligand-4 (Dll4) that is being evaluated in oncology in patients with advanced malignancies. Over the course of the next several years, we and sanofi-aventis plan to advance an average of two to three new antibodies into clinical development each year.

Research and Development Technologies:

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of secreted proteins can have clinical benefit.

Regeneron scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST, as well as aflibercept, and VEGF Trap-Eye which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. $VelociSuite^{TM}$ is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies.

VelociSuite™

VelociSuite consists of $VelociMmune^{@}$, $VelociGene^{@}$, $VelociMouse^{@}$, and $VelociMab^{TM}$. The VelociMmune mouse platform is utilized to produce fully human monoclonal antibodies. VelociMmune was generated by exploiting our VelociGene technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. VelociMmune mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. VelociMmune and our entire VelociSuite offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the Velocimmune technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knockout models, a color or fluorescent marker is substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body, during normal body functioning, as well as in disease processes. For the optimization of pre-clinical development and toxicology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

The *VelociMouse* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, Regeneron's VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab* platform for the rapid generation of expression cell lines for our Traps and our *VelocImmune* human monoclonal antibodies.

Antibody Collaboration with sanofi-aventis

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$75 million of research from the collaboration's inception through December 31, 2008 and will fund up to \$100 million per year in 2009 through 2012. Sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/45% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of \$21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

License Agreement with AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made two \$20.0 million annual, non-refundable payments to us, one in February 2007 and the other in February 2008. AstraZeneca is required to make up to four additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first two additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

License Agreement with Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made two \$20.0 million annual, non-refundable payments to us, one in April 2007 and the other in June 2008. Astellas is required to make up to four additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first two additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

Academic VelocImmune® Investigators Program

In September 2008, we entered into an agreement that will provide researchers at Columbia University Medical Center with access to our *VelocImmune* technology platform. Under the agreement, scientists at Columbia will use *VelocImmune* mice to generate antibodies against their research targets and will conduct research to discover potential human therapeutics based on the antibodies. We have an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products and will pay Columbia a low single-digit royalty on ensuing product sales.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We are using our *VelociGene* technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our *VelociGene* technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse ES cells which can be used to produce knockout mice. These materials are available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, as amended in September 2008, we are entitled to receive a minimum of \$24.5 million over the five-year period beginning September 2006, including \$1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which are being supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Research Programs:

Oncology and Angiogenesis

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In 1994, we discovered a second family of angiogenic growth factors, termed Angiopoietins, and we have received patents covering members of this family. Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. Angiopoietins are being evaluated in preclinical research by us and our academic collaborators. Our preclinical studies have revealed that VEGF and Angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Manipulation of both VEGF and Angiopoietins seems to be of value in blocking vessel growth. We have research programs focusing on several targets in the areas of oncology and angiogenesis.

Tumors depend on the growth of new blood vessels (a process called "angiogenesis") to support their continued growth. Therapies that block tumor angiogenesis, specifically those that block VEGF, the key initiator of tumor angiogenesis, recently have been validated in human cancer patients. However, anti-VEGF approaches do not work in all patients, and many tumors can become resistant to such therapies.

In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. We are in the process of initiating Phase 1 clinical development of a fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune*® technology.

Metabolic and Related Diseases

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in integrating peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program in this area encompasses the study of peripheral (hormonal) regulators of food intake and metabolism in health and disease. We have identified several targets in these therapeutic areas and are evaluating potential antibodies to evaluate in preclinical studies.

Muscle Diseases and Disorders

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle research program is currently focused on conducting in vivo and in vitro experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. We have several molecules in late stage research and are evaluating them for possible further development.

Other Therapeutic Areas

We also have research programs focusing on ophthalmology, inflammatory and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Manufacturing

Our manufacturing facilities are located in Rensselaer, New York and consist of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space. At December 31, 2008, we employed 246 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2008

Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the good manufacturing practice (GMP) regulations of the health authority. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies. If our manufacturing facilities fail to comply with FDA and other regulatory requirements, we will be required to suspend manufacturing. This would likely have a material adverse effect on our financial condition, results of operations, and cash flow.

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies (see "Risk Factors – Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs."). Our competitors include Genentech, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Abbott Laboratories, sanofi-aventis, Merck & Co., Amgen Inc., Roche, and others. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also be significant if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even when we achieve product commercialization, one or more of our competitors may achieve product commercialization earlier than we do or obtain patent protection that dominates or adversely affects our activities. Our ability to compete will depend on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

ARCALYST® (rilonacept). There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company, Novartis, and Xoma Ltd. are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has filed applications in the U.S. and Europe seeking regulatory approval of its IL-1 antibody in CAPS. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. These drug candidates could offer competitive advantages over ARCALYST. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize ARCALYST.

Aflibercept and VEGF Trap-Eye. Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to our VEGF Trap in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate.

In particular, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and a number of pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Pfizer, and Imclone Systems Incorporated (now a wholly-owned subsidiary of Eli Lilly). Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Pfizer and Onyx Pharmaceuticals (together with its partner Bayer) are selling and marketing oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of wet AMD, DME, and other eye indications. Lucentis was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a significant competitive challenge in this indication. The National Eye Institute initiated a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. Avastin (Genentech) is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other areas.

REGN88. We are developing REGN88 for the treatment of rheumatoid arthritis as part of our global, strategic collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex Corporation), Remicade® (Centocor, Inc.), and Humira® (Abbott), and other marketed therapies makes it difficult to successfully develop and commercialize REGN88. REGN88 is a human monoclonal antibody targeting the interleukin-6 receptor. Roche is developing ActemraTM (tocilizumab) an antibody against the interleukin-6 (IL-6) receptor. Roche's antibody is approved for marketing and sale in Europe and is the subject of a filed Biologics License Application with the FDA for the treatment of rheumatoid arthritis. Roche's IL-6 receptor antibody, other clinical candidates in development, and the drugs on the market to treat rheumatoid arthritis could offer competitive advantages over REGN88. This could delay or impair our ability to successfully develop and commercialize REGN88.

REGN421. We are also developing REGN421 for the treatment of various cancers as part of our antibody collaboration with sanofi-aventis. Many companies are developing therapeutic molecules designed to block angiogenesis. A variety of different approaches have been employed, including developing a number of antagonists to VEGF and Dll4 and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to REGN421 in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate. In particular, OncoMed Pharmaceuticals, Inc. has a Dll4 antibody in Phase 1 clinical development.

REGN475. We are also developing REGN475 for the treatment of pain as part of our antibody collaboration with sanofi-aventis. The availability of effective FDA approved non-steroidal anti-inflammatory drugs (NSAIDs) including NSAIDs available over-the-counter without a prescription, and other marketed therapies, may make it difficult to successfully develop and commercialize REGN475. REGN475 is a human monoclonal antibody targeting Nerve Growth Factor (NGF). Pfizer is also developing an antibody against NGF that is in Phase 3 clinical trials for the treatment of pain due to osteoarthritis. Pfizer's NGF antibody, other clinical candidates in development, and other drugs on the market, including over-the-counter medications, to treat pain could offer competitive advantages over REGN475, which could delay or impair our ability to successfully develop and commercialize REGN475.

Other Areas. Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics that are the focus of other research or development programs we are now conducting. These competitors include Amgen and Genentech, as well as many others. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

If a competitor announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, the announcement may have an adverse effect on our operations or future prospects or on the market price of our Common Stock.

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties or other consideration for use of their technology. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see "Risk Factors - We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights."). Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. We are the nonexclusive licensee of a number of additional U.S. patents and patent applications. We also rely upon trade secrets, know-how, and continuing technological innovation in an effort to develop and maintain our competitive position. We or our licensors or collaborators have filed patent applications on various products and processes relating to our product candidates as well as other technologies and inventions in the United States and in certain foreign countries. We intend to file additional patent applications, when appropriate, relating to improvements in these technologies and other specific products and processes. We plan to aggressively prosecute, enforce, and defend our patents and other proprietary technology.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process patent applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of ARCALYST® (rilonacept) and our product candidates (see "Risk Factors – *If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.*"). All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an Investigational New Drug Application, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase 3, large-scale clinical trials are

conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product candidate are then submitted to the FDA in the form of a Biologics License Application, or BLA, for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

Various federal, state, and foreign statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, and other aspects of pharmaceutical product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

In addition to the foregoing, our present and future business will be subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations.

Business Segments

We manage our business as one segment which includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions and the development and commercialization of these discoveries. This segment also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and our grant from the NIH, (ii) ARCALYST® (rilonacept) product sales for the treatment of CAPS, and (iii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology. Prior to 2007, our operations were managed in two business segments: research and development, and contract manufacturing. In 2006, the contract manufacturing segment included all revenues and expenses related to the commercial production of a product under a contract with Merck, which expired in October 2006. For financial information about these segments, see Note 21, "Segment Information", beginning on page F-33 in our Financial Statements.

Employees

As of December 31, 2008, we had 919 full-time employees, of whom 185 held a Ph.D. and/or M.D., or PharmD degree. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

Available Information

We make available free of charge on or through our Internet website http://www.regeneron.com our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through December 31, 2008, we had a cumulative loss of \$875.9 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of December 31, 2008, cash, cash equivalents, restricted cash, and marketable securities totaled \$527.5 million and represented 79% of our total assets. We have invested available cash balances primarily in money market funds and U.S. Treasury, U.S. government agency, corporate, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by Statement of Financial Accounting Standards No. (SFAS) 115, Accounting for Certain Investments in Debt and Equity Securities. Marketable securities totaled \$278.0 million at December 31, 2008, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that is charged against income. For example, during the year ended December 31, 2008, we recorded charges for other-than-temporary impairments totaling \$2.5 million related to two marketable securities in our investment portfolio. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are studying aflibercept, VEGF Trap-Eye, ARCALYST, and our antibody candidates in a wide variety of indications. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are being, or are planned to be, studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some

cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST in only a small number of patients with CAPS. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (Amgen, Inc.), Enbret® (Immunex Corporation), and Remicade® (Centocor, Inc.), ARCALYST affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST may interfere with the body's ability to fight infections. Treatment with Kineret (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. These side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in approved indications.

 $ARCALYST^{@}$ (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST. Nineteen of 55 subjects (35%) who received ARCALYST for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST® (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. Although we obtained regulatory approval for ARCALYST for the treatment of CAPS in the United States, we may be unable to obtain regulatory approval of ARCALYST in any other country or in any other indication. Regulatory agencies outside the United States may require additional information or data with respect to any future submission for ARCALYST for the treatment of CAPS.

If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST for the treatment of CAPS or any of our product candidates in those countries.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell $ARCALYST^{\otimes}$ (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly

and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated rules and listing standards covering a variety of subjects. Compliance with these rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial

reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2008, which report is included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2008. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies; and
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and possible legislation which could ease the entry of competing follow-on biologics into the marketplace are examples of changes and possible changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to \$400 million between 2009 and 2012 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respe

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of $ARCALYST^{\circledast}$ (rilonacept) and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the manufacture, development, or ultimate commercialization of our product candidates.

We rely on third party service providers to support the distribution of ARCALYST and many other related activities in connection with the commercialization of ARCALYST for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® (rilonacept) and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures or a business interruption at our manufacturing facility in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST and our product candidates at our manufacturing facility in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, or other problems at the facility.

Certain raw materials necessary for manufacturing and formulation of ARCALYST and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofiaventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize $ARCALYST^{\circledast}$ (rilonacept) in this indication.

Our only approved product is ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. As a result, there may be too few patients with CAPS to profitably commercialize ARCALYST in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (beracizumab), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, Inc., and Pfizer. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, ranibizumab (Lucentis®), for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute is conducting a Phase 3 trial comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST. This is one of the reasons we discontinued the development of ARCALYST in adult rheumatoid arthritis. In addition, even if ARCALYST is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma, and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has filed applications in the U.S. and Europe seeking regulatory approval of its IL-1 antibody in CAPS. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. Novartis has stated that its IL-1 antibody demonstrated long-lasting clinical remission in patients with CAPS and that its clinical candidate could develop into a major therapeutic advance in the treatment of CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. The successful development of these competing molecules could impair our ability to successfully commercialize ARCALYST.

We have plans to develop ARCALYST for the treatment of certain gout indications. Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST in these diseases.

The successful commercialization of ARCALYST® (rilonacept) and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have announced plans to initiate a Phase 3 program studying the use of ARCALYST for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® (rilonacept) in the United States for the treatment of a group of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST. Physicians may not prescribe ARCALYST, and CAPS patients may not be able to afford ARCALYST, if third party payers do not agree to reimburse the cost of ARCALYST therapy and this would adversely affect our ability to commercialize ARCALYST profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since ARCALYST and our product candidates in clinical development, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Our move to new facilities in mid-2009 could lead to disruptions in our business operations.

We plan to move most of our laboratories and headquarters to new facilities in mid-2009. There is a risk that this physical move could lead to damage to equipment or other business assets or the loss of important data, or that we could encounter problems with our new facilities, which could disrupt or delay our business operations.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their party patents;
- public concern as to the safety or effectiveness of ARCALYST® (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- · arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2008, our five largest shareholders plus Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, beneficially owned 55.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2008. As of December 31, 2008, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 19.1% the shares of Common Stock then outstanding. Under our investor agreement with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2012 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2008, holders of Class A Stock held 22.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, plus any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in us taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of December 31, 2008:

our current executive officers and directors beneficially owned 13.3% of our outstanding shares of Common Stock, assuming
conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are
exercisable within 60 days of December 31, 2008, and 28.0% of the combined voting power of our outstanding shares of
Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60
days of December 31, 2008; and

• our five largest shareholders plus Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, beneficially owned 55.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2008. In addition, these six shareholders held 59.6% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2008.

Pursuant to an investor agreement, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty
 percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board
 of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofiaventis or our aflibercept collaboration with sanofiaventis, sanofiaventis will be bound by certain "standstill" provisions, which contractually prohibit sanofiaventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. Under our main operating lease, as amended, we currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York.

In December 2006, we entered into a new operating lease agreement (as amended in October 2007 and September 2008) to lease approximately 348,000 square feet of laboratory and office space at our current Tarrytown location, which includes approximately 118,000 square feet retained from our current space and approximately 230,000 square feet in new facilities that are under construction and expected to be completed in mid-2009. The term of the lease commenced effective June 2008 and will expire in June 2024. Under the new lease, we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In November 2007, we entered into a new operating sublease for approximately 10,000 square feet of office space in Tarrytown, New York. The lease expires in September 2009 and we have the option to extend the term for two additional terms of three months each. In April 2008, we entered into a new operating sublease for approximately 16,200 square feet of office space in Tarrytown, New York. The lease expires in March 2010 and we have the option to extend the term one additional term of six months. In October 2008, we entered into a new operating sublease for approximately 14,100 square feet of office space in Bridgewater, New Jersey. The lease commences in January 2009 and expires in July 2011.

We own facilities in Rensselaer, New York, consisting of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space.

The following table summarizes the information regarding our current real property leases:

			Current Monthly	
	Square		Base Rental	Renewal Option
Location	Footage	Expiration	Charges (1)	Available
Tarrytown, New York ¹²	130,000	June, 2009	§ 171,300	None
Tarrytown, New York ⁽²⁾	230,000	June, 2024	(3)	Three 5-year terms
Tarrytown, New York ⁽²⁾	118,000	June, 2024	§ 212,200	Three 5-year terms
Tarrytown, New York ⁽⁴⁾	10,000	September, 2009	\$ 22,000	Two 3-month terms
Tarrytown, New York ⁽⁴⁾	16,200	March, 2010	§ 32,700	One 6-month term
Bridgewater, New Jersey ⁽⁵⁾	14,100	July, 2011	\$ 21,700	None

⁽¹⁾ Excludes additional rental charges for utilities, taxes, and operating expenses, as defined.

- (3) Rental payments will commence in August 2009.
- (4) Relates to sublease in Tarrytown, New York as described above.
- (5) Relates to sublease in Bridgewater, New Jersey as described above.

We believe that our existing owned and leased facilities are adequate for ongoing research, development, manufacturing, and administrative activities. In the future, we may lease, operate, or purchase additional facilities in which to conduct expanded research and development activities and manufacturing and commercial operations.

Upon completion of the new facilities, as described above, we will retain 118,000 square feet of space in our current facility and take over 230,000 square feet in the newly constructed buildings.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of our security holders during the last quarter of the fiscal year ended December 31, 2008.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value \$.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for the Common Stock as reported by The NASDAQ Global Select Market:

	High	Low
2007		
First Quarter	\$22.84	\$17.87
Second Quarter	28.74	17.55
Third Quarter	21.78	13.55
Fourth Quarter	24.90	16.77
2008		
First Quarter	\$25.25	\$15.61
Second Quarter	21.68	13.75
Third Quarter	24.00	13.29
Fourth Quarter	22.82	12.62

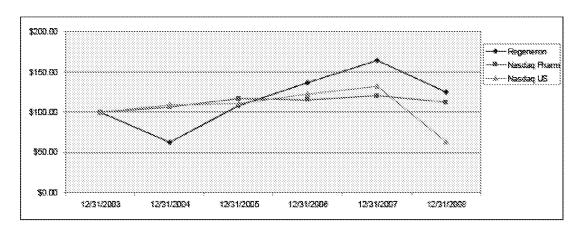
As of February 13, 2009, there were 479 shareholders of record of our Common Stock and 42 shareholders of record of our Class A Stock.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

The information under the heading "Equity Compensation Plan Information" in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Report on Form 10-K.

STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) The Nasdaq Pharmaceuticals Stocks Index and (ii) The Nasdaq Stock Market (U.S.) Index for the period from December 31, 2003 through December 31, 2008. The comparison assumes that \$100 was invested on December 31, 2003 in our Common Stock and in each of the foregoing indices. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices. The historical stock price performance of our Common Stock shown in the graph below is not necessarily indicative of future stock price performance.



	12/31/2003	12/31/2004	12/31/2005	12/31/200 6	12/31/2007	12/31/2008
Regeneron						
regulation.	w*************************************					
Nasdaq Pharm	100.00	106.51	117.29	114.81	120.74	112.34
Nasdaq US						

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2008, 2007, and 2006 and at December 31, 2008 and 2007 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2005 and 2004 and at December 31, 2006, 2005, and 2004 are derived from our audited financial statements not included in this report.

	Year Ended December 31,					
	2008	2007	2006	2005	2004	
		(In thousands	, except per	share data)		
Statement of Operations Data Revenues						
Contract research and development	\$192,208	\$ 96,603	S 51,1 36	\$ 52.447	\$113,157	
Research progress payments					42,770	
Contract manufacturing			12311	13,746	18,090	
Technology licensing	40,000	28,421				
Net product sales	6.249	105.004	00.447		174.017	
Expenses	238,457	125,024	63,447	66,193	174,017	
Research and development	278,016	201,613	137,064	155,581	136,095	
Contract manufacturing			8 146	9,557	15,214	
Selling, general, and administrative	49,348	37,865	25,892	25,476	17,062	
Cost of goods sold	923					
	328,287	239,478	171,102	190,614	168,371	
Income (loss) from operations	(89,830)	(114,454)	(107.655)	(124.421)	5,646	
Other income (expense) Other contract income				30,640	42,750	
Investment income	18,161	20.897	16.548	10,381	5,478	
Interest expense	(7,752)	(12,043)	(12.043)	(12,046)	(12,175)	
Loss on early extinguishment of debt	(938)					
	9,471	8,854	4,505	28,975	36,053	
Net income (loss) before income tax expense and cumulative						
effect of a change in accounting principle	(80,359)	(105,600)	(103,150)	(95,446)	41,699	
Income tax expense Net income (loss) before cumulative effect of a	2,351					
change in accounting principle	(82,710)	(105,600)	(103,150)	(95,446)	41,699	
Cumulative effect of adopting Statement of Financial						
Accounting Standards No. 123R ("SFAS 123R")			813			
Net income (loss)	\$ (82,710)	\$ (105,600)	\$ (102,337)	\$ (95,446)	\$ 41,699	
Net income (loss) per share, basic						
Net income (loss) before cumulative effect of	+ (. ~~)	+ (, =0)	. (. =0)			
a change in accounting principle	\$ (1.05)	\$ (1.59)		\$ (1.71)	\$ 0.75	
Cumulative effect of adopting SFAS 123R Net income (loss)	\$ (1.05)	\$ (1.59)	0.01 \$ (1.77)	\$ (1.71)	\$ 0.75	
Net income (loss) Net income (loss) per share diluted	\$ (1.05)	\$ (1.59)	<u> </u>		\$ 0.74	
**************************************		***************************************	*************	er	or	

	At December 31,				
	2008	2007	2006	2005	2004
		(In	n thousand	s)	
Balance Sheet Data					
Cash, cash equivalents, restricted cash, and marketable					
securities (current and non-current)	\$527,461	\$846,279	\$522,859	\$316,654	\$348,912
Total assets	670,038	936,258	585,090	423,501	473,108
Notes payable - current portion		200,000			
Notes payable - long-term portion			200,000	200,000	200,000
Stockholders' equity	418,852	460,267	216,624	114,002	182,543

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is now available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We also have six clinical development programs, including three late-stage clinical programs. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in rheumatoid arthritis, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through December 31, 2008, we had a cumulative loss of \$875.9 million. In the absence of significant revenues from the commercialization of ARCALYST or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST; advance new product candidates into clinical development from our existing research programs utilizing our technologies for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

As a company that does not expect to be profitable over the next several years, management of cash flow is extremely important. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. We are reimbursed for some of these research and development activities by our collaborators. Our principal sources of cash to-date have been from (i) sales of common equity, both in public offerings and to our

collaborators, including sanofi-aventis, (ii) a private placement of convertible debt, which was repaid in full during 2008, and (iii) funding from our collaborators in the form of up-front payments, research progress payments, and payments for our research and development activities.

In 2008, our research and development expenses totaled \$278.0 million. In 2009, we expect these expenses to increase substantially as we (i) continue to expand our research and preclinical and clinical development activities in connection with our antibody collaboration with sanofi-aventis, (ii) expand our VEGF Trap-Eye, ARCALYST, and aflibercept clinical programs, and (iii) increase our research and development headcount.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2008 was 810 compared with 627 in 2007 and 573 in 2006. In 2008 our average headcount increased primarily to support our expanded research and development activities in connection with our antibody collaboration with sanofi-aventis. In 2007 our average headcount increased primarily to support our expanded development programs for VEGF Trap-Eye and ARCALYST and our plans to move our first antibody candidate into clinical trials. In 2009, we expect our average headcount to increase to approximately 950-1,000, primarily to support the further expansion of our research, development, and marketing activities as described above, especially in connection with our antibody collaboration with sanofi-aventis.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2008 and plans for 2009 are as follows:

Clinical Program	2008 Events	2009 Plans
ARCALYST [®] (rilonacept; also known as IL-1 Trap)	 Received FDA approval for CAPS Launched ARCALYST commercially in CAPS Reported data from a Phase 2 study in the prevention of gout flares in patients initiating urate-lowering drug therapy 	 Initiate Phase 3 development program of ARCALYST in the prevention of gout flares in patients initiating urate- lowering drug therapy and in acute gout
Aflibercept (VEGF Trap – Oncology)	 Reported final data from Phase 2 single-agent trial in advanced ovarian cancer Reported results from four Phase 1 dose-escalation studies in combination with chemotherapy in solid tumors Completed enrollment of Phase 2 single-agent study in symptomatic malignant ascites (SMA) 	 Initiate Phase 2 1st-line study in metastatic colorectal cancer in combination with chemotherapy Report results of Phase 2 single-agent study in SMA Continue enrollment of four Phase 3 studies
VEGF Trap-Eye (intravitreal injection)	 Presented positive final data through 52 weeks from the Phase 2 trial in wet AMD Bayer HealthCare initiated second Phase 3 trial (VIEW 2) in wet AMD outside the United States Initiated a Phase 2 study in DME 	 Complete enrollment in VIEW 1 and VIEW 2 trials Continue enrolling patients in the Phase 2 DME trial
Monoclonal Antibodies	 Filed IND for REGN421 (anti-Dll4) Filed IND for REGN475 (anti-NGF) 	 Initiate Phase 1 trial for REGN421 in oncology Initiate Phase 1 trial for REGN475 Report data from Phase 1 trial of REGN88 (anti-IL-6R) in rheumatoid arthritis Advance additional antibody candidate(s) into clinical development

Critical Accounting Policies and Use of Estimates

A summary of the significant accounting policies that impact us is provided in Note 2 to our Financial Statements, beginning on page F-7. The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- It requires an assumption (or assumptions) regarding a future outcome; and
- Changes in the estimate or the use of different assumptions to prepare the estimate could have a material effect on our results of operations or financial condition.

Management believes the current assumptions used to estimate amounts reflected in our financial statements are appropriate. However, if actual experience differs from the assumptions used in estimating amounts reflected in our financial statements, the resulting changes could have a material adverse effect on our results of operations, and in certain situations, could have a material adverse effect on our liquidity and financial condition. The critical accounting estimates that impact our financial statements are described below.

Revenue Recognition

Contract Research and Development Revenue

We recognize contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104) and Emerging Issues Task Force 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21). We earn contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize our technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in Successfully advancing product candidates in a drug developme

We enter into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. We may share the costs of research and development activities with our collaborator, such as in our VEGF Trap-Eye collaboration with Bayer HealthCare, or we may be reimbursed for all or a significant portion of the costs of our research and development activities, such as in our aflibercept and antibody collaborations with sanofi-aventis. We record our internal and third-party development costs associated with these collaborations as research and development expenses. When we are entitled to reimbursement of all or a portion of the research and development expenses that we incur under a collaboration, we record those reimbursable amounts as contract research and development revenue proportionately as we recognize our expenses. If the collaboration is a cost-sharing arrangement in which both we and our collaborator perform development work and share costs, in periods when our collaborator incurs development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of the collaborator's development expenses that we are obligated to reimburse. In addition, we record revenue in connection with a government research grant using a proportional performance model as we incur expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically and could result in material changes to the amount of revenue recognized each year in the future. In addition, our estimated performance periods may change if development programs encounter delays or we and our collaborators decide to expand or contract our clinical plans for a drug candidate in various disease indications. For example, for the year ended December 31, 2007, we recognized \$2.6 million less in contract research and development revenue, compared to amounts recognized in 2006, in connection with non-refundable up-front payments previously received from sanofi-aventis pursuant to the companies' aflibercept collaboration, due to an extension of our estimated performance period. In addition, during the fourth quarter of 2008, we extended our estimated performance period in connection with the up-front and milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened our estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in our estimates resulted in the recognizion of \$0.4 million less in contract research and development revenue in the fourth quarter of 2008, compared to amounts recognized in connection with these deferred payments in each of the prior three quarters of 2008. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize an

Product Revenue

In March 2008, ARCALYST® (rilonacept) became available for prescription in the United States for the treatment of CAPS. We recognize revenue from product sales in accordance with SAB 104. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distributor fees, and other sales-related costs. We account for these reductions in accordance with Emerging Issues Task Force Issue No. 01-9, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products) (EITF 01-9), and Statement of Financial Accounting Standards No. (SFAS) 48, Revenue Recognition When Right of Return Exists, as applicable. In accordance with EITF 01-9 and SFAS 48, since we currently have limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or we can reasonably estimate returns and (ii) rebates have been processed or we can reasonably estimate rebates. We review our estimates of rebates payable each period and record any necessary adjustments in the current period's net product sales.

Clinical Trial Expenses

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations (CROs). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts with CROs are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient

monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the years ended December 31, 2008 or 2007.

Stock-based Employee Compensation

We account for stock-based employee compensation under the provisions of SFAS 123R, Share-Based Payment. We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with previously issued employee and board of director option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future.

The assumptions used in computing the fair value of option awards reflect our best estimates but involve uncertainties related to market and other conditions, many of which are outside of our control. Changes in any of these assumptions may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in future periods.

In addition, we have granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, these options' performance conditions are considered to be probable of attainment.

Marketable Securities

We consider our marketable securities, which consist primarily of U.S. government, corporate, and asset-backed securities, to be "available-for-sale," as defined by SFAS 115, *Accounting for Certain Investments in Debt and Equity Securities*. These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that is charged against income.

On a quarterly basis, we review our portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. Such factors include the length of time and the extent to which market value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of our ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.

As a result of our quarterly reviews of our marketable securities portfolio, during 2008 and 2007, we recorded charges for other-than-temporary impairment of our marketable securities totaling \$2.5 million and \$5.9 million, respectively. However, the current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in our investment portfolio and that such declines could result in additional charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

Depreciation of Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. In some situations, the life of the asset may be extended or shortened if circumstances arise that would lead us to believe that the estimated life of the asset has changed. The life of leasehold improvements may change based on the extension of lease contracts with our landlords. Changes in the estimated lives of assets will result in an increase or decrease in the amount of depreciation recognized in future periods.

Results of Operations

Years Ended December 31, 2008 and 2007

Net Loss

Regeneron reported a net loss of \$82.7 million, or \$1.05 per share (basic and diluted), for the year ended December 31, 2008, compared to a net loss of \$105.6 million, or \$1.59 per share (basic and diluted) for 2007. The decrease in net loss was principally due to revenues earned in 2008 in connection with our November 2007 antibody collaboration with sanofi-aventis, partly offset by higher research and development expenses.

Revenues

Revenues for the years ended December 31, 2008 and 2007 consist of the following:

(In millions)	2008	2007
Contract research & development revenue		
Sanofi-aventis	\$154.0	\$ 51.7
Bayer HealthCare	31.2	35.9
Other	7.0	9.0
Total contract research & development revenue	192.2	96.6
Technology licensing revenue	40.0	28.4
Technology licensing revenue Net product sales	6.3	
Total revenue	\$238.5	\$125.0

The contract research and development revenue we earn from sanofi-aventis, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

	Years e	nded
	Decembe	er 31,
Sanofi-aventis Contract Research & Development Revenue	2008	2007
(In millions)		
Aflibercept:		
Regeneron expense reimbursement	\$ 35.6	\$38.3
Recognition of deferred revenue related to up-front payments	8.8	8.8
Total affibercept	44.4	47.1
Antibody:		
Regeneron expense reimbursement	97.9	3.7
Recognition of deferred revenue related to up-front payment	10.5	0.9
Recognition of revenue related to VelociGene agreement	1.2	
Total antibody	109.6	4.6
Total sanofi-aventis contract research & development revenue	\$154.0	<u>\$51.7</u>

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in 2008 compared to 2007, primarily due to lower costs related to manufacturing aflibercept clinical supplies. Recognition of deferred revenue relates to sanofi-aventis' up-front aflibercept payments. As of December 31, 2008, \$52.4 million of the original \$105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2008, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of \$72.2 million under the discovery agreement and \$25.7 million of development costs, related primarily to REGN88, under the license agreement, compared to \$3.0 million and \$0.7 million respectively, in 2007. Recognition of deferred revenue under the antibody collaboration related to sanofiaventis' \$85.0 million up-front payment. As of December 31, 2008, \$73.6 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in August 2008, we entered into a separate *VelociGene* agreement with sanofi-aventis. For the year ended December 31, 2008, we recognized \$1.2 million in revenue related to this agreement.

The contract research and development revenue we earn from Bayer HealthCare, as detailed below, consists partly of cost sharing of Regeneron VEGF Trap-Eye development expenses and partly of recognition of revenue related to a non-refundable \$75.0 million up-front payment and \$20.0 million milestone payment.

	Years	ende d
	Decem	ber 31,
Bayer HealthCare Contract Research & Development Revenue	2008	2007
(In millions)		
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$18.8	\$20.0
Recognition of deferred revenue related to up-front and milestone payments	12.4	15.9
Total Bayer HealthCare contract research & development revenue	\$31.2	\$35.9

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue. In the fourth quarter of 2007, we and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps, timelines, and costs, as well as the projected responsibilities of each of the companies. In addition, in the fourth quarter of 2007, we and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. The \$75.0 million up-front licensing payment and the \$20.0 million milestone payment (which was received in August 2007 and not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue

over the related estimated performance period. In periods when we recognize VEGF Trap-Eye development expenses that we incur under the collaboration, we also recognize, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare decreased in 2008 compared to 2007. Under the terms of the collaboration, in 2008, the first \$70.0 million of agreed-upon VEGF Trap-Eye development expenses incurred by Regeneron and Bayer HealthCare under a global development plan were shared equally, and we were solely responsible for up to the next \$30.0 million. Since both we and Bayer HealthCare incurred higher VEGF Trap-Eye development expenses in 2008 compared to 2007, during the fourth quarter of 2008, we were solely responsible for most of the collaboration's VEGF Trap-Eye development expenses, which partly contributed to the revenue decrease in 2008 compared to 2007. In addition, the decrease was due in part to the cumulative catchup recognized in 2007 from the inception of the collaboration in October 2006, as described above. Recognition of deferred revenue related to Bayer HealthCare's \$75.0 million up-front and \$20.0 million milestone payments also decreased in 2008 from 2007 as a result of the cumulative catch-up. As of December 31, 2008, \$66.7 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$4.9 million and \$5.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. For the years ended December 31, 2008 and 2007, we recognized \$40.0 million and \$28.4 million, respectively, of technology licensing revenue related to these agreements.

For the year ended December 31, 2008, we recognized as revenue \$6.3 million of ARCALYST® (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated. At December 31, 2008, deferred revenue related to ARCALYST net product sales totaled \$4.0 million.

Expenses

Total operating expenses increased to \$328.3 million in 2008 from \$239.5 million in 2007. Our average headcount in 2008 increased to 810 from 627 in the same period of 2007 principally as a result of our expanding research and development activities which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2008 and 2007 include a total of \$32.5 million and \$28.1 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the year ended December 31, 2008			
	Expenses before			
	inclusion of Non-cash	Non-cash		
	Compensation	Compensation	Expenses as	
Expenses	Expense	Expense	Reported	
(In millions)				
Research and development	\$259.0	\$19.0	\$278.0	
Selling, general, and administrative	35.9	13.5	49.4	
Cost of goods sold	0.9		0.9	
Total operating expenses	\$295.8	\$32.5	\$328.3	

	For the year ended December 31, 2007			
	Expenses before			
i	inclusion of Non-cash	Non-cash		
	Compensation	Compensation	Expenses as	
Expenses	Expense	Expense	Reported	
(in millions)				
Research and development	\$185.4	\$16.2	\$201.6	
Selling, general, and administrative	<u> 26.0</u>	11.9	<u>37.9</u>	
Total operating expenses	\$211.4	\$28.1	<u>\$239.5</u>	

The increase in total Non-cash Compensation Expense in 2008 was partly attributable to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2007 in comparison to the fair market value of annual employee option grants made in recent years prior to 2006. In addition, Non-cash Compensation Expense in 2008 and 2007 included \$2.2 million and \$0.1 million, respectively, in connection with a December 2007 Restricted Stock award.

Research and Development Expenses

Research and development expenses increased to \$278.0 million for the year ended December 31, 2008 from \$201.6 million for 2007. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2008 and 2007:

	Year Ended December 3		mber 31,
Research and Development Expenses	2008	2007	Increase
(In millions)			
Payroll and benefits ⁽¹⁾	\$ 81.7	\$ 60.6	\$ 21.1
Clinical trial expenses	49.3	37.6	11.7
Clinical manufacturing costs ⁽²⁾	53.8	47.0	6.8
Research and preclinical development costs	29.6	23.2	6.4
Occupancy and other operating costs	33.6	22.6	11.0
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses (3)	30.0	10.6	19.4
Total research and development	\$278.0	\$201.6	\$ 76.4

Includes \$16.7 million and \$13.2 million of Non-cash Compensation Expense for the years ended December 31, 2008 and 2007, respectively.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, which includes our VIEW 1 trial in wet AMD, (ii) ARCALYST® (rilonacept), which includes our Phase 2 gout flare prevention clinical study, and (iii) monoclonal antibodies, which includes REGN88 as well as clinical-related preparatory activities for REGN421. Clinical manufacturing costs increased due primarily to higher expenses related to VEGF Trap-Eye and monoclonal antibodies, including REGN88. These increases were partially offset by a reduction in manufacturing costs associated with ARCALYST and aflibercept. Research and preclinical development costs increased principally in connection with our higher headcount, expanded research and development activities, and new operating lease for our Tarrytown, New York facilities, which commenced in June 2008. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD, which Bayer HealthCare initiated in 2008.

⁽²⁾ Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$2.3 million and \$3.0 million of Non-cash Compensation Expense for the years ended December 31, 2008 and 2007, respectively.

⁽³⁾ Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. In the fourth quarter of 2007, we commenced recognizing cost-sharing of our and Bayer Healthcare's VEGF Trap-Eye development expenses.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	Year e	Year ended December 31,		
			Increase	
Project Costs	2008	2007	(Decrease)	
(In millions)				
ARCALYST® (rilonacept)	\$ 39.2	\$ 38.1	\$ 1.1	
Affibercept	32.1	33.7	(1.6)	
VEGF Trap-Eye	82.7	53.7	29.0	
REGN88	21.4	13.6	7.8	
Other research programs & unallocated costs	102.6	62.5	40.1	
Total research and development expenses	\$278.0	\$201.6	<u>S 76.4</u>	

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators, where applicable, continue to explore further development of ARCALYST, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors", under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. As a result, we can not predict whether the commercialization of ARCALYST in CAPS will result in a significant net cash benefit to us.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$49.4 million in 2008 from \$37.9 million in the same period of 2007. In 2008, we incurred \$5.2 million of selling expenses related to ARCALYST® (rilonacept) for the treatment of CAPS. General and administrative expenses increased in 2008 due to (i) higher compensation expense primarily resulting from increases in administrative headcount to support our expanded research and development activities, (ii) higher recruitment and related costs associated with expanding our headcount, (iii) higher fees for professional services related to various general corporate matters, and (iv) higher administrative facility-related costs.

Cost of Goods Sold

During the year ended December 31, 2008, we began recognizing revenue and cost of goods sold from net product sales of ARCALYST. We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not being included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold for 2008 was \$0.9 million and consisted primarily of royalties and other period costs related to ARCALYST commercial supplies.

Other Income and Expense

Investment income decreased to \$18.2 million in 2008 from \$20.9 million in the 2007, due primarily to lower yields on our cash and marketable securities. In addition, in 2008 and 2007, deterioration in the credit quality of specific marketable securities in our investment portfolio subjected us to the risk of not being able to recover these securities' carrying values. As a result, in 2008 and 2007, we recognized charges of \$2.5 million and \$5.9 million related to securities from three issuers and two issuers, respectively, which we considered to be other than temporarily impaired. In 2008, these charges were partially offset by realized gains of \$1.2 million on sales of marketable securities during the year.

Interest expense of \$7.8 million and \$12.0 million for the years ended December 31, 2008 and 2007, respectively, was attributable to our 5.5% Convertible Senior Subordinated Notes due October 17, 2008. During the second and third quarters of 2008, we repurchased a total of \$82.5 million in principal amount of these convertible notes for \$83.3 million. In connection with these repurchases, we recognized a \$0.9 million loss on early extinguishment of debt, representing the premium paid on the notes plus related unamortized debt issuance costs. The remaining \$117.5 million of convertible notes were repaid in full upon their maturity in October 2008.

Income Tax Expense

In the third quarter of 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards, that would otherwise have expired over the next several years, to offset income for tax purposes. As a result, we incurred and paid income tax expense of \$3.1 million, which relates to U.S. federal and New York State alternative minimum tax and included \$0.2 million of interest and penalties. This expense was partly offset by a \$0.7 million income tax benefit, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

Years Ended December 31, 2007 and 2006

Net Loss

Regeneron reported a net loss of \$105.6 million, or \$1.59 per share (basic and diluted), for the year ended December 31, 2007, compared to a net loss of \$102.3 million, or \$1.77 per share (basic and diluted), for 2006.

Revenues

Revenues for the years ended December 31, 2007 and 2006 consist of the following:

(In millions)	2007	2006
Contract research & development revenue		
Sanofi-aventis	\$ 51.7	\$47.8
Bayer HealthCare	35.9	
Other	9.0	3.3
Total contract research & development revenue	96.6	51.1
Contract manufacturing revenue		12.3
Technology licensing revenue	28.4	
Total revenue	\$125.0	\$63.4

We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

	Years	ended
	Decem	ber 31,
Sanofi-aventis Contract Research & Development Revenue	2007	2006
(in millions)		
Aflibercept:		
Regeneron expense reimbursement	\$38.9	\$36.4
Recognition of deferred revenue related to up-front payments	8.8	11.4
Total affibercept	47.1	47.8
Antibody:		
Regenerun expense remibursement	3.7	
Recognition of deferred revenue related to up-front payment	0.9	
Total antibody	4.6	
Total sanofi-aventis contract research & development revenue	\$51.7	\$47.8

Sanofi aventis' reimbursement of Regeneron's aflibercept expenses increased in 2007 compared to 2006, primarily due to higher preclinical and clinical development costs. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments decreased in 2007 from 2006 due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of December 31, 2007, \$61.2 million of the original \$105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2007, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of \$3.0 million under the collaboration's discovery agreement and \$0.7 million of REGN88 development costs under the license agreement. Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' \$85.0 million up-front payment. As of December 31, 2007, \$84.1 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in the fourth quarter of 2007, we commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catchup. As a result, in the fourth quarter of 2007, we recognized contract research and development revenue of \$35.9 million, consisting of (i) \$15.9 million related to the \$75.0 million up-front licensing payment and the \$20.0 million milestone payment, and (ii) \$20.0 million related to the portion of our 2007 VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. As of December 31, 2007, \$79.1 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$5.5 million and \$0.5 million in 2007 and 2006, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue in 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in 2006 was \$1.2 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the \$20.0 million non-refundable, up-front payment, which we received in February 2007, was deferred and recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the \$20.0 million non-refundable, up-front payment, which we received in April 2007, was deferred and recognized as revenue ratably over the twelve month period beginning in June 2007. For the year ended December 31, 2007, we recognized \$28.4 million of technology licensing revenue related to these agreements.

Expenses

Total operating expenses

Total operating expenses increased to \$239.5 million in 2007 from \$171.1 million in 2006. Our average employee headcount in 2007 increased to 627 from 573 in 2006, primarily to support our expanded development programs for VEGF Trap-Eye and ARCALYST® (rilonacept) and our activities to move our first antibody candidate (REGN88) into clinical trials. Operating expenses in 2007 and 2006 include a total of \$28.1 million and \$18.6 million of Non-cash Compensation Expense, as detailed below:

	Expenses before			
	inclusion of Non-cash	Non-cash		
	Compensation	Compensation	Expenses as	
Expenses	Expense	Expense	Reported	
(In millions)				
Research and development	\$185.4	\$16.2	\$201.6	
Selling, general, and administrative	<u> 26.0</u>	119	37.9	
Total operating expenses	\$211.4	\$28.1	\$239.5	
	For the year ended December 31, 2006			
	For the year er	nded December 31	, 2006	
	For the year er Expenses before	nded December 31	, 2006	
		nded December 31 Non cash	, 2006	
	Expenses before		Expenses as	
Expenses	Expenses before inclusion of Non-cash	Non cash		
Expenses [In millions]	Expenses before inclusion of Non-cash Compensation	Non cash Compensation	Expenses as	
	Expenses before inclusion of Non-cash Compensation	Non cash Compensation	Expenses as	
(fa millions)	Expenses before inclusion of Non-cash Compensation Expense	Non cash Compensation Expense	Expenses as Reported	

The increase in total Non-cash Compensation Expense in 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

For the year ended December 31, 2007

\$18.6

\$171.1

Expenses before

\$152.5

Research and Development Expenses

Research and development expenses increased to \$201.6 million for the year ended December 31, 2007 from \$137.1 million for 2006. The following table summarizes the major categories of our research and development expenses for the years ended December 31, 2007 and 2006:

	Year Ended December 31,		
Research and Development Expenses	2007	2006	Increase
(In millions)			
(1)	\$	\$	
Payroll and benefits ⁽¹⁾	60.6	44.8	\$15.8
Clinical trial expenses	37.6	14.9	22.7
Clinical manufacturing costs ⁽²⁾	47.0	39.2	7.8
	23.2	17.5	5.7
Occupancy and other operating costs	22.6	20.7	1.9
Cost sharing of Bayer HealthCare VEGF Trap-Lye development expenses (3)	10.6		10.6
Total research and development	\$201.6	\$137.1	\$64.5

- (1) Includes \$13.2 million and \$8.6 million of Non-cash Compensation Expense for the years ended December 31, 2007 and 2006, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$3.0 million and \$1.8 million of Non-cash Compensation Expense for the years ended December 31, 2007 and 2006, respectively.
- (3) In the fourth quarter of 2007, when we commenced recognizing cost-sharing of our and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, we recognized as additional research and development expense a cumulative catch-up of \$10.6 million of VEGF Trap-Eye development expenses that we were obligated to reimburse to Bayer HealthCare.

Payroll and benefits increased primarily due to the increase in employee headcount, as described above, annual compensation increases effective in 2007, and higher Non-cash Compensation Expense, as described above. Clinical trial expenses increased due primarily to higher costs related to our Phase 3 study of VEGF Trap-Eye in wet AMD, which we initiated in the third quarter of 2007, and our ongoing Phase 1 and 2 studies of VEGF Trap-Eye in wet AMD. Clinical manufacturing costs increased due primarily to higher costs related to manufacturing ARCALYST and preclinical and clinical supplies of REGN88, which were partly offset by lower costs related to manufacturing aflibercept and VEGF Trap-Eye. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs, including REGN88, and utilization of our proprietary technology platforms. Occupancy and other operating costs increased primarily as a result of higher Company headcount and our expanded research and development activities.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	Year ended December 31,		
Project Costs	2007	2006	Increase
(In millions)			
ARCALYST® (rilonacept)	\$ 38.1	\$ 29.6	\$ 8.5
Aflibercept	33.7	30.7	3.0
VEGF Trap-Eye	53.7	21.9	31.8
REGN88	13.6		13.6
Other research programs & unallocated costs	62.5	54.9	7.6
Total research and development expenses	\$201.6	\$137.1	\$64.5

For the reasons described above in Results of Operations for the years ended December 31, 2008 and 2007, under the caption "Research and Development Expenses", and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. As a result, we can not predict whether the commercialization of ARCALYST in CAPS will result in a significant net cash benefit to us.

Contract Manufacturing Expenses

We had no contract manufacturing expenses in 2007 compared to \$8.1 million in 2006, due to the expiration of our manufacturing agreement with Merck in October 2006.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$37.9 million in 2007 from \$25.9 million in the same period of 2006 primarily due to (i) higher Non-cash Compensation Expense, as described above, (ii) higher compensation expense principally due to annual increases effective in 2007 and higher administrative headcount to support our expanded research and development activities, (iii) recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) market research and related expenses incurred in 2007 in connection with our ARCALYST and VEGF Trap-Eye programs.

Other Income and Expense

Investment income increased to \$20.9 million in 2007 from \$16.5 million in 2006, resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). This increase was partly offset by a \$5.9 million charge in 2007 related to marketable securities which we considered to be other than temporarily impaired in value. In the second half of 2007, deterioration in the credit quality of marketable securities from two issuers has subjected us to the risk of being unable to recover their full principal value, which totals \$14.0 million. Interest expense was \$12.0 million in 2007 and 2006. Interest expense was attributable primarily to our 5.5% Convertible Senior Subordinated Notes due October 17, 2008.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repaid in 2008), purchases of our equity securities by our collaborators, including sanofiaventis, revenue earned under our past and present research and development agreements, including our agreements with sanofiaventis and Bayer HealthCare, our past contract manufacturing agreements, and our technology licensing agreements, ARCALYST product revenue, and investment income.

Years Ended December 31, 2008 and 2007

At December 31, 2008, we had \$527.5 million in cash, cash equivalents, restricted cash and marketable securities compared with \$846.3 million at December 31, 2007. Under the terms of our non-exclusive license agreements with AstraZeneca and Astellas, each company made two \$20.0 million annual, non-refundable payments to us, one in 2007 and the other in 2008. In August 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in our Phase 3 study of VEGF Trap-Eye in wet AMD. In December 2007, we received an \$85.0 million upfront payment in connection with our new antibody collaboration with sanofi-aventis. Sanofi-aventis also purchased 12 million newly issued, unregistered shares of our Common Stock in December 2007 for gross proceeds to us of \$312.0 million.

Cash (Used in) Provided by Operations

Net cash used in operations was \$89.1 million in 2008, and net cash provided by operations was \$27.4 million in 2007 and \$23.1 million in 2006. Our net losses of \$82.7 million in 2008, \$105.6 million in 2007, and \$102.3 million in 2006 included \$32.5 million, \$28.1 million, and \$18.7 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of \$11.3 million, \$11.5 million, and \$14.6 million in 2008, 2007, and 2006, respectively.

At December 31, 2008, accounts receivable increased by \$16.9 million, compared to end-of-year 2007, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, prepaid expenses and other assets increased by \$6.6 million at December 31, 2008 compared to end-of-year 2007 due to a \$12.5 million payment to Cellectis S.A. in July 2008, described below, which is being amortized in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis. Our deferred revenue balances at December 31, 2008 decreased by \$26.8 million, compared to end-of-year 2007, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by the deferral of \$4.0 million of ARCALYST® (rilonacept) net product sales at December 31, 2008.

At December 31, 2007, accounts receivable increased by \$10.8 million compared to end-of-year 2006 due to higher receivable balances related to our collaborations with sanofi-aventis and Bayer HealthCare. Also, prepaid expenses and other assets increased \$9.6 million at December 31, 2007 compared to end-of-year 2006 due primarily to higher prepaid clinical trial costs. Our deferred revenue balances at December 31, 2007 increased by \$89.8 million, compared to end-of-year 2006, due primarily to (i) the \$85.0 million up-front payment received from sanofi-aventis, (ii) the \$20.0 million milestone payment from Bayer HealthCare which was deemed to be non-substantive and fully deferred, and (iii) the two \$20.0 million up-front payments received from each of AstraZeneca and Astellas, all as described above, partly offset by 2007 revenue recognition, principally from amortization of these deferred payments and prior year deferred payments from sanofi-aventis and Bayer HealthCare. Accounts payable, accrued expenses, and other liabilities increased \$18.2 million at December 31, 2007 compared to end-of-year 2006, primarily due to a \$4.9 million cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration and higher accruals in 2007 for payroll costs and clinical-related expenses.

At December 31, 2006, accounts receivable balances decreased by \$29.0 million compared to end-of-year 2005, due to the January 2006 receipt of a \$25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, in connection with an amendment to our aflibercept collaboration to include Japan, and lower amounts due from sanofi aventis for reimbursement of aflibercept development expenses. Also, our deferred revenue balances at December 31, 2006 increased by \$60.8 million compared to end-of-year 2005, due primarily to the October 2006 \$75.0 million up-front payment from Bayer, as described above, partly offset by 2006 revenue recognition from deferred sanofi-aventis up-front payments.

The majority of our cash expenditures in 2008, 2007, and 2006 were to fund research and development, primarily related to our clinical programs and, in 2008 and 2007, our preclinical human monoclonal antibody programs. In 2008, 2007, and 2006, we made interest payments totaling \$9.3 million, \$11.0 million, and \$11.0 million, respectively, on our convertible senior subordinated notes.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$30.8 million in 2008, and net cash used in investing activities was \$85.7 million and \$155.1 million in 2007 and 2006, respectively. In 2008, sales or maturities of marketable securities exceeded purchases by \$65.7 million, whereas in 2007 and 2006, purchases of marketable securities exceeded sales or maturities by \$67.3 million and \$150.7 million, respectively. Capital expenditures in 2008 include costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December 2006 Tarrytown, New York operating lease, as described below. Capital expenditures in 2007 included the purchase of land and a building in Rensselaer for \$9.0 million.

Net cash used in financing activities was \$192.9 million in 2008, and net cash provided by financing activities was \$319.4 million and \$185.4 million in 2007 and 2006, respectively. In the second and third quarters of 2008, we repurchased \$82.5 million in principal amount of our convertible senior subordinated notes for \$83.3 million. The remaining \$117.5 million of convertible notes were repaid in full upon their maturity in October 2008. In 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of our Common Stock for gross proceeds to us of \$312.0 million. In 2006, we completed a public offering of 7.6 million shares of our Common Stock and received proceeds, after expenses, of \$174.6 million. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were \$7.9 million in 2008, \$7.6 million in 2007, and \$10.4 million in 2006.

Fair Value of Marketable Securities

At December 31, 2008 and 2007, we held marketable securities whose aggregate fair value totaled \$278.0 million and \$345.7 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	2008		200	7
Investment type	Fair Value	Percent	Fair Value	Percent
US Treasury securities	\$113.9	11%		
U.S. government agency securities	58.3	21%	\$ 50.5	15%
U.S. government guaranteed corporate bonds	29.8	11%		
U.S. government guaranteed collateralized mortgage obligations	17.4	6%	48.8	14%
Corporate bonds	37.1	13%	110.7	32%
Asset-backed securities	17.8	7%	45.2	13%
Commercial paper			72.8	21%
Other	3.7	1%	17.7	5%
Total marketable securities	\$278.0	100%	\$345.7	100%

In addition, at December 31, 2008 and 2007, we had \$249.5 million and \$500.6 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2008, as marketable securities in our portfolio matured or paid down, we purchased primarily U.S. Treasury securities, U.S. government agency obligations and U.S. government-guaranteed debt. This shift toward higher quality securities reduced the risk profile, as well as the overall yield, of our portfolio during 2008.

In particular, we reduced the proportion of asset-backed securities in the portfolio as they deteriorated in credit quality and declined in value due to higher delinquency rates on the underlying collateral supporting these securities. Of the \$17.8 million of asset-backed securities that we held at December 31, 2008, \$10.0 million were backed by prime and sub-prime residential mortgages and home equity loans. The remaining \$7.8 million were backed by automotive loans and credit card receivables, of which one \$4.9 million security matured in February 2009. The estimated fair value of our asset-backed securities generally ranged from 80% to 95% of par value at December 31, 2008. We purchased these securities in early 2007 when they were all rated triple-A by at least one of the major rating agencies. In addition, our asset-backed securities are all senior tranches that are paid-down before other subordinated tranches as the loans in the underlying collateral are repaid. Through December 31, 2008, we continued to receive monthly payments of principal and interest on our asset-backed securities holdings. If the monthly principal and interest payments continue at approximately the current rate, we anticipate that all of the asset-backed securities in our portfolio will be repaid within the next two years, and most would be repaid in 2009. However, further deterioration of the current economic environment and/or higher delinquency rates in the underlying collateral supporting an asset-backed security in our investment portfolio could result in future impairment charges related to these securities, which could be material.

In addition, we reduced the proportion of corporate bonds in our portfolio from 32% at December 31, 2007 to 13% at December 31, 2008, due to the deterioration of the credit quality of many corporate bond issuers. At the end of 2008, we held \$37.1 million of corporate bonds issued by financial services companies, of which \$5.1 million matured in January 2009 and another \$21.6 million are scheduled to mature by the end of 2009. During 2008, we recognized other-than-temporary impairment charges of \$2.5 million related to corporate securities in our portfolio. Further deterioration in the credit quality of financial services companies whose debt we hold could result in additional impairment charges, which could be material.

In September 2006, the Financial Accounting Standards Board (FASB) issued SFAS 157, Fair Value Measurements. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. We adopted the provisions of SFAS 157 as of January 1, 2008, for financial instruments. Although the adoption of SFAS 157 did not materially impact our financial condition, results of operations, or cash flows, we are now required to provide additional disclosures as part of our financial statements. In addition, in October 2008, the FASB issued FASB Staff Position (FSP) 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active, which clarifies the application of SFAS 157 in a market that is not active. FSP 157-3 also reaffirms the notion of fair value as an exit price as of the measurement date. FSP 157-3 was effective upon issuance for financial statements that had not yet been issued. We adopted FSP 157-3 for the quarter ended September 30, 2008.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers are Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions. We have determined that the provisions of SFAS 157 are applicable to our marketable securities, which totaled \$278.0 million as of December 31, 2008. At December 31, 2008, less than 1% of our marketable securities represented Level 3 assets.

Changes in Level 3 marketable securities during the year ended December 31, 2008 were as follows:

	Level 3
	Marketable
(In millions)	Securities
Balance January 1, 2008	§ 7.9
Settlements	(8.2)
Realized gain	1.1
Impairments	(0.7)
Balance December 31, 2008	\$ 0.1

During the year ended December 31, 2008, there were no transfers of marketable securities between Level 2 and Level 3 classifications.

Our methods for valuing our marketable securities are described in Note 2 to our financial statements included in this Annual Report on Form 10-K. With respect to valuations for pricing our Level 2 marketable securities, we consider quantitative and qualitative factors such as financial conditions and near term prospects of the issuer, recommendations of the investment advisors and forecasts of economic, market, or industry trends. We also review our investment advisors' policies and procedures for valuation and, for a sample of valuations, review the inputs supporting the valuations and independently test the valuations through the use of an alternative third-party vendor. For valuations that we determine for our Level 3 marketable securities, we regularly monitor these securities and adjust their valuations as deemed appropriate based on the facts and circumstances.

Collaborations with the sanofi-aventis Group

Aflibercept

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. Sanofi-aventis made a non-refundable up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for \$45.0 million.

In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In connection with this amendment, sanofiaventis made a \$25.0 million non-refundable payment to us.

In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a \$25.0 million non-refundable up-front payment to us, which was

received in January 2006. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

We have agreed to manufacture clinical supplies of aflibercept at our plant in Rensselaer, New York. Sanofi-aventis has agreed to be responsible for providing commercial scale manufacturing capacity for aflibercept.

Under the collaboration agreement, as amended, agreed upon worldwide aflibercept development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs. Since inception of the collaboration agreement through December 31, 2008, we and sanofi-aventis have incurred \$446.5 million in agreed upon development expenses related to aflibercept. Currently, multiple clinical studies to evaluate aflibercept as both a single agent and in combination with other therapies in various cancer indications are ongoing, and we and sanofi-aventis plan to initiate additional aflibercept clinical studies in 2009.

Sanofi-aventis funded \$35.6 million, \$38.3 million, and \$36.4 million, respectively, of our aflibercept development costs in 2008, 2007, and 2006, of which \$6.3 million, \$10.5 million, and \$6.8 million, respectively, were included in accounts receivable as of December 31, 2008, 2007, and 2006. In addition, the up-front payments of \$80.0 million in September 2003 and \$25.0 million in January 2006 from sanofi-aventis were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2008, 2007, and 2006, we recognized \$8.8 million, \$8.8 million, and \$11.4 million of revenue, respectively, related to these up-front payments.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of aflibercept development expenses will terminate and we will retain all rights to aflibercept.

Antibodies

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$75 million of research from the collaboration's inception through December 31, 2008 and will fund up to \$100 million per year in 2009 through 2012. The discovery agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate (called Shared Phase 3 Trial Costs) will be shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of

development expenses that were fully funded by sanofi-aventis (or half of \$27.8 million as of December 31, 2008) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the license agreement, we will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The first three therapeutic antibodies to enter clinical development under the collaboration are REGN88, that is being evaluated in rheumatoid arthritis, REGN421, that is being evaluated in oncology in patients with advanced malignancies, and REGN475, that is being evaluated in pain.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured.

In 2008 and 2007, sanofi-aventis funded \$72.2 million and \$3.0 million, respectively, of our expenses under the collaboration's discovery agreement and \$25.7 million and \$0.7 million, respectively, of our development costs, primarily for REGN88, under the license agreement. Of these amounts, \$25.5 million and \$3.7 million were included in accounts receivable as of December 31, 2008 and 2007, respectively. In addition, the \$85.0 million up-front payment received from sanofi-aventis in December 2007 was recorded to deferred revenue and is being recognized as contract research and development revenue over the period during which we expect to perform services. In 2008 and 2007, we recognized \$10.5 million and \$0.9 million of revenue, respectively related to this up-front payment.

In connection with the collaboration, in August 2008, we entered into a separate agreement with sanofi-aventis to use our proprietary *VelociGene*[®] technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. The agreement provides for minimum annual order quantities for the term of the agreement which extends through December 2012, for which we expect to receive payments totaling a minimum of \$21.5 million, of which \$0.6 million had been received as of December 31, 2008.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-aventis within thirty days of the date that sanofi-aventis elects to jointly develop such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party and, in the case of the discovery agreement, a termination right for sanofi-aventis under other limited defined circumstances. Prior to December 31, 2012, sanofi-aventis has the right to terminate the discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

In December 2007, we sold sanofi-aventis 12 million newly issued, unregistered shares of Common Stock at an aggregate cash price of \$312.0 million, or \$26.00 per share of Common Stock. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with us, which contains certain demand rights, "standstill provisions", and other restrictions, which are more fully described in Note 8 to our Financial Statements.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, VEGF Trap-Eye. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of \$75.0 million. In August 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD, and are eligible to receive up to \$90 million in additional development and regulatory milestones related to the VEGF Trap-Eye program. We are also eligible to receive up to an additional \$135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$63.0 million at December 31, 2008) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. Within the United States, we are responsible for any future commercialization of VEGF Trap-Eye and retain exclusive rights to any future profits from commercialization. In 2007, we initiated the VIEW 1 trial in wet AMD and, in 2008, Bayer HealthCare initiated the VIEW 2 trial in wet AMD. In addition, in late 2008, we initiated a Phase 2 study of VEGF Trap-Eye in patients with DME. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

The \$75.0 million up-front payment and \$20.0 million non-substantive milestone payment from Bayer HealthCare were recorded to deferred revenue. In 2008 and 2007, we recognized \$12.4 million and \$15.9 million, respectively, of revenue related to these deferred payments. We did not recognize revenue in connection with our collaboration with Bayer HealthCare in 2006.

Under the terms of the agreement, in 2009 and thereafter, all agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared equally. In 2008, the first \$70.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next \$30.0 million, which resulted in a net payment of \$11.3 million to Bayer HealthCare by us in 2008. In 2007, the first \$50.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next \$40.0 million, which resulted in a net reimbursement of \$9.4 million from Bayer HealthCare to us in 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007. At December 31, 2008 and 2007, accrued expenses included \$9.8 million and \$4.9 million, respectively, due to Bayer HealthCare. In addition, at December 31, 2007, accounts receivable included \$2.8 million due from Bayer HealthCare.

Bayer HealthCare has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to VEGF Trap-Eye.

License Agreements with AstraZeneca and Astellas

Under these non-exclusive license agreements, AstraZeneca and Astellas each made two \$20.0 million annual, non-refundable payments to us, one in 2007 and the other in 2008. AstraZeneca and Astellas are each required to make up to four additional annual payments of \$20.0 million, subject to each licensee's ability to terminate its license agreement with us after making two more payments or earlier if the technology does not meet minimum performance criteria.

National Institutes of Health Grant

Under our five-year grant from the NIH, we are entitled to receive a minimum of \$24.5 million over a five-year period, subject to compliance with the grant's terms and annual funding approvals, including \$1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2008 and 2007, we recognized \$4.9 million and \$5.5 million, respectively, of revenue related to the NIH Grant, of which \$1.3 million and \$1.0 million, respectively, was receivable at the end of 2008 and 2007. In 2009, we expect to receive funding of approximately \$5 million for reimbursement of Regeneron expenses related to the NIH Grant.

Convertible Debt

In 2001, we issued \$200.0 million aggregate principal amount of convertible senior subordinated notes, which bore interest at 5.5% per annum, payable semi-annually, and that matured in October 2008. During the second and third quarters of 2008, we repurchased \$82.5 million in principal amount of our notes for \$83.3 million. The remaining \$117.5 million of outstanding convertible notes were repaid in full upon their maturity in October 2008.

License Agreement with Cellectis

In July 2008, we and Cellectis S.A. entered into an Amended and Restated Non-Exclusive License Agreement. The amended license agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to the amended license agreement, in July 2008, we made a non-refundable \$12.5 million payment to Cellectis and agreed to pay Cellectis a low single-digit royalty based on revenue received by us from any future licenses or sales of our *VelociGene®* or *VelocImmune®* products and services. No royalties are payable with respect to our *VelocImmune* license agreements with AstraZeneca and Astellas or our November 2007 collaboration with sanofi-aventis. Moreover, no royalties are payable on any revenue from commercial sales of antibodies from our *VelocImmune* technology.

We are amortizing our \$12.5 million payment to Cellectis in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis. In 2008, we recognized \$2.7 million of expense related to this agreement.

In July 2008, we and Cellectis also entered into a Subscription Agreement pursuant to which we purchased 368,301 ordinary shares of Cellectis in November 2008 at a price of EUR 8.63 per share (which was equivalent to \$10.98 at the EUR exchange rate on the date of purchase).

Operating Lease - Tarrytown, New York Facilities

Under our main operating lease, as amended, we currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York. In December 2006, we entered into a new operating lease agreement (as amended in October 2007) to lease approximately 257,000 square feet of laboratory and office space at our current Tarrytown location, which included approximately 27,000 square feet that we currently occupy (our retained facilities) and approximately 230,000 square feet in new facilities that are currently under construction and expected to be completed in mid-2009. In September 2008, we amended the operating lease agreement to increase the amount of retained space we will lease from approximately 27,000 square feet to approximately 118,000 square feet, for an amended total under the new lease of approximately 348,000 square feet. The term of the new lease commenced effective June 2008 and will expire in June 2024. Under the new lease we also have various options and rights on additional space at the Tarrytown site, and will continue to lease our present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for our retained facilities only. The lease provides for monthly payments over the term of the lease related to our retained facilities, the costs of construction and tenant improvements for our new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, we issued a letter of credit in the amount of \$1.6 million to our landlord, which is collateralized by a \$1.6 million bank certificate of deposit.

Capital Expenditures

Our additions to property, plant, and equipment totaled \$34.9 million in 2008, \$19.6 million in 2007, and \$3.3 million in 2006. In 2009, we expect to incur approximately \$50 to \$60 million in capital expenditures (net of Tarrytown tenant improvement costs that will be reimbursed by our landlord in connection with our new operating lease), primarily in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and our new Tarrytown operating lease, as described above. We currently expect to incur approximately \$30 million in capital expenditures in 2010.

Funding Requirements

Our total expenses for research and development from inception through December 31, 2008 have been approximately \$1,630 million. We have entered into various agreements related to our activities to develop and commercialize product candidates and utilize our technology platforms, including collaboration agreements, such as those with sanofi-aventis and Bayer HealthCare, and agreements to use our *Velocigene®* technology platform. We incurred expenses associated with these agreements, which include an allocable portion of general and administrative costs, of \$230.6 million, \$108.2 million, and \$43.4 million in 2008, 2007, and 2006, respectively.

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 50-60% of our expenditures for 2009 will be directed toward the preclinical and clinical development of product candidates, including ARCALYST® (rilonacept), aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88, REGN421, and REGN475); approximately 25-30% of our expenditures for 2009 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2009 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

We currently anticipate that in 2009 the commercialization of ARCALYST for the treatment of CAPS will not materially enhance or otherwise materially impact our cash flows.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2008. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

	Payments Due by Period				
		Less than			Greater than
	Total	one year	1 to 3 years	3 to 5 years	5 years
			(In million		
Operating leases ⁽¹⁾	\$230.1	\$ 9.1	\$26.8	\$27.2	8167.0
Purchase obligations ⁽²⁾	126.3	65.7	59.3	1.3	
Fotal contractual obligations	\$356.4	<u>\$74.8</u>	<u>\$86.1</u>	\$28.5	<u> </u>

⁽¹⁾ Includes projected obligations based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities under construction in Tarrytown, New York, as described above. Excludes future contingent rental costs for utilities, real estate taxes, and operating expenses. In 2008, these costs were \$8.4 million.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare will share agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as described above. In addition, under our collaboration agreements with sanofi-aventis and Bayer HealthCare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by sanofi-aventis and Bayer HealthCare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for our aflibercept collaboration with sanofi-aventis, royalties on product sales in Japan) otherwise payable to us unless we agree to reimburse these expenses at a faster rate at our option. Given the uncertainties related to drug development (including the development of aflibercept and co-developed antibody candidates in collaboration with sanofi-aventis and VEGF Trap-Eye in collaboration with Bayer HealthCare) such

⁽²⁾ Purchase obligations primarily relate to (i) research and development commitments, including those related to clinical trials, (ii) capital expenditures for equipment acquisitions, and (iii) license payments. Our obligation to pay certain of these amounts may increase or be reduced based on certain future events. Open purchase orders for the acquisition of goods and services in the ordinary course of business are excluded from the table above.

as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer HealthCare will become profitable.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST® (rilonacept) for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates.

Other than letters of credit totaling \$1.7 million, including a \$1.6 million letter of credit issued to our landlord in connection with our operating lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of December 31, 2008, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In November 2007, the Emerging Issues Task Force issued Statement No. 07-1, *Accounting for Collaborative Arrangements* (EITF 07-1). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and will be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. We are required to adopt EITF 07-1 for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of EITF 07-1 will have a material impact on our financial statements.

In March 2008, the FASB issued SFAS 161, *Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement 133.* SFAS 161 enhances required disclosures regarding derivatives and hedging activities, including enhanced disclosures regarding how (a) an entity uses derivative instruments, (b) derivative

instruments and related hedged items are accounted for under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, and (c) derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years and interim periods beginning after November 15, 2008. We are required to adopt SFAS 161 for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of SFAS 161 will have a material impact on our financial statements.

In April 2008, the FASB issued FASB Staff Position (FSP) FAS 142-3, *Determination of the Useful Life of Intangible Assets*. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R, and other generally accepted accounting principles (GAAP). This FSP is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. We are required to adopt FSP FAS 142-3 for the fiscal year beginning January 1, 2009. Our management does not anticipate that the adoption of this FSP will have a material impact on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in U.S. government, corporate, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent unfavorable change in interest rates would result in approximately a \$1.9 million decrease in the fair value of our investment portfolio at both December 31, 2008 and 2007.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. In the second half of 2007, we recognized a \$5.9 million charge related to marketable securities from two issuers which we considered to be other than temporarily impaired in value. In 2008, an additional \$0.7 million impairment charge was recognized related to one of these securities and a \$1.8 million charge was recognized related to another marketable security which we considered to be other than temporarily impaired in value.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included on pages F-1 through F-34 of this report. The supplementary financial information required by this Item is included at pages F-34 of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that

it files or submits under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation our management has concluded that our internal control over financial reporting was effective as of December 31, 2008. The effectiveness of our internal control over financial reporting as of December 31, 2008 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

ITEM OD	B. OTHER	INICODM	$\Lambda TION$
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None.

PART III

ITEM 10. DIRECTORS. EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our officers, directors and employees. The full text of our code of business conduct and ethics can be found on the Company's website (http://www.regeneron.com) under the "Corporate Governance" heading on the "About Us" page.

ITEM 11. EXECUTIVE COMPENSATION

The information called for by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item will be included in our definitive proxy statement with respect to our 2009 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and therefore have been omitted.

3. Exhibits

Exhibit		
Number		Description
3.1 3.2	(p) (a)	Restated Certificate of Incorporation filed February 11, 2008 with the New York Secretary of State - By-Laws of the Company, currently in effect (amended through November 9, 2007).
10.1 + 10.2 +	(b) (q)	- 1990 Amended and Restated Long. Term Incentive Plan Amended and Restated 2000 Long-Term Incentive Plan.
10.2.1 + 10.2.2 +	(c)	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors and named executive officers. - Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.2.3 +	(d)	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the Registrant's executive officers - Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Company and Leonard S. Schleifer, M.D., Ph.D.
10.4* + 10.5 +		 Employment Agreement dated as of December 31 1998, between the Company and P Roy Vagelos M D Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008.
∄0.6* 10.7*	(f) (g)	 II. 1 License Agreement dated June 26, 2002, by and among the Company Immunex Corporation, and Amgen Inc. Collaboration, License and Option Agreement, dated as of March 28, 2003, by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and the Company.
10.8* 10.8.1*	(h) (e)	 Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals. Amendment No. 1 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron
10.8.2 10.8.3*	(j)	Pharmaceuticals, Inc., effective as of December 31, 2004. Amendment No. 2 to Collaboration Agreement by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals Inc., effective as of January 7, 2005. - Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and Regeneron Pharmaceuticals, Inc., effective as of December 21, 2005.
10.8.4* 10.9	(j) (h)	Amendment No. 4 to Collaboration Agreement, by and between sanish avents U.S. LLC (successor in interest to Avents Pharmaceuticals. Inc.) and Regeneron Pharmaceuticals. Inc. effective as of January 31, 2006. - Stock Purchase Agreement, dates as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and Regeneron
10.10* 10.11*	(k)	Pharmaceuticals, Inc. License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regement Pharmaceuticals, inc. Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007 by and between
10.12	(n)	- Non-Exclusive Electrice and Material Transfer Agreement, dated as of February 3, 2007 by and between AstraZeneca UK Limited and Regeneron Pharmaceuticals, Inc. - Lease, dated as of December 21, 2006, by and between BMR Landmark at Eastview LLC and Regeneron Pharmaceuticals inc.
10.12.1*	(o)	- First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., effective as of October 24, 2007.
10.12.2 10.13*	(s) (n)	Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc. effective as of September 30, 2008. - Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
10.14* 10.15*	(p)	Discovery and Preclinical Development Agreement, dated as of November 28, 2007, by and between Avenus Pharmaceuticals Inc. - License and Collaboration Agreement, dated as of November 28, 2007, by and among Aventis Pharmaceuticals Inc., sanofi-aventis Amerique Du Nord and Regeneron Pharmaceuticals, Inc.

Exhibit	
Number	Description
10.16 (p)	Stock Purchase Agreement, dated as of November 28, 2007, by and among sanoti-aventis Amerique Du Nord.
	sanofi-aventis USTLC and Regeneren Pharmaceuticals. Inc
10.17 (p)	- Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC,
	Aventis Pharmaceuticals Inc., sanofi-aventis Amerique du Nord, and Regeneron Pharmaceuticals, Inc.
10.18* (r)	Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Cellectis.
	S.A. and Regeneron Pharmaceuticals, Inc.
10.19 (r)	- Subscription Agreement, dated as of July 1, 2008 by and between Cellectis, S.A. and Regeneron Pharmaceuticals,
	Inc.
12.1	 Statement to computation of ratio of earnings to combined fixed charges of Regeneron Pharmaceuticals. Inc.
23.1	- Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.

Description:

31.1

31.2

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(a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.

Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.

- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.

- (b) Incorporated by reference from the Company's registration statement on Form S-1 (file number 33-39043).
- (c) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.
- (d) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.
- (e) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc. for the fiscal year ended December 31, 2004, filed March 11, 2005.
- (f) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2002, filed August 13, 2002.
- (g) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended March 31, 2003, filed May 15, 2003.
- (h) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2003, filed November 12, 2003.
- (i) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.
- (j) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the fiscal year ended December 31, 2005, filed February 28, 2006.
- (k) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.
- (l) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2006, filed March 12, 2007.
- (m) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
- (n) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended March 31, 2007, filed May 4, 2007.

- (o) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc for the quarter ended September 30, 2007, filed November 7, 2007.
- (p) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc for the year ended December 31, 2007, filed February 27, 2008.
- (q) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc. filed June 17, 2008.
- (r) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended June 30, 2008, filed August 1, 2008.
- (s) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc. for the quarter ended September 30, 2008, filed November 5, 2008.
- * Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.
- + Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

Dated: New York, New York February 26, 2009

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Murray A. Goldberg, Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, and each of them, his true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title
/s/ Leonard S. Schleifer	President, Chief Executive Officer,
Leonard S. Schleifer, M.D., Ph.D.	and Director (Principal Executive Officer)
/s/ Murray A. Goldberg	Senior Vice President, Finance &
Murray A. Goldberg	Administration, Chief Financial Officer, Treasurer, and Assistant
	Secretary (Principal Financial Officer)
/s/ Douglas S. McCorkle	Vice President, Controller, and
Douglas S. McCorkle	
/s/ George D. Yancopoulos	Executive Vice President, Chief Scientific
George D. Yancopoulos, M.D., Ph.D.	Officer, President, Regeneron Research Laboratories, and Director
/s/ P. Roy Vagelos	Chairman of the Board
P. Roy Vagelos, M.D.	
/s/ Charles A. Baker	Director
Charles A. Baker	
/s/ Michael S. Brown	Director
Michael S. Brown, M.D.	
/s/ Alfred G. Gilman	Director
Alfred G. Gilman, M.D., Ph.D.	
/s/ Joseph L. Goldstein	Director
Joseph L. Goldstein, M.D.	
/s/ Eric M. Shooter	Director
Eric M. Shooter, Ph.D.	
/s/ George L. Sing	Director
George L. Sing	

REGENERON PHARMACEUTICALS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Regeneron Pharmaceuticals, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. at December 31, 2008 and December 31, 2007, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting and eva

As discussed in note 2 to the financial statements, effective January 1, 2006, the Company changed its method of accounting for share-based payment, to conform with FASB Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-based Payment."

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PricewaterhouseCoopers LLP

New York, New York February 26, 2009

REGENERON PHARMACEUTICALS, INC. BALANCE SHEETS

December 31, 2008 and 2007

	2008	2007
	(In tho	usands,
ACOPTE	except sl	nare data)
ASSETS		
Current assets Cash and cash equivalents	\$ 247.796	\$ 498,925
Marketable securities	226,954	267.532
Accounts receivable from the sanofi-aventis Group	33,302	14,244
Accounts receivable - other	1.910	4.076
Prepaid expenses and other current assets	11,480	13,052
Total current assets	521.442	797,829
Restricted cash	1,650	1,600
Marketable securities	51,061	78.222
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	87,853	58,304
Other assets	8.032	30,304
Total assets	\$ 670,038	\$ 936,258
LIABILITIES and STOCKHOLDERS' EQUITY	· · · · · · · · · · · · · · · · · · ·	<u> </u>
Current liabilities		
Accounts payable and accrued expenses	\$ 36,168	\$ 39,232
Deferred revenue from sanofi-aventis, current portion	21,390	18,855
Disferred revenue - other current portion	26.114	25,577
Notes payable		200,000
Total current liabilities	83,672	283,664
Deferred revenue from sanoti-aventis	105,586	126.431
Deferred revenue - other	56,835	65,896
Other long term liabilities	5.093	00,000
Total liabilities	251,186	475,991
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.01 par value, 30,000,000 shares authorized; issued		
and outstanding—none		
Class A Stock, convertible, \$.001 par value: 40,000,000 shares authorized; shares issued and outstanding - 2,248,698 in 2008 and 2,260,266 in 2007	2	2
Common Stock \$ 001 par value: 160 000 000 shares authorized: shares issued	L	L
and outstanding 77 642 203 in 2008 and 76,592,218 in 2007	78	77
Additional paid-in capital	1,294,813	1,253,235
Accumulated deficit	(875,927)	(793,217)
Accumulated other comprehensive income (loss)	(114)	170
Total stockholders, equity	418,852	460,267
Total liabilities and stockholders' equity	\$ 670,038	\$ 936,258

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2008, 2007, and 2006

	2008	2007	2006
Revenues		nds, except per	
Contract research and development Other contract research and development	\$153,972 38,23 6	\$ 51,687 44,916	\$ 47,763 3,373
Contract manufacturing Technology licensing	40 DOD	28,421	12,311
Net product sales	6,249 238.457	125,024	63,447
Expenses			
Research and development Scilling, general, and administrative	278,016 49.348	201,613 37.86 5	137,064 25,892
Contract manufacturing Cost of goods sold	923		8,146
	328,287	239,478	<u>171,102</u>
Loss from operations	(89.830)	(114.454)	1107.655)
Other income (expense) Investment income	18,161	20,897	16,548
Interest expense Loss on early extinguishment of debt	(7.752) (938)	(12.043)	(12.043)
	9.171	8.854	4.505
Net loss before income tax expense and cumulative effect of a change in accounting principle	(80.359)	(105,600)	(103,150)
Income tax expense	2351		
Net loss before cumulative effect of a change in accounting principle	(82.710)	(105.600)	(103 150)
Cumularive effect of adopting Statement of Financial Accounting Standards No. 123R ("SEAS 123R")			813
Net loss	<u>8 (82 710)</u>	\$ (105,600)	<u>\$ (102,337)</u>
Net loss per share, basic and diluted: Net loss before cumulative effect of a change in accounting			
principle Cumulative effect of adopting SFAS 123R	\$ (1.05)	\$ (1.59)	\$ (1.78) 0.01
Net loss	<u>5 (1.05)</u>	<u>\$ (1.59)</u>	<u> </u>
Weighted average shares outstanding, basic and diluted	78.827	66,334	57,970

 ${\it The\ accompanying\ notes\ are\ an\ integral\ part\ of\ the\ financial\ statements}.$

REGENERON PHARMACEUTICALS, INC. STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2008, 2007, and 2006

					A ccumulated		
		Additional			Other	Total	
Class A Stock	Common Stock	Paid-in	Unearned	Accumulated	Comprehensive	Stockholders'	Comprehensive
Shares Amount	Shares Amount	Capital	Compensation	Deficit	Income (Loss)	Equity	Loss
			(In tho	usands)			
Balance December 31, 2005 2,347 \$2	54.092 \$54	s 700.011	\$(315)	\$ (\$A\$, 290)	\$(476)	\$ 114,002	
Issuance of Common Stock in a public offering at \$23.43 per share Cost associated with issuance	7:00 8	Ers.628				175.028	
of equity							
securities		(412)				(412)	
Issuance of Common Stock in connection soft exercise of stock options, net of shares tendered Issuance of Common	1243 1	16.391				10.392	
Stock in							
connection							
with							
Company							
401(k)							
Savings Plan							
contribution Conversion of Class A Spick to Common Stock (77) Forfeiture of	121 77	1.884				1,884	
restricted							
Common							
Stock under							
Long-Term							
Incentive							
Plan Stock based	(2)			APOTEX	V. REGENERON	IPR2022-015	24

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Triple	compensation expense Adjustment		18.641				18,641	
ureamend components								
Sequence of the property of th								
Margine of Mar								
STANE								
\$\$\$ 1980								
September			(315)	315				
100	Committee effect of adopting SFAS 123R		(813)				(813)	
Common C								
Seminoral de la company de la	Change in				(102,337)		(102,337)	\$(102,337 <u>)</u>
Securities	unrealized							
11	marketable					239	239	239
Security								
Common Stock 1		2 63 131 63	964 467		(687-617)	(231)	216.624	<u>\$(162.098)</u>
Section Sect	Common							
### Company	connection							
glana in distance of State in Common Stock to Sance in Common Stock in Common S	exercise							
SSI								
Common Stock to	of shares	886 I	7618				7619	
Stock to sanofi- aventis 12.00 12 311,988 312,000 Cos. associated with associated securities to sanofi- aventis 23.00 20.00 2								
sanofi- aventis 12,00 12 311,988 312,000 Close RECOLLEGE RECOLL								
aventis 12,000 12 311,988 312,000 Cose associated with assumes of equity securities ta Samit avends (219)								
Executive securities to securi		12 000 12	311 988				312,000	
of equity securities to sample avenus (219) (219) Issuance of Common Stock in connection with	Cost	12,330 12	311,000				312,333	
Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution 65 1,367	securines to sample							
Common Stock in connection with Company 401(k) Savings Plan contribution 65 1,367			(219)				(210)	
Stock in connection with Company 401(k) Savings Plan contribution 65 1,367								
connection with Company 401(k) Savings Plan contribution 65 1,367 1,367								
with Company 401(k) Savings Plan 65 1,367 1,367								
401(k) Savings Plan contribution 65 1,367 1,367								
Savings Plan 5 1,367 1,367	Company							
contribution 65 1,367 1,367								
	contribution Issuance of	65	1,367				1,367	

restricted Common Stock under Long: Ferm Internive Flan 500 1 (f) Conversion	
of Class A	
Stock to	
Common Stock (10) 10	
Stock (10) 10 Stock based compensation expense ZR-075 Net loss,	
2007 (105,600) \$(105,600) Change in ne; unrealized gain floss) on marketable securities 401 481 461	
Balance December 31 2007 2,200 2 76,592 17 1,253,235 (793,217) 170 460,267 <u>\$(105,19</u> 6	
Essance of Common Stack iff Common Stack iff Common with	
Issuance of	
Common	
Stock in	
connection with	
Company	
401 (k)	
Savings Plan	
contribution 59 1,107 1,107	
Conversion of Class A Stock to Common Stock	
Stock-based	
compensation	
expense 32,523 Net loss 2008 82,710 82,710 82,710 1,82,710	
Change in	

APOTEX V. REGENERON IPR2022-01524 REGENERON EXHIBIT 2008 PAGE 4422

gain (loss) on			
marketable			
securities	(284)	(284)	(284)
_			
Balance December			
December			
\$1.2008 2.249 \$2 77.642 \$78 \$1.294.813 \$1.875.920	\$(114)	\$ 418.852	5 (82,994)

unrealized

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2008, 2007, and 2006

	2008	2007 (In thousands	2006
Cash flows from operating activities		(in thousands	7
Net loss	\$ (82,710)	\$(105,600)	\$(102,337)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities Depreciation and amortization	11,287	11,487	14,592
Non-cash compensation expense	32,523	28.075	18,673
Loss on early extinguishment of debt	938		
Net realized loss on marketable securities	1,310	5,943	(010)
Cumulative effect of a change in accounting principle Changes in assets and liabilities			(813)
(Increase) decrease in accounts receivable	(16,892)	(10,827)	29,028
(Increase) decrease in prepaid expenses and other assets	(6,560)	(9.649)	155
Decrease in inventory (Decrease) increase in deferred revenue	(26,834)	89,764	3,594 60.833
(Decrease) increase in accounts payable, accrued expenses, and other	(£0,007)	93.704	04,635
liabilities	(2,148)	18,179	(652)
Total adjustments	(6,376)	132,972	125,412
Net cash (used in) provided by operating activities	(89,086)	27,372	23,075
Cash flows from investing activities			
Purchases of marketable securities	(581,139)	(594,446)	(456,893)
Sales or maturities of marketable securities	(24.057)	(10.446)	306 199
Capital expenditures Increase in restricted cash	(34,857) (50)	(18,446)	(2,811) (1, 600)
Net cash provided by (used in) investing activities	30,815	(85,723)	(155,105)
Cash flows from financing activities Repurchases or repayment of notes payable	(200,807)		
Net proceeds from the issuance of Common Stock	7.949	319,400	185,008
Other			390
Net cash (used in) provided by financing activities	(192,858)	319,400	<u> 185 398</u>
Net (decrease) increase in cash and cash equivalents	(251,129)	261 049	53.368
Cash and cash equivolents at beginning of period	498,925	237.876	184,508
Cash and cash equivalents at end of period	<u>\$ 247.796</u>	<u>§ 498.925</u>	<u>\$ 237,876</u>
Supplemental disclosure of cash flow information Cash paid for interest Cash paid for income taxes	\$ 9,348 \$ 3,079	\$ 11,000	\$ 11,000

 ${\it The\ accompanying\ notes\ are\ an\ integral\ part\ of\ the\ financial\ statements}.$

REGENERON PHARMACEUTICALS, INC. NOTES TO FINANCIAL STATEMENTS For the years ended December 31, 2008, 2007, and 2006

(Unless otherwise noted, dollars in thousands, except per share data)

1. Organization and Business

Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") was incorporated in January 1988 in the State of New York. The Company is engaged in the research, development, and commercialization of therapeutics to treat human disorders and conditions. In 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for the Company's first commercial drug product, ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company's facilities are primarily located in New York. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, obtaining regulatory approvals, commercializing products, and obtaining and enforcing patents.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

For purposes of the statement of cash flows and the balance sheet, the Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

Marketable Securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company generally invests its excess cash in obligations of the U.S. government and its agencies, investment grade debt securities issued by corporations, governments, and financial institutions, bank deposits, asset-backed securities, commercial paper, and money market funds that invest in these instruments. The Company considers its marketable securities to be "available-for-sale," as defined by Statement of Financial Accounting Standards No. ("SFAS") 115, Accounting for Certain Investments in Debt and Equity Securities. These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in the Company's investment portfolio is deemed to be other-than-temporary, the Company writes down the security to its current fair value and recognizes a loss that is charged against income. As described under "Use of Estimates" below, on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary.

Capitalization of Inventory Costs

The Company does not capitalize inventory costs associated with commercial supplies of drug product until it has received marketing approval from the FDA. Prior to receipt of FDA approval, costs for manufacturing supplies of drug product are recognized as research and development expenses in the period that the costs were incurred. Therefore, these pre-approval manufacturing costs are not included in cost of goods sold when revenue is recognized from the sale of those supplies of drug product.

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. In 2008, subsequent to receipt of such marketing approval, ARCALYST shipments to the Company's customers consisted of supplies of inventory manufactured and expensed prior to FDA approval. At December 31, 2008, the Company had no inventoried costs related to ARCALYST.

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	7-30 years
Laboratory and other equipment	3-5 years
Furniture and fixtures	ā years

Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the lease term, without assuming renewal features, if any, are exercised. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

Accounting for the Impairment of Long-Lived Assets

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount in accordance with SFAS 144, Accounting for the Impairment or Disposal of Long-Lived Assets. For all periods presented, no impairment losses were recorded.

Patents

As a result of the Company's research and development efforts, the Company has obtained, applied for, or is applying for, a number of patents to protect proprietary technology and inventions. All costs associated with patents are expensed as incurred.

Leases

The Company accounts for its lease agreements pursuant to SFAS 13, *Accounting for Leases*. On certain of its lease agreements, the Company may receive rent holidays and other incentives. The Company recognizes lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays that defer the commencement date of required payments. In addition, lease incentives that the Company receives are treated as a reduction of rent expense over the term of the related agreements.

Revenue Recognition

a. Contract Research and Development Revenue

The Company recognizes contract research and development revenue and research progress payments in accordance with Staff Accounting Bulletin No. ("SAB") 104, Revenue Recognition and Emerging Issues Task Force No. ("EITF") 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. The Company earns contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation

associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, such as in the Company's VEGF Trap-Eye collaboration with Bayer HealthCare LLC, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities, such as in the Company's aflibercept and antibody collaborations with the sanofi-aventis Group. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as contract research and development revenue proportionately as the Company recognizes its expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, in periods when the Company's collaborator incurs development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expenses, the portion of the collaborator's development expenses that the Company is obligated to reimburse. In addition, the Company records revenue in connection with a government research grant using a proportional performance model as it incurs expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and entire in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, estimated performance periods may change if development programs encounter delays or the Company and its collaborators decide to expand or contract the clinical plans for a drug candidate in various disease indications. For example, for the year ended December 31, 2007, the Company recognized \$2.6 million less in contract research and development revenue, compared to amounts recognized in 2006, in connection with non-refundable up-front payments previously received from sanofi-aventis pursuant to the companies' aflibercept collaboration, due to an extension of the Company's estimated performance period. In addition, during the fourth quarter of 2008, the Company extended its estimated performance period in connection with the up-front and milestone payments previously received from Bayer HealthCare pursuant to the companies' VEGF Trap-Eye collaboration and shortened its estimated performance period in connection with up-front payments from sanofi-aventis pursuant to the companies' aflibercept collaboration. The net effect of these changes in the Company's estimates resulted in the recognized in connection with these deferred payments in each of the prior three quarters of 2008, and a collaborator terminates an agreement in accordance with the terms of the agreement, the Company would recognize any unamortized remainder of an up-front or previously deferred payment at the

b. Contract Manufacturing

The Company manufactured product and performed services for a third party under a contract manufacturing agreement which expired in October 2006. Contract manufacturing revenue was recognized as product was shipped and as services were performed.

c. VelocImmune® Technology Licensing

The Company enters into non-exclusive license agreements with third parties that allow the third party to utilize the Company's *VelocImmune* technology in its internal research programs. The terms of these agreements include annual, non-refundable payments and entitle the Company to receive royalties on any future sales of products discovered by the third party using the Company's *VelocImmune* technology. Annual, non-refundable payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective annual license periods.

d. Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST® (rilonacept) for the treatment of CAPS. The Company recognizes revenue from product sales in accordance with SAB 104. Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and the Company has no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distribution fees, and other sales-related costs. The Company accounts for these reductions in accordance with EITF 01-9, Accounting for Considerations Given by a Vendor to a Customer (Including a Reseller of the Vendor's Products), and SFAS 48, Revenue Recognition When Right of Return Exists, as applicable. In accordance with EITF 01-9 and SFAS 48, since the Company currently has limited historical return and rebate experience for ARCALYST, product sales revenues are deferred until (i) the right of return no longer exists or the Company can reasonably estimate returns and (ii) rebates have been processed or the Company can reasonably estimate rebates. The Company reviews its estimates of rebates payable each period and records any necessary adjustments in the current period's net product sales.

Investment Income

Interest income, which is included in investment income, is recognized as earned.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements, the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by contract research organizations ("CROs"). CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these startup costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be

significantly wider, as many of the Company's contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates. The Company's estimates and assumptions for clinical expense recognition could differ significantly from its actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

Stock-based Employee Compensation

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123, *Accounting for Stock-Based Compensation*. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate, at the time of grant, the number of awards that are expected to be forfeited and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Effective January 1, 2005 and prior to the Company's adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that were not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by \$0.8 million and is included in the Company's operating results in 2006 as a cumulative-effect adjustment of a change in accounting principle.

Income Taxes

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain.

Comprehensive Income (Loss)

The Company presents comprehensive income (loss) in accordance with SFAS 130, *Reporting Comprehensive Income*. Comprehensive income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities. The net effect of income taxes on comprehensive income (loss) is immaterial. Comprehensive losses for the years ended December 31, 2008, 2007, and 2006 have been included in the Statements of Stockholders' Equity.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities (see Note 3), and receivables from sanofi-aventis and Bayer HealthCare (see Note 4).

Per Share Data

Net income (loss) per share, basic and diluted, is computed on the basis of the net income (loss) for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock outstanding, and of common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the "treasury stock method" when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's formerly outstanding convertible senior subordinated notes, which are included under the "if-converted method" when dilutive. The computation of diluted net loss per share for the years ended December 31, 2008, 2007, and 2006 does not include common stock equivalents, since such inclusion would be antidilutive.

Risks and Uncertainties

Developing and commercializing new medicines entails significant risk and expense. Since its inception, the Company has not generated any significant sales or profits from the commercialization of ARCALYST® (rilonacept) or any of the Company's other product candidates. Before revenues from the commercialization of the Company's current or future product candidates can be realized, the Company (or its collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render the Company's products and technologies uncompetitive or obsolete. The Company may be subject to legal claims by third parties seeking to enforce patents to limit or prohibit the Company from marketing or selling its products. The Company is also dependent upon the services of its employees, consultants, collaborators, and certain third-party suppliers, including single-source unaffiliated third-party suppliers of certain raw materials and equipment. Regeneron, as licensee, licenses certain technologies that are important to the Company's business which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate the Company's licenses.

The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) up-front, license, milestone, and reimbursement payments from the Company's collaborators and other entities related to the Company's development activities and technology platforms, (ii) payments for past contract manufacturing activities, (iii) ARCALYST product sales, and (iv) investment income. Contract research and development revenue in 2008 was primarily earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 10 for the terms of these agreements). These collaboration agreements contain early termination provisions that are exercisable by sanofi-aventis or Bayer HealthCare, as applicable.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Estimates which could have a significant impact on the Company's financial statements include:

• Periods over which payments, including non-refundable up-front, license, and milestone payments, are recognized as revenue in connection with collaboration and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms.

- Product rebates and returns in connection with the recognition of revenue from product sales.
- Periods over which certain clinical trial costs, including costs for clinical activities performed by contract research organizations, are recognized as research and development expenses.
- The fair value of stock options on their date of grant using the Black-Scholes option-pricing model, based on assumptions with respect to (a) expected volatility of the Company's Common Stock price, (b) the periods of time for which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (c) expected dividend yield on the Company's Common Stock, and (d) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. In addition, in connection with the recognition of stock-based employee compensation expense, the Company is required to estimate, at the time of grant, the number of stock option awards that are expected to be forfeited.
- The Company's determination of whether marketable securities are other than temporarily impaired. The Company conducts a quarterly review of its portfolio of marketable securities, using both quantitative and qualitative factors, to determine, for securities whose current fair value is less than their cost, whether the decline in fair value below cost is other-than-temporary. In making this determination, the Company considers factors such as the length of time and the extent to which fair value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of the Company's ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.
- Useful lives of property, plant, and equipment.
- The extent to which deferred tax assets and liabilities are offset by a valuation allowance.

Future Impact of Recently Issued Accounting Standards

In November 2007, the Emerging Issues Task Force issued Statement No. 07-1, Accounting for Collaborative Arrangements ("EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008, and will be applied retrospectively as a change in accounting principle for collaborative arrangements existing at the effective date. The Company is required to adopt EITF 07-1 for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of EITF 07-1 will have a material impact on the Company's financial statements.

In March 2008, the Financial Accounting Standards Board ("FASB") issued SFAS 161, *Disclosures about Derivative Instruments and Hedging Activities – an Amendment of FASB Statement 133*. SFAS 161 enhances required disclosures regarding derivatives and hedging activities, including enhanced disclosures regarding how (a) an entity uses derivative instruments, (b) derivative instruments and related hedged items are accounted for under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, and (c) derivative instruments and related hedged items affect an entity's financial position, financial performance, and cash flows. SFAS 161 is effective for fiscal years and interim periods beginning after November 15, 2008. The Company is required to adopt SFAS 161 for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of SFAS 161 will have a material impact on the Company's financial statements.

In April 2008, the FASB issued FASB Staff Position ("FSP") FAS 142-3, *Determination of the Useful Life of Intangible Assets*. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS 142, *Goodwill and Other Intangible Assets*. The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset

under SFAS 141R under this and other generally accepted accounting principles ("GAAP"). This FSP is effective for fiscal years beginning after December 15, 2008. Early adoption is prohibited. The Company is required to adopt FSP FAS 142-3 for the fiscal year beginning January 1, 2009. Management does not anticipate that the adoption of this FSP will have a material impact on the Company's financial statements.

3. Marketable Securities

Marketable securities at December 31, 2008 and 2007 consisted of debt securities, as detailed below, and, in 2008, equity securities whose fair value was \$3.7 million and cost was \$4.1 million. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized holding gains and losses on those securities at December 31, 2008 and 2007:

	Amortized	Fair	Unr	ing	
At December 31, 2008	Cost Basis	Value	Gains	(Losses)	Net
Maturities within one year					
U.S. government obligations	\$ 170,993	\$172,253	\$1,260		\$1,260
Corporate bonds	26,893	26,661	25	\$ (257)	(232)
Asset-backed securities	16,939	16,248		(691)	(691)
U.S. government guaranteed collateralized mortgage obligations	11.742	11.792	50		50
	226,567	226,954	1,335	(948)	387

Maturities between one and three years	00.050	00.011	00	(104)	(40)
U.S. government guaranteed corporate bonds	29,853	29,811	82 77	(124) (109)	(42)
Corporate bonds Asset-backed securities	10.446 1.821	10.414	11		(3 2)
	1,821 5.29 6	1,556 5,569	273	(265)	(265)
U.S. government guaranteed collateralized mortgage obligations	47,416	47,350	432	(400)	(CC)
				(498)	(66)
	\$ 273,983	3274,3174	<u>\$1,767</u>	\$ (1.446)	<u>\$ 321</u>
At December 31, 2007					
Maturities within one year	\$ 50.386	\$ 50.475	\$ 89		\$ 89
U.S. government obligations Corresponde and municipal bonds	ა ას,აის 69.213	\$ 50,475 69.263		\$ (24)	\$ 89
Asset-backed securities	32.671	32,388	74 42	(325)	(283)
U.S. government guaranteed collateralized mortgage obligations	41.268	41,318	57	(323)	(200)
Commercial paper	64.846	64,870	25	(1)	24
Certificates of deposit	9.220	9,218	20	(2)	(2)
	267,604	267,532	287	(359)	(72)
Maturities between one and two years					
Corporate and municipal bonds	49,724	49,947	289	(66)	223
Asset-backed securities	12,949	12,838	34	(145)	(111)
U.S. government guaranteed collateralized mortgage obligations	7,346	7,485	139	•••••	139
Commercial paper	7.952	7,952			
	77,971	78,222	462	(211)	251
	\$ 345,575	\$345,754	\$ 749	\$ (570)	\$ 179
		<u> </u>	<u></u>		::: <u></u> ::

REGENERON PHARMACEUTICALS, INC. NOTES TO FINANCIAL STATEMENTS (Continued) For the years ended December 31, 2008, 2007, and 2006

(Unless otherwise noted, dollars in thousands, except per share data)

At December 31, 2008, marketable securities included an additional unrealized holding loss of \$0.4 million related to one equity security in the Company's marketable securities portfolio. At December 31, 2007, cash equivalents included an unrealized holding loss of \$9 thousand.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at December 31, 2008 and 2007. The debt securities listed at December 31, 2008 mature at various dates through December 2011.

	Less than 12 Months		12 Months o	r Greater	Total		
		Unrealized		Unrealized		Unrealized	
At December 31, 2008	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss	
Corporate bonds	\$15,559	5(287)	\$ 2,933	\$ (79)	\$18,492	\$ (366)	
Government guaranteed							
corporate bonds	11,300	(124)			11,300	(124)	
Asset-backed securities	8,700	(87)	9,104	(869)	17,804	(956)	
Equity securities	3,608	(436)			3,608	(436)	
	\$39,167	\$(934)	\$12,037	\$(948)	<u>\$51,204</u>	\$(1,882)	
At December 31, 2007							
Corporate and municipal bonds	\$36,979	\$ (89)	\$ 3,056	\$ (1)	\$40,035	\$ (90)	
Asset backed securities	18,674	(360)	5,566	(109)	24,240	(469)	
U.S. government guaranteed							
collateralized mortgage							
obligation			6,824	(7)	6.824	(7)	
Commercial paper	14,950	(2)			14,950	(2)	
Certificates of deposit	9.218	(2)			9.218	(2)	
	\$79,821	\$(453)	\$15,446	\$(117)	\$95,267	\$ (570)	

Realized gains and losses are included as a component of investment income. For the year ended December 31, 2008, realized gains on sales of marketable securities totaled \$1.2 million and realized losses on sales of marketable securities were not significant. For the years ended December 31, 2007 and 2006, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

In September 2006, the FASB issued SFAS 157, Fair Value Measurements. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with accounting principles generally accepted in the United States, and expands disclosures about fair value measurements. The Company adopted the provisions of SFAS 157 for financial instruments as of January 1, 2008. Although the adoption of SFAS 157 did not materially impact the Company's financial condition, results of operations, or cash flows, the Company is now required to provide additional disclosures as part of its financial statements. In addition, in October 2008, the FASB issued FSP 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active, which clarifies the application of SFAS 157 in a market that is not active. FSP 157-3 also reaffirms the notion of fair value as an exit price as of the measurement date. FSP 157-3 was effective upon issuance for financial statements that had not yet been issued and adopted by the Company for the year ended December 31, 2008.

SFAS 157 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers are Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The Company's assets that are measured at fair value on a recurring basis, and that are subject to the disclosure requirements of SFAS 157 at December 31, 2008, were as follows:

		Fair Value Measurements at Reporting Date Using		
		Quoted Prices in		Significant
	Fair Value at	Active Markets for	Significant Other	Unobservable
	December 31,	Identical Assets	Observable Inputs	Inputs
Description	2008	(Level 1)	(Level 2)	(Level 3)
Available-for-sale marketable securities	\$278,015	\$3,608	\$274,307	\$100

Marketable securities included in Level 2 above were valued using a market approach utilizing prices and other relevant information generated by market transactions involving identical or comparable assets. During the year ended December 31, 2008, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the security's principal value. As a result, the Company recognized a \$1.8 million charge related to this Level 2 marketable security, which the Company considered to be other than temporarily impaired.

Marketable securities included in Level 3 above were valued using information provided by the Company's investment advisors, including quoted bid prices which take into consideration the securities' current lack of liquidity. During the year ended December 31, 2007, deterioration in the credit quality of marketable securities from two issuers subjected the Company to the risk of not being able to recover the full principal value of these securities. As a result, the Company recognized a \$5.9 million charge related to these marketable securities, which the Company considered to be other than temporarily impaired. During the year ended December 31, 2008, the Company recognized an additional \$0.7 million other-than-temporary impairment charge related to one of these marketable securities.

Changes in marketable securities included in Level 3 above during the twelve month period ended December 31, 2008 were as follows:

	Level 3
	Marketable
	Securities
Balance: January 1, 2008	\$7,950
Settlements	(8,194)
Realized gain	1,044
Impairments	(700)
Balance, December 31, 2008	\$ 100

There were no unrealized gains or losses related to the Company's Level 3 marketable securities for the year ended December 31, 2008. In addition, there were no purchases of Level 3 marketable securities and no transfers of marketable securities between the Level 2 and Level 3 classifications during the period.

As described in Note 2 above under "Use of Estimates", on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. As a result of these quarterly reviews, in 2008 and 2007, the Company recorded charges for other-than-temporary impairment of its marketable securities totaling \$2.5 million and \$5.9 million, respectively, as described above, which are included as a component of investment income. However, the current economic environment, the deterioration in the credit quality of some of the issuers of securities that the Company holds, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in the Company's investment portfolio and that such declines could result in additional charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

4. Accounts Receivable

Accounts receivable as of December 31, 2008 and 2007 consist of the following:

2008	2007
Receivable from sanofi-aventis (see Note 10) \$33.30	
Receivable from Bayer HealthCare (see Note 10)	2,797
Other <u>19</u>	
\$35.2	2 \$18.320

5. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Land	2,117	\$ 2,117
Building and improvements	74,343	66,208
Leasehold Improvements	2,720	13,982
Construction-in-progress	24,520	4,677
Laboratory and other equipment	75,935	61,717
Furniture, computer and office equipment, and other	7,501	6,080
	187,136	154.781
Less, accumulated depreciation and amortization	(99,283)	(96,477)
	87,853	\$ 58,304

Construction-in-progress at December 31, 2008 included \$13.4 million of tenant improvement and equipment costs in connection with the Company's new leased facilities in Tarrytown, New York that are currently under construction. See Note 9a.

Depreciation and amortization expense on property, plant, and equipment amounted to \$10.6 million, \$10.4 million, and \$14.3 million for the years ended December 31, 2008, 2007, and 2006, respectively. Included in these amounts was \$0.7 million of depreciation and amortization expense related to contract manufacturing that was capitalized into inventory for the year ended December 31, 2006.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Accounts payable	5 6,268	5 8.128
Payable due to Bayer HealthCare (see Note 10)	9,799	4,892
Accrued payroll and related costs	5,948	14,514
Accrued clinical trial expense	4,273	5,609
Accrued expenses, other	9,880	3,797
Interest payable on convertible notes		2,292
	\$36,168	\$39,232

7. Deferred Revenue

Deferred revenue as of December 31, 2008 and 2007 consists of the following:

	2008	2007
Current partion		
Received from sanofi-aventis (see Note 10)	\$ 21,390	\$ 18,855
Received from Bayer HealthCare (see Note 10)	9,884	13 179
Received for technology license agreements (see Note 11)	11,579	11,579
Other	4,651	819
	\$ 47,504	\$ 44,432
Long-term portion		
Received from sanofi-aventis (see Note 10)	\$105,586	\$126,431
Received from Bayer HealthCare (see Note 10)	56,835	65,896
	\$162,421	\$192,327

8. Stockholders Equity

The Company's Restated Certificate of Incorporation provides for the issuance of up to 40 million shares of Class A Stock, par value \$0.001 per share, and 160 million shares of Common Stock, par value \$0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's board of directors (the "Board") is authorized to issue up to 30 million shares of preferred stock, in series, with rights, privileges, and qualifications of each series determined by the Board.

In November 2006, the Company completed a public offering of 7.6 million shares of Common Stock at a price of \$23.03 per share and received proceeds, after expenses, of \$174.6 million.

In September 2003, sanofi-aventis purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for \$45.0 million. See Note 10.

In December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for an aggregate cash price of \$312.0 million. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with the Company. Under the investor agreement, sanofi-aventis has three demand rights to require the Company to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Company's Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the License and Collaboration Agreement under the Company's antibody collaboration with sanofi-aventis (see Note 10) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept (see Note 10), sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of the Company's Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Sanofi-aventis has also agreed not to dispose of any shares of the Company's Common Stock that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2012, subject to certain limited exceptions. Following December 20, 2012, sanofi-aventis will be permitted to sell shares of the Company's Common Stock (i) in a registered underwritten public offering undertaken pursuant to the demand registration rights granted to sanofi-aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of the Company's Common Stock every three months and a

more of the outstanding shares of the Company's Common Stock, and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by the Company's Board of Directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of the Company's voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by the Company's Board of Directors or proportionally with the votes cast by the Company's other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of the Company's Class A Stock and Common Stock, and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

9. Commitments and Contingencies

a. Operating Leases

The Company currently leases laboratory and office facilities in Tarrytown, New York under operating lease agreements. In December 2006, the Company entered into a new operating lease agreement to lease laboratory and office space that is now under construction and expected to be completed in mid-2009 at the Company's current Tarrytown location, plus retain a portion of the Company's existing space. In October 2007 and September 2008, the Company amended the December 2006 operating lease agreement to increase the amount of new and existing space to be leased. The term of the lease commenced effective June 30, 2008 and will expire in June 2024. Under the new lease the Company also has various options and rights on additional space at the Tarrytown site, and will continue to lease its present facilities until the new facilities are ready for occupancy. In addition, the lease contains three renewal options to extend the term of the lease by five years each and early termination options for the Company's retained facilities only. The lease provides for monthly payments over the term of the lease related to the Company's retained facilities, the costs of construction and tenant improvements for the Company's new facilities, and additional charges for utilities, taxes, and operating expenses.

In connection with the new lease agreement, in December 2006, the Company issued a letter of credit in the amount of \$1.6 million to its landlord, which is collateralized by a \$1.6 million bank certificate of deposit. The certificate of deposit has been classified as restricted cash at December 31, 2008 and 2007.

In November 2007, the Company entered into a new operating sublease for additional office space in Tarrytown, New York. The lease expires in September 2009 and contains two renewal options to extend the term of the sublease by three months each. In April 2008, the Company entered into a new operating sublease for additional office space located in Tarrytown, New York. The lease expires in March 2010 and contains one renewal option to extend the term of the sublease by six months. In October 2008 the Company entered into a new sublease with sanofi-aventis U.S. Inc. for office space in Bridgewater, New Jersey. The lease commences in January 2009 and expires in July 2011.

The Company formerly leased manufacturing, office, and warehouse facilities in Rensselaer, New York under an operating lease agreement. The lease provided for base rent plus additional rental charges for utilities, taxes, and operating expenses, as defined. In June 2007, the Company exercised a purchase option under the lease and, in October 2007, purchased the land and building.

The Company leases certain laboratory and office equipment under operating leases which expire at various times through 2011.

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REGENERON PHARMACEUTICALS, INC. NOTES TO FINANCIAL STATEMENTS (Continued) For the years ended December 31, 2008, 2007, and 2006

(Unless otherwise noted, dollars in thousands, except per share data)

Based, in part, upon budgeted construction and tenant improvement costs related to our new operating lease for facilities that are under construction in Tarrytown, New York, as described above, at December 31, 2008, the estimated future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2009	\$ 8,707	\$419	\$ 9,126
2010	13,121	241	13,362
2011	13,252	146	13,398
2012	13,428		13,428
2013	13.764		13,764
Thereafter	166,973		166,973
	\$229,245	\$806	\$230,051

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
2008	\$10,111	\$416	\$10.527
2007	4,632	363	4,995
2006	4,492	307	4,799

As described above, the term of the Company's operating lease for its new facilities in Tarrytown, New York commenced in mid-2008; as a result, the Company began recognizing rent expense in connection with this new lease, even though actual rent payments will not commence until August 2009. In addition to its rent expense for various facilities, the Company paid additional rental charges for utilities, real estate taxes, and operating expenses of \$8.4 million, \$8.8 million, and \$8.7 million for the years ended December 31, 2008, 2007, and 2006, respectively.

b. Convertible Debt

In October 2001, the Company issued \$200.0 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company of \$192.7 million, after deducting the initial purchasers' discount and out-of-pocket expenses (collectively, "Deferred Financing Costs"). The Notes bore interest at 5.5% per annum, payable semi-annually, and matured on October 17, 2008. Deferred Financing Costs, which were included in other assets, were amortized as interest expense over the period from the Notes' issuance to stated maturity. During the second and third quarters of 2008, the Company repurchased \$82.5 million in principal amount of the Notes for \$83.3 million and recognized a \$0.9 million loss on early extinguishment of debt, representing the premium paid on the Notes plus related unamortized Deferred Financing Costs. The remaining \$117.5 million of outstanding Notes were repaid in full upon their maturity in October 2008.

c. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with related and unrelated companies, scientific collaborators, universities, and consultants. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company, services to be provided, and ownership rights to certain proprietary technology developed under the agreements. Some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.25% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

Certain agreements under which the Company is required to pay fees permit the Company, upon 30 to 90-day written notice, to terminate such agreements. With respect to payments associated with these agreements, the Company incurred expenses of \$3.5 million, \$1.0 million, and \$1.1 million for the years ended December 31, 2008, 2007, and 2006, respectively.

In connection with the Company's receipt of marketing approval from the FDA for ARCALYST® (rilonacept) for the treatment of CAPS, in 2008, the Company commenced paying royalties under various licensing agreements based on ARCALYST net product sales. For the year ended December 31, 2008, ARCALYST royalties totaled \$0.6 million and are included in cost of goods sold.

In July 2008, the Company and Cellectis S.A. ("Cellectis") entered into an Amended and Restated Non-Exclusive License Agreement (the "Cellectis Agreement"). The Cellectis Agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which the Company licensed certain patents and patent applications from Cellectis. Pursuant to the Cellectis Agreement, in July 2008, the Company made a non-refundable \$12.5 million payment to Cellectis (the "Cellectis Payment") and agreed to pay Cellectis a low single-digit royalty based on revenue received by the Company from any future licenses or sales of the Company's *VelociGene*® or *VelocImmune*® products and services. No royalties are payable with respect to the Company's *VelocImmune* license agreements with AstraZeneca UK Limited ("AstraZeneca") and Astellas Pharma Inc. ("Astellas") or the Company's November 2007 collaboration with sanofi-aventis. Moreover, no royalties are payable on any revenue from commercial sales of antibodies from the Company's *VelocImmune* technology.

The Company began amortizing the Cellectis Payment in the second quarter of 2008 in proportion to past and future anticipated revenues under the Company's license agreements with AstraZeneca and Astellas and the Discovery and Preclinical Development Agreement under the Company's November 2007 collaboration with sanofi-aventis. In 2008, the Company recognized \$2.7 million of expense in connection with the Cellectis Payment.

10. Research and Development Agreements

The Company has entered into various agreements related to its activities to develop and commercialize product candidates and utilize its technology platforms. Amounts earned by the Company in connection with these agreements, which were recognized as contract research and development revenue, totaled \$192.2 million, \$96.6 million, and \$51.1 million in 2008, 2007, and 2006, respectively. Total Company incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost-sharing of a collaborator's development expenses, where applicable (see Bayer HealthCare below), were \$230.6 million, \$108.2 million and \$43.4 million in 2008, 2007, and 2006, respectively. Significant agreements of this kind are described below.

a. The sanofi-aventis Group

Aflibercept 4 6 1

In September 2003, the Company entered into a collaboration agreement (the "Aventis Agreement") with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.), to jointly develop and commercialize affibercept. In connection with this agreement, sanofi-aventis made a non-refundable up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for \$45.0 million.

In January 2005, the Company and sanofi-aventis amended the Aventis Agreement to exclude intraocular delivery of aflibercept to the eye ("Intraocular Delivery") from joint development under the agreement, and product rights to aflibercept in Intraocular Delivery reverted to Regeneron. In connection with this amendment, sanofi-aventis made a \$25.0 million non-refundable payment to Regeneron (the "Intraocular Termination Payment") in January 2005.

In December 2005, the Company and sanofi-aventis amended the Aventis Agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a \$25.0 million non-refundable up-front payment to the Company, which was received in January 2006. Under the Aventis Agreement, as amended, the Company and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan, for disease indications included in the companies' collaboration. The Company is entitled to a royalty of approximately 35% on annual sales of aflibercept in Japan, subject to certain potential adjustments. The Company may also receive up to \$400 million in milestone

payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

Under the Aventis Agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of these development expenses, or half of \$446.5 million as of December 31, 2008, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits and Japan royalties, or at a faster rate at Regeneron's option. Regeneron has the option to conduct additional pre-Phase III studies at its own expense. In connection with the January 2005 amendment to the Aventis Agreement, the Intraocular Termination Payment of \$25.0 million will be considered an aflibercept development expense and will be subject to 50% reimbursement by Regeneron to sanofi-aventis, as described above, if the collaboration becomes profitable. In addition, if the first commercial sale of an aflibercept product in Intraocular Delivery predates the first commercial sale of an aflibercept product under the collaboration by two years, Regeneron will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, Regeneron's obligation to reimburse sanofi-aventis, for 50% of aflibercept development expenses will terminate, and the Company will retain all rights to aflibercept.

Revenue related to payments from sanofi-aventis under the Aventis Agreement, as amended, is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The up-front payments received in September 2003 and January 2006, of \$80.0 million and \$25.0 million, respectively, and reimbursement of Regeneron-incurred development expenses, are being recognized as contract research and development revenue over the related performance period. The Company recognized \$44.4 million, \$47.1 million, and \$47.8 million of contract research and development revenue in 2008, 2007, and 2006, respectively, in connection with the Aventis Agreement, as amended. At December 31, 2008 and 2007, amounts receivable from sanofi-aventis totaled \$6.3 million and \$10.5 million, respectively, and deferred revenue was \$52.4 million and \$61.2 million, respectively, in connection with the Aventis Agreement.

Antibodies

In November 2007, the Company entered into a global, strategic collaboration (the "Antibody Collaboration") with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. In connection with the collaboration, in December 2007, sanofi-aventis purchased 12 million newly issued; unregistered shares of the Company's Common Stock for \$312.0 million (see Note 8).

The Antibody Collaboration is governed by a Discovery and Preclinical Development Agreement (the "Discovery Agreement") and a License and Collaboration Agreement (the "License Agreement"). The Company received a non-refundable up-front payment of \$85.0 million from sanofi-aventis under the Discovery Agreement. In addition, sanofi-aventis will fund up to \$475 million of the Company's research for identifying and validating potential drug discovery targets and developing fully human monoclonal antibodies against such targets through December 31, 2012, subject to specified funding limits of \$75 million for the period from the collaboration's inception through December 31, 2008, and \$100 million annually in each of the next four years. The Discovery Agreement will expire on December 31, 2012; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the Discovery Agreement, sanofi-aventis has the option to license rights to the candidate under the License Agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with the Company through product approval. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the License Agreement, the Company will retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The first three therapeutic antibodies that are being co-developed by the Company and sanofi-aventis under the License Agreement are REGN88, REGN421, and REGN475.

Under the License Agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") will be shared 80% by sanofi-aventis and 20% by Regeneron. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of \$27.8 million as of December 31, 2008) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products.

Sanofi-aventis will lead commercialization activities for products developed under the License Agreement, subject to the Company's right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (Regeneron) and ending at 55% (sanofi-aventis)/45% (Regeneron), and losses outside the United States at 55% (sanofi-aventis)/45% (Regeneron). In addition to profit sharing, the Company is entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured.

With respect to each antibody product which enters development under the License Agreement, sanofi-aventis or the Company may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. The Company may also opt-out of the further development of an antibody product if it gives notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the License Agreement. Each of the Discovery Agreement and the License Agreement contains other termination provisions, including for material breach by the other party and, in the case of the Discovery Agreement, a termination right for sanofi-aventis under certain circumstances, including if certain minimal criteria for the discovery program are not achieved. Prior to December 31, 2012, sanofi-aventis has the right to terminate the Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to the Company the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2012. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate. Upon expiration of the Discovery Agreement, sanofi-aventis has an option to license the Company's VelocImmune® technology for agreed upon consideration.

In connection with the Antibody Collaboration, in August 2008, the Company entered into a separate agreement with sanofi-aventis to use Regeneron's proprietary *VelociGene*® technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease (the "*VelociGene* Agreement"). The VelociGene Agreement provides for minimum annual order quantities for the term of the agreement which extends through December 2012, for which the Company expects to receive payments totaling a minimum of \$21.5 million.

Revenue related to payments from sanofi-aventis under the Antibody Collaboration is being recognized in accordance with SAB 104 and EITF 00-21 (see Note 2). The (i) \$85.0 million up-front payment received in December 2007, (ii) reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements, and (iii) \$21.5 million of aggregate minimum payments under the *VelociGene* Agreement are being recognized as contract research and development revenue over the related performance period. In connection with the Antibody Collaboration, the Company recognized \$109.6 million and \$4.6 million of contract research and development revenue in 2008 and 2007, respectively. In addition, at December 31, 2008 and 2007, amounts receivable from sanofi-aventis totaled \$27.0 million and \$3.7 million and deferred revenue was \$74.6 million and \$84.1 million, respectively.

b. Bayer HealthCare LLC

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to the Company of \$75.0 million. In addition, the Company is eligible to receive up to \$110 million in development and regulatory milestones related to the VEGF Trap-Eye program, of which the Company received a \$20.0 million milestone payment in August 2007 in connection with the initiation of a Phase 3 trial of VEGF Trap-Eye in the neovascular form of age-related macular degeneration ("wet AMD"). The Company is also eligible to receive up to an additional \$135 million in sales milestones when and if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer HealthCare out of its share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$63.0 million as of December 31, 2008) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. Within the United States, the Company is responsible for any future commercialization of VEGF Trap-Eye and retains exclusive rights to any future profits from commercialization.

Agreed upon VEGF Trap-Eye development expenses incurred by both companies in 2007 and 2008 under a global development plan, were shared as follows:

2007: The first \$50.0 million was shared equally and the Company was solely responsible for up to the next \$40.0 million.

2008: The first \$70.0 million was shared equally and the Company was solely responsible for up to the next \$30.0 million.

In 2009 and thereafter, all development expenses will be shared equally. Neither party was reimbursed for any development expenses that it incurred prior to 2007. The Company is also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

Bayer HealthCare has the right to terminate the Bayer Agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to VEGF Trap-Eye.

For the period from the collaboration's inception in October 2006 through September 30, 2007, all up-front licensing, milestone, and cost-sharing payments received or receivable from Bayer HealthCare had been fully deferred and included in deferred revenue for financial statement purposes. In the fourth quarter of 2007, Regeneron and Bayer HealthCare approved a global development plan for VEGF Trap-Eye in wet AMD. The plan included estimated development steps, timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. In addition, in the fourth quarter of 2007, Regeneron and Bayer HealthCare reaffirmed the companies' commitment to a DME development program and had initial estimates of development costs for VEGF Trap-Eye in DME. As a result, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's VEGF Trap-Eye development expenses. The \$75.0 million up-front licensing payment and \$20.0 million milestone payment (which was not considered substantive) from Bayer HealthCare are being recognized as contract research and development revenue over the related estimated performance period in accordance with SAB 104 and EITF 00-21 (see Note 2). In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron,

the Company also recognizes, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse. In the fourth quarter of 2007, the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses through a cumulative catch-up.

In 2008, the Company recognized \$31.2 million of contract research and development revenue from Bayer HealthCare, consisting of \$12.4 million related to the up-front licensing and milestone payments and \$18.8 million related to the portion of the Company's 2008 VEGF Trap-Eye development expenses that was reimbursable from Bayer HealthCare. In 2007, the Company recognized \$35.9 million of contract research and development revenue from Bayer HealthCare, consisting of \$15.9 million related to the up-front licensing and milestone payments and \$20.0 million related to the portion of the Company's 2007 VEGF Trap-Eye development expenses that was reimbursable from Bayer HealthCare. In addition, in 2008 and 2007, the Company recognized as additional research and development expense \$30.0 million and \$10.6 million, respectively, of VEGF Trap-Eye development expenses that the Company was obligated to reimburse to Bayer HealthCare.

In connection with cost-sharing of VEGF Trap-Eye development expenses under the collaboration, \$9.8 million and \$4.9 million was payable to Bayer HealthCare at December 31, 2008 and 2007, respectively, and \$2.8 million was receivable from Bayer HealthCare at December 31, 2007. In addition, at December 31, 2008 and 2007, deferred revenue from the Company's collaboration with Bayer HealthCare was \$66.7 million and \$79.1 million, respectively.

c. Serono, S.A. (now part of Merck KGaA)

In December 2002, the Company entered into an agreement (the "Serono Agreement") with Serono S.A. to use Regeneron's proprietary *VelociGene*® technology platform to provide Serono with knock-out and transgenic mammalian models of gene function ("Materials"). The Serono Agreement contains provisions for minimum yearly order quantities. In connection with its orders for Materials, Serono makes advance payments to Regeneron, which are accounted for as deferred revenue. Regeneron recognizes revenue and reduces the deferred revenue balance as Materials are shipped to and accepted by Serono. In 2008, 2007, and 2006, the Company recognized \$0.9 million, \$2.4 million, and \$1.8 million, respectively, of contract research and development revenue in connection with the Serono Agreement.

d. National Institutes of Health

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. As amended, the NIH grant provides a minimum of \$24.5 million in funding over a five-year period, including \$1.5 million in funding to optimize certain existing technology, subject to compliance with its terms and annual funding approvals, for the Company's use of its *VelociGene* technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells which can be used to produce knockout mice. In 2008, 2007, and 2006, the Company recognized contract research and development revenue of \$4.9 million, \$5.5 million, and \$0.5 million, respectively, from the NIH Grant.

11. Technology Licensing Agreements

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made two \$20.0 million annual, non-refundable payments to the Company, one in 2007 and the other in 2008. Each annual payment is deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. AstraZeneca is required to make up to four additional annual payments of \$20.0 million, subject to their ability to terminate the agreement after making two such additional payments or earlier if the technology does not meet minimum performance criteria. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's *VelocImmune* technology. In connection with the AstraZeneca license agreement, for the years ended December 31, 2008 and 2007, the Company recognized \$20.0 million and \$17.1 million of revenue. In addition, deferred revenue at both December 31, 2008 and 2007 was \$2.9 million.

In March 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made two \$20.0 million annual, non-refundable payments to the Company, one in 2007 and the other in 2008. Each annual payment is deferred and, recognized as revenue ratably over approximately the ensuing twelve-month period. Astellas is required to make up to four additional annual payments of \$20.0 million, subject to their ability to terminate the agreement after making two such additional payments or earlier if the technology does not meet minimum performance criteria. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune* technology. In connection with the Astellas license agreement, for the years ended December 31, 2008 and 2007, the Company recognized \$20.0 million and \$11.3 million of revenue. In addition, deferred revenue at both December 31, 2008 and 2007 was \$8.7 million.

12. Manufacturing Agreement

During 1995, the Company entered into a long-term manufacturing agreement with Merck & Co., Inc., as amended, (the "Merck Agreement") to produce an intermediate (the "Intermediate") for a Merck pediatric vaccine at the Company's Rensselaer, New York facility. The Company modified portions of its facility for manufacture of the Intermediate and assisted Merck in securing regulatory approval for such manufacture in the Company's facility. The Merck Agreement called for the Company to manufacture Intermediate for Merck for a specified period of time (the "Production Period"), with certain minimum order quantities each year. The Production Period commenced in November of 1999 and, as amended, extended through October 2006, at which time the Merck Agreement terminated.

Merck agreed to reimburse the Company for the capital costs to modify the facility ("Capital Costs"). Merck also agreed to pay an annual facility fee (the "Facility Fee") of \$1.0 million beginning March 1995, subject to annual adjustment for inflation. During the Production Period, Merck agreed to reimburse the Company for certain manufacturing costs, pay the Company a variable fee based on the quantity of Intermediate supplied to Merck, and make additional bi-annual payments ("Additional Payments"), as defined. In addition, Merck agreed to reimburse the Company for miscellaneous costs during the Production Period ("Internal Costs"). These payments were recognized as contract manufacturing revenue as follows: (i) payments for Internal Costs were recognized as the activities were performed, (ii) the Facility Fee and Additional Payments were recognized over the period to which they related, (iii) payments for Capital Costs were deferred and recognized as Intermediate was shipped to Merck, and (iv) payments related to the manufacture of Intermediate during the Production Period were recognized after the Intermediate was tested and approved by, and shipped (FOB shipping point) to, Merck. In 2006, Merck contract manufacturing revenue totaled \$12.3 million, which included \$1.2 million of previously deferred Capital Costs.

13. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. For the year-ended December 31, 2008, the Company recognized as revenue \$6.3 million of ARCALYST net product sales for which the right of return no longer existed and rebates could be reasonably estimated. At December 31, 2008, deferred revenue related to ARCALYST net product sales totaled \$4.0 million.

Cost of goods sold related to ARCALYST sales totaled \$0.9 million for the year ended December 31, 2008 and consisted primarily of royalties (see Note 9c). In 2008, ARCALYST shipments to the Company's customers consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST; therefore, the costs of these supplies were not included in costs of goods sold. At December 31, 2008, the Company had no inventoried costs related to ARCALYST.

14. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan which, as amended and restated (the "2000 Incentive Plan"), provides for the issuance of up to 28,816,184 shares of Common Stock in respect of awards. In addition, shares of Common Stock previously approved by shareholders for

issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant. The maximum term of options that have been awarded under the 2000 Incentive Plan is ten years.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the Restricted Stock, which has not vested, will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts, if any, paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

Phantom Stock awards provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of the Company's Common Stock as determined by the Committee, equal to the sum of the fair market value of a share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests. Stock Bonus awards are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Company's Common Stock. Subject to the provisions of the 2000 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

During 1990, the Company established the 1990 Incentive Plan which, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, received awards as determined by a committee of independent directors. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. Awards under the 1990 Incentive Plan consisted of Incentive Stock Options and Nonqualified Stock Options which generally vested on a pro rata basis over a three or five year period and have a term of ten years.

The 1990 and 2000 Incentive Plans contain provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined.

As of December 31, 2008, there were 6,912,833 shares available for future grants under the 2000 Incentive Plan.

REGENERON PHARMACEUTICALS, INC. NOTES TO FINANCIAL STATEMENTS (Continued) For the years ended December 31, 2008, 2007, and 2006

(Unless otherwise noted, dollars in thousands, except per share data)

a. Stock Options

Transactions involving stock option awards during 2006, 2007, and 2008 under the 1990 and 2000 Incentive Plans are summarized in the table below.

			Weighted-	
			Average	
			Remaining	
			Contractual	Intrinsic
	Number of	Weighted - Average	Term	Value
Stock Options:	Shares	Exercise Price	(in years)	(in thousands)
Outstanding at December 31, 2005	14 719 492	\$14.23		
2006: Granted	2,742,260	\$19.59		
Forfetted	(338,122)	\$10.51		
Expired	(172,218)	\$24.23		
Exercised	(1,408,907)	\$ 9.84		
Outstanding at December 31, 2006	15,542,505	\$15.54		
2007: Granted	3.415,743	\$21.78		
Forfeited	(220,342)	\$14.43		
Expired	(50.759)	\$13.73		
Exercised	(1,014,791)	\$10.58		
Ourstanding at December 31, 2007	17.672.356	\$17.05		
2008: Granted	4,126,600	\$17.38		
Forfelted	(515,298)	\$16.58		
Expired	(34,242)	\$26.81		
Exercised	(1.115,506)	\$ 9.61		
Outstanding at December 31, 2008	20,133,910	\$17.53	6.62	\$59,268
Vested and expected to vest at December 31, 2008	19.596.843	\$17.52	6.57	\$58,354
Exercisable at December 31, 2006	7,890,856	\$17.41		
Exercisable at December 31, 2007	9.369.665	\$17.02		
Exercisable at December 31, 2008	10,994,371	\$17.43	5.08	\$42,791

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2008, 2007, and 2006 was \$11.9 million, \$12.6 million, and \$13.2 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The Company grants stock options with exercise prices that are equal to or greater than the market price of the Company's Common Stock on the date of grant. The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2006, 2007, and 2008. The fair value of each option granted under the 2000 Incentive Plan during 2008, 2007, and 2006 was estimated on the date of grant using the Black-Scholes option-pricing model.

		Weighted-	Weighted-
	Number of	Average Exercise	Average Fair
	Options Granted	Price	Value
2006			
Exercise price equal to market price	2,742,260	\$19.59	\$12.82
2007:			
Exercise price equal to market price	3,415,743	\$21.78	\$11.13
2008			
Exercise price equal to market price	4,126,600	\$17.38	\$ 8.45

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The following table summarizes stock option information as of December 31, 2008:

		Options Outstandi	ng	Options :	Exercisable
		Weighted-			
		Average	Weighted-		Weighted-
Range of	Number	Remaining	Average	Number	Average
Exercise Prices	Outstanding	Contractual Life	Exercise Price	Exercisable	Exercise Price
\$4.83 to \$9.49	3,721,142	4.02	\$ 8.95	2,815,152	5 9 10
\$9.53 to \$13.00	3,588,129	5.93	\$12.25	3,069,391	\$12.36
\$13.05 to \$16.80	3,832,641	9.57	\$16.53	287,491	\$15.26
\$17.33 to \$20.32	3,508,707	6.95	\$19.90	2,076,331	\$19.85
\$20.37 to \$2 2. 12	3,193,837	8.91	\$21.68	752,577	\$21.79
\$22.25 to \$37.94	2,229,454	3.38	\$31.41	1,933,429	\$32.56
\$51.56 to \$51.56	60,000	1.16	\$51.56	60,000	\$51.56
\$4.83 to \$51.56	20,133,910	6.62	\$17.53	10,994,371	\$17.43

For the years ended December 31, 2008, 2007, and 2006, \$30.3 million, \$28.0 million, and \$18.4 million, respectively, of non-cash stock-based employee compensation expense related to stock option awards was recognized in operating expenses. As of December 31, 2008, there was \$46.3 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 2.0 years. In addition, there were 1,302,260 performance-based options which were unvested as of December 31, 2008 of which, subject to the optionee satisfying certain service conditions, 664,760 options would vest upon achieving certain defined sales targets for the Company's products and 637,500 options would vest upon achieving certain development milestones for the Company's product candidates. Potential compensation cost, measured on the grant date, related to these performance options totals \$9.1 million and will begin to be recognized only if, and when, these options' performance conditions are considered to be probable of attainment.

Fair value Assumptions:

Using the Black-Scholes option-pricing model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with previously issued employee and board of director option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future.

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2008, 2007, and 2006.

	2008	2007	2006
Expected volatility			67%
Expected lives from grant date	5.5 years	5.6 years	6.5 years
Expected dividend yield	0%	0%	0%
Risk-free interest rate	1.73%	3.60%	4.51%

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the years ended December 31, 2006, 2007, and 2008 is summarized below:

		Weighted - Average
	Number of	Grant Date
Restricted Stock:	Shares	Fair Value
Outstanding at December 31, 2005	95,188	\$11.16
2006: Forfeited	(1,703)	\$ 9.74
Released	(93.485)	\$11.18
Outstanding at December 31, 2006	_	
2007: Granted	500,000	\$21.92
Outstanding at December 31, 2007	500,000	\$21.92
2008: Outstanding at December 31, 2008	500,000	\$21,92

In December 2007, the Company awarded a grant of Restricted Stock to the Company's executive vice president. In accordance with generally accepted accounting principles, the Company records unearned compensation in Stockholders' Equity related to grants of Restricted Stock awards. This amount is based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restriction on these shares lapse, which is five years for the grant made in 2007. In addition, unearned compensation in Stockholders' Equity is reduced due to forfeitures of Restricted Stock resulting from employee terminations. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation is combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

In connection with the 2007 grant of Restricted Stock, the Company recorded unearned compensation in Stockholders' Equity of \$11.0 million, which was combined with additional paid-in capital. In connection with forfeitures of past Restricted Stock awards, the Company reduced unearned compensation by \$17 thousand in 2006. The Company recognized non-cash stock-based employee compensation expense from Restricted Stock awards of \$2.2 million, \$0.1 million, and \$0.3 million in 2008, 2007, and 2006, respectively. As of December 31, 2008, there were 500,000 unvested shares of Restricted Stock outstanding and \$8.7 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 4.0 years.

15. Executive Stock Purchase Plan

In 1989, the Company adopted an Executive Stock Purchase Plan (the "Plan") under which 1,027,500 shares of Class A Stock were reserved for restricted stock awards. The Plan provides for the compensation committee of the board of directors to award employees, directors, consultants, and other individuals ("Plan participants") who render service to the Company the right to purchase Class A Stock at a price set by the compensation committee. The Plan provides for the vesting of shares as determined by the compensation committee and, should the Company's relationship with a Plan participant terminate before all shares are vested, unvested shares will be repurchased by the Company at a price per share equal to the original amount paid by the Plan participant. During 1989 and 1990, a total of 983,254 shares were issued, all of which vested as of December 31, 1999. As of December 31, 2008, there were 44,246 shares available for future grants under the Plan.

16. Employee Savings Plan

In 1993, the Company adopted the provisions of the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan provide for employees who have met defined service requirements to participate in the Savings Plan by electing to contribute to the Savings Plan a percentage of their compensation to be set aside to pay their future retirement benefits, as defined. The Savings Plan, as amended and restated, provides for

the Company to make discretionary contributions ("Contribution"), as defined. The Company recorded Contribution expense of \$1.5 million in 2008, \$1.4 million in 2007, and \$1.3 million in 2006; such amounts were accrued as liabilities at December 31, 2008, 2007, and 2006, respectively. During the first quarter of 2009, 2008, and 2007, the Company contributed 81,086, 58,575, and 64,532 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

17. Income Taxes

For the year ended December 31, 2008, the Company incurred a net loss for tax purposes and recognized a full tax valuation against deferred taxes. During 2008, the Company implemented a tax planning strategy to utilize net operating loss carry-forwards (which were otherwise due to expire in 2008 through 2012) on its 2007 U.S. federal and New York State income tax returns that were filed in September 2008. The tax planning strategy included electing, for tax purposes only, to capitalize \$142.1 million of 2007 research and development ("R&D") costs and amortize these costs over ten years for tax purposes. By capitalizing these R&D costs, the Company was able to generate taxable income for tax year 2007 and utilize the net operating loss carry-forwards to offset this taxable income. As a result, the Company incurred and paid income tax expense of \$3.1 million in 2008, which related to U.S. federal and New York State alternative minimum tax ("AMT") and included \$0.2 million of interest and penalties. This expense was partly offset by the Company's recognition of a \$0.7 million income tax benefit for the year ended December 31, 2008, resulting from a provision in the Housing Assistance Tax Act of 2008 that allows the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2008 U.S federal income tax return.

For the year ended December 31, 2007, the Company had projected to incur a net loss for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes was recorded in 2007. Subsequently, the Company implemented the tax planning strategy described above, which resulted in taxable income in 2007 on which the Company recognized and paid U.S. federal and New York State AMT in 2008. For the year ended December 31, 2006, the Company incurred a net loss for tax purposes and recognized a full tax valuation against deferred taxes. Accordingly, no provision or benefit for income taxes was recorded in 2006.

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental tax credit carry-forwards as of December 31, 2008 and 2007 is as follows:

	2008	2007
Deferred tax assets		
Net operating loss carry-forward	\$ 161,790	\$ 166,714
Fixed assets	18,612	17,245
Deferred revenue	85,251	96,148
Deferred compensation	22,942	15.159
Research and experimental tax credit carry-forward	22,295	25,446
Capitalized research and development costs	59,661	15,236
Other	9,825	7,036
Valuation allowance	(380,376)	(342,984)
	_	_

The Company's valuation allowance increased by \$37.4 million in 2008, due primarily to the increase in the temporary difference related to capitalized research and development costs, resulting from the implementation of the tax planning strategy described above. In 2007, the Company's valuation allowance increased by \$30.7 million, due primarily to the temporary difference related to deferred revenue, principally resulting from the non-refundable, up-front payment received from sanofi-aventis in December 2007 (see Note 10).

Effective January 1, 2007, the Company adopted the provisions of FASB Interpretation No. 48 ("FIN 48"), Accounting for Uncertainty in Income Taxes - an interpretation of FASB Statement No. 109. The implementation of FIN 48 had no impact on the Company's financial statements as the Company has not recognized any income tax positions that were deemed uncertain under the recognition thresholds and measurement attributes prescribed by FIN 48.

The Company is primarily subject to U.S. federal and New York State income tax. The Company's effective income tax rate is generally zero for all years presented. The difference between the Company's effective income tax rate and the U.S federal statutory rate of 35% is attributable to state tax benefits and tax credit carry-forwards offset by an increase in the deferred tax valuation allowance. The Company's 1998 and subsequent tax years remain open to examination by U.S. federal and state tax authorities.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2008 and 2007, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2008, the Company had available for tax purposes unused net operating loss carry-forwards of \$415.4 million which will expire in various years from 2018 to 2028 and included \$17.0 million of net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of Incentive Stock Options, the tax benefit from which, if realized, will be credited to additional paid-in capital. The Company's research and experimental tax credit carry-forwards expire in various years from 2009 to 2028. Under the Internal Revenue Code and similar state provisions, substantial changes in the Company's ownership have resulted in an annual limitation on the amount of net operating loss and tax credit carry-forwards that can be utilized in future years to offset future taxable income. This annual limitation may result in the expiration of net operating losses and tax credit carry-forwards before utilization.

18. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition. Legal costs associated with the Company's resolution of legal proceedings are expensed as incurred.

19. Net Loss Per Share Data

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. In 2008, 2007, and 2006, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	December 31,		
	2008	2007	2006
Net loss (Numerator)	\$(82,710)	\$(105,600)	\$(102,337)
Weighted-average shares, in thousands (Denominator)	78,827	66,334	57,970
Basic and diluted ner loss per share	s (1.05)	S (1.59)	\$ (1.77)

Shares issuable upon the exercise of options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the diluted per share amounts because their effect would have been antidilutive, include the following:

	December 31,		
	2008	2007	2006
Options:			
Weighted average number, in thousands	17,598	15,385	14,139
Weighted average exercise price	\$ 17.31	\$ 15.97	\$ 14.41
Restricted Stock:			
Weighted average number, in thousands	500	21	23
Convertible Debt:			
Weighted average number, in thousands		6,611	6,611
Conversion price		\$ 30.25	\$ 30.25

REGENERON PHARMACEUTICALS, INC. NOTES TO FINANCIAL STATEMENTS (Continued) For the years ended December 31, 2008, 2007, and 2006

(Unless otherwise noted, dollars in thousands, except per share data)

20. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at December 31, 2008, 2007, and 2006 were \$7.0 million, \$1.7 million, and \$0.8 million of accrued capital expenditures, respectively.

Included in accounts payable and accrued expenses at December 31, 2007, 2006, and 2005 were \$1.1 million, \$1.4 million, and \$1.9 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2008, 2007, and 2006, the Company contributed 58,575, 64,532, and 120,960 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at December 31, 2008, 2007, and 2006 were \$1.7 million, \$2.2 million, and \$1.5 million of accrued interest income, respectively.

21. Segment Information

In 2008 and 2007, the Company managed its business as one segment which included all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. This segment also included revenues and expenses related to (i) research and development activities conducted under the Company's collaboration agreements with third parties and the Company's grant from the NIH, (ii) ARCALYST® (rilonacept) product sales for the treatment of CAPS, and (iii) the supply of specified, ordered research materials using Regeneron-developed proprietary technology. In 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing; therefore, segment information has only been provided for 2006 in the table below. In 2006, the contract manufacturing segment included all revenues and expenses related to the commercial production of a product under a contract with Merck, which expired in October 2006. The accounting policies for the segments are the same as those described above in Summary of Significant Accounting Policies.

The following table presents information about reported segments for the year ended December 31, 2006.

	Research &	Contract	Reconciling	
2006	Development	Manufacturing	Items	Total
Revenues	\$ 51.136	\$ 12.311		\$ 63,447
Depreciation and amortization	13,549	(1)	\$ 1,043	14,592
Non-cash compensation expense	18,357	318	(813) ⁽²⁾	17.862
Interest expense		_	12,043	12,043
Net income (loss)	(111,820)	4.165	5.318 ⁽³⁾	(102.337)
Capital expenditures	3,339	_	_	3,339
Total assets	56,843	3	528, 24 4 ⁽⁴⁾	585,090

⁽¹⁾ Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

Represents the cumulative effect of adopting SFAS 123R.

⁽³⁾ Represents investment income net of interest expense related to convertible notes issued in October 2001 (see Note 9). For the year ended December 31, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 2).

⁽⁴⁾ Includes cash and cash equivalents, marketable securities, restricted cash (where applicable), prepaid expenses and other current assets, and other assets.

22. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2008 and 2007 are set forth in the following tables.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	Ended	Ended	Ended	Ended
	March 31, 2008	June 30, 2008	September 30, 2008	December 31, 2008
		(Unaudited)		
Revenues	\$ 56,383	\$ 60,653	\$ 65,584	\$ 55,837
Net loss	(11,618)	(18,459)	(21,115)	(31,518)
Net loss per share, basic and diluted.	\$ (0.15)	\$ (0.23)	\$ (0.27)	\$ (0.40)
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	Ended	Ended	Ended	Ended
	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007 ⁽¹⁾
	(Unaudited)			
Revenues	\$ 15.788	\$ 22,195	\$ 22,311	\$ 64,730
Net loss	(29,917)	(26,774)	(35,838)	(13,071)
Not loss per share, basic and diluted	\$ 60.460	\$ (0.41)	\$ (0.54)	K (0.10)

As described above in Note 10, effective in the fourth quarter of 2007, the Company determined the appropriate accounting policy for payments from Bayer HealthCare. As a result, in the fourth quarter of 2007, when the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost-sharing of the Company's and Bayer HealthCare's 2007 VEGF Trap-Eye development expenses, the Company recognized contract research and development revenue from Bayer HealthCare of \$35.9 million and additional research and development expense of \$10.6 million.

As of November 14, 2008

Leonard S. Schleifer, M.D., Ph.D. President and Chief Executive Officer, Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591-6707

Dear Len:

This employment agreement will replace and update the agreement dated December 20, 2002 between Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") and you. The compensation obligations of the Company under this agreement (the "Agreement") will be reduced by any amounts actually paid by any affiliate, subsidiary, and related entity controlled by or under common control with the Company ("Related Entity").

1. <u>Employment</u>.

- (a) You will continue to serve, during the Employment Term, as President and Chief Executive Officer of the Company with the customary responsibilities and authority of such positions and in accordance with the Company's By-Laws. You will report directly and only to the Board of Directors. If elected, you will also continue to serve as a Director of the Company. The Company shall during the Employment Term recommend and propose you as a Director of the Company and any Related Entity and, if the Chairman of the Board of Directors as of the date hereof at any time ceases to serve as such, as Chairman of the Board of Directors. To the extent you are not elected Chief Executive Officer of any Related Entity, such Chief Executive Officer shall report to you.
- (b) During the Employment Term, you shall devote substantially all of your business time and attention to the performance of your duties for the Company and serve the Company diligently and to the best of your ability. You may, however, perform teaching, consulting, patient care, and other activities as you have done from time to time in the past, provided that they do not materially conflict with the performance of your duties to the Company. In addition, you may manage your personal investments and be involved in civic and charitable activities so long as such activities do not materially interfere with your providing services hereunder. During the Employment Term, you shall not serve as a member of a board of directors of any other for-profit corporation (other than a Related Entity) without the prior written consent of the Board of Directors (which consent shall not be unreasonably withheld). In no event will the provisions of this Agreement in any way modify, alter, reduce, or limit the fiduciary obligations you owe to the Company as an officer and Director of the Company.
- 2. <u>Term.</u> Except for earlier termination as provided in paragraph 4 hereof, your employment under this Agreement (the "Employment Term") is for an initial term that commenced on February 12, 1998 and ended on December 31, 2003 (the "Initial Term") and automatically extended since then. Unless notice is given of an intent not to extend the Initial Term or any extension thereof, by you or by the Company by written notice at least ninety (90) days prior to each December 31 during the Employment Term, the Employment Term shall be deemed as of such 90th day to have been extended and continue until the end of the following calendar year unless otherwise terminated as provided in paragraph 4 hereof.

3. <u>Compensation/Benefits</u>.

- (a) During the Employment Term, you have received base salary at an annual rate of not less than \$575,000, paid currently at periodic intervals in accordance with the Company's payroll practices for salaried employees. Adjustments in your base salary during the term of this Agreement (which shall thereafter be your "Base Salary") have been and may be effected from time to time upon the recommendation of the Compensation Committee and the approval of the Board of Directors based upon an annual review by the Compensation Committee, but your Base Salary, once increased, shall in no event be decreased; provided, however, that in the event there is a general reduction of compensation applicable to senior executives generally, nothing herein shall preclude the Board of Director's ability to reduce your Base Salary consistent with this reduction. You shall also participate in and be the beneficiary of any cash bonus payments, stock option and other equity programs, incentive programs, pension plans, profit sharing plans and other benefit programs and fringe benefit programs implemented by the Company and otherwise available to executive officers, nonindependent directors, and employees of the Company, at a level commensurate with your position, in accordance with the terms and conditions of such programs.
- (b) You have separately entered into one or more stock purchase agreements and stock option award agreements with the Company. With the sole exception of the provisions in this Agreement regarding vesting and exercisability of stock options, nothing in this Agreement will affect any term or provision of any stock purchase or stock option award agreement you have entered into or will enter into with the Company under any stock purchase or incentive plan of the Company and the stock options to purchase common shares previously granted to you shall remain outstanding, and in effect, in accordance with their respective terms.
- (c) The Company will during the Employment Term maintain insurance on your life in the amount of \$1,000,000 payable to such beneficiary as you designate. You may change the designated beneficiary of this policy at any time. The Company will not borrow against or otherwise encumber the policy or proceeds thereof. The Company will also during the Employment Term maintain for your benefit a long term disability policy that will pay you at least 65 percent of your Base Salary during such period as you are unable, for physical or mental reasons, to perform the responsibilities of your current position, with such benefits commencing no later than six (6) months after incurrence of the disability.

- (d) During the Employment Term, subject to paragraph 14(o)(i), the Company will pay for or will reimburse the reasonable costs of your medical malpractice insurance and all customary, ordinary, and necessary business expenses incurred by you in the performance of your duties (including expenses related to equipment you customarily and normally use in connection with the performance of your duties to the Company), provided that you present such vouchers, receipts, or other documentation as are required by the regular procedures of the Company for the reimbursement of such expenses. In addition, during the Employment Term, the Company will pay you a monthly automobile cash allowance of \$1,500 plus all expenses of maintaining and operating your automobile in accordance with current policy.
- (e) You shall be entitled to at least four (4) weeks of vacation per year, which vacation may be taken at such times as you elect with due regard to the needs of the Company.
- (f) Subject to paragraph 14(o) (i), the Company will pay, or will reimburse the reasonable costs of any legal, accounting or other professional services you incur in connection with your tax preparation and financial planning to an annual maximum of (i) the amount for financial planning and similar benefits generally made available to other senior executives of the Company for such year, plus (ii) \$12,500 per year (together, the "Maximum Annual Professional Services Reimbursement Amount"), including, without limitation, a tax gross-up reimbursement, so long as the total direct reimbursement and tax gross-up reimbursement is no more than the Maximum Annual Professional Services Reimbursement Amount per year. For calendar years commencing after December 31, 2004, any accrued unused amount that would have been reimbursed under this paragraph 3(f) during such year will be forfeited to the extent reimbursable expenses are not incurred during the applicable year. For calendar years prior to 2004, any unused amounts under the annual reimbursable cap (the "Grandfathered Reimbursements") under this Agreement and the February 12, 1998 agreement between you and the Company shall continue to be available to you for reimbursement of legal, accounting or other professional service expenses (and tax gross ups) you incur in connection with your tax preparation and financial planning under the terms of this Section 3(f). For the avoidance of doubt, all reimbursements shall first be deemed to come from the annual allowance that, if unused, is subject to forfeiture.
- (g) During the Employment Term (and, subject to the terms of this paragraph, thereafter), the Company will continue to designate you as its nominee at the club at which you are currently designated as the nominee of the Company (the "Club") and, subject to paragraph 14(o)(i), pay any dues or other expenses incurred with regard to your use of the Club. After your termination of employment with the Company, you shall, at your election made to the Company within 45 days thereafter: (i) elect not to be designated by the Company as the nominee for the Company's Club membership; (ii) if permitted by the Club, have the Company transfer the Company's Club membership to you, with the Company having its bond either returned or assumed by you (in which case you would pay the Club any dues or other Club expenses incurred thereafter and, if you assumed the bond, would pay the Company the amount of the bond); or (iii) have the Company continue your designation as nominee for the Company's Club membership (in which case you would pay the dues and other Club expenses incurred thereafter and deposit the amount of the Club bond with the Company, with such amount (as adjusted in the same manner as the bond) returned to you by the Company at the earlier of such time as it receives a refund of the bond or you elect to cease being designated as the Company's nominee at the Club). Notwithstanding anything else herein, this obligation shall survive any termination of your employment with the Company.

- (h) Following any termination of your employment with the Company, if and to the extent the Company maintains any health benefit plans (and without any obligation to do so), you and your (and, after your death, your wife's) dependents shall be entitled to continue to participate therein by paying an amount equal to the COBRA cost thereof for the remainder of your life and that of your spouse at the time of such termination of employment. Notwithstanding anything else herein, this provision shall survive any termination of your employment with the Company.
- 4. <u>Termination</u>. Except as otherwise provided in paragraph 2, the Employment Term shall end upon the earliest of the following to occur:
 - (a) Your death.
 - (b) Upon a vote of the Board of Directors and notice to you of termination as a result of your Permanent Disability. Permanent Disability means your inability, by reason of any physical or mental impairment, to substantially perform the significant aspects of your regular duties as contemplated by this Agreement and which inability is reasonably contemplated to continue for at least one (1) year from its incurrence and at least ninety (90) days from the date of such vote. Any question as to the existence, extent, or potentiality of your Permanent Disability shall be determined by a qualified independent physician selected by you (or, if you are unable to make such selection, by an adult member of your immediate family), and reasonably acceptable to the Company. Such physician's written determination of your Permanent Disability shall, upon delivery to the Company, be final and conclusive for purposes of this Agreement; provided, however, that no such determination shall be final and conclusive with respect to any disability coverage under paragraph 3(c).
 - (c) Your Involuntary Termination, as set forth in paragraph 6 below.
 - (d) Your Removal for Cause, as set forth in paragraph 7(a) below.
 - (e) Your voluntary termination (other than termination on account of death, Permanent Disability or termination by you for Good Reason) upon ninety (90) days prior written notice; provided, however, that the Company may waive such notice requirement in a written waiver delivered to you.

5. <u>Death and Disability</u>.

- (a) If the Employment Term terminates by reason of your death or your Permanent Disability as provided in paragraph 4, then, except as provided in this paragraph 5(a), no further compensation will become payable to you under this Agreement, other than any earned but unpaid Base Salary, earned but unpaid bonuses, the pro rata portion of incentive compensation earned for services rendered through the date of your death or Permanent Disability, any deferred compensation and all other payments, benefits or fringe benefits to which you may be entitled under the terms of any applicable compensation arrangement or benefit, equity or fringe benefit plan or program or grant (other than any severance plan) or this Agreement (collectively, "Entitlements"). Entitlements shall be calculated and paid as set forth in paragraph 5(c) below. You shall also be entitled to the Stock Option Treatment (as set forth in paragraph 8(f) below). In the event of your termination on account of your Permanent Disability, the Company shall pay you 100% of your Base Salary which you would have received during the eighteen (18) month period following your date of termination, such payment to be made in lump sum on the sixtieth (60th) day following termination, reduced by the projected amount of disability payments you are expected to receive during such period, calculated at the time of your termination, and assuming your continuous disability for the full (18) month period, and the Company shall also (i) continue to provide for insurance and other payments that are to be made under disability policies or plans paid for or maintained by the Company, (ii) continue to provide life insurance at a level of coverage comparable to the coverage in effect for you at the time of your termination on account of Permanent Disability, and (iii) pay you a monthly amount equal to COBRA premiums for medical and dental coverage as set forth in subparagraph (b) below, in each case upon the same terms and conditions (except for the requirement of your continued
- (b) With respect to monthly amount for medical and dental coverage provided under paragraph 5(a), you shall be required to pay the applicable COBRA premium for you and your dependents, or to obtain coverage for you and your dependents under substitute arrangements, and you shall be paid a monthly amount by the Company equal to such amount, and to the extent you incur tax that you would not have incurred as an active employee as a result of the aforementioned coverage, you shall receive from the Company an additional gross-up payment in the amount necessary, subject to paragraph 14(o)(i), so that you will have no additional cost for receiving such items or any additional payment.
- (c) Earned but unpaid bonus shall mean any declared but unpaid bonus for any prior bonus period and, if the bonus for the current bonus period is other than totally discretionary, a pro rata portion of the calculated bonus for the bonus period based on days in the bonus period. Any incentive compensation shall be deemed earned and shall be paid based on actual results during the measuring period and a pro rata measurement of the days in the incentive period prior to termination of your services compared to total days in the incentive period. Such pro rata bonus and incentive compensation shall be paid to you at the same time and form that bonuses and incentive compensation are paid to other active participants. Any deferred compensation shall be paid in accordance with the terms of the applicable plan. Base Salary shall be paid in accordance with normal payroll practice.

6. <u>Involuntary Termination</u>.

- (a) Involuntary Termination shall mean either your termination by the Company in accordance with paragraph 6(b) hereof, or your resignation in accordance with paragraph 6(c) hereof.
- (b) Termination By The Company Without Cause: Your termination by the Company shall be considered to be "without cause" if (i) you are terminated or dismissed, for reasons other than your death, Permanent Disability or "Removal for Cause," as President or Chief Executive Officer, unless you have previously consented in writing to such removal or dismissal (which consent may be given or withheld in your sole discretion); provided, however, that your termination or dismissal as President shall not be a Termination by the Company without Cause if the person appointed President reports to you, or (ii) prior to your sixty-fifth (65th) birthday, the Company gives notice of nonextension of the Employment Term pursuant to paragraph 2 hereof.
- (c) Termination By You For Good Reason: Your resignation shall be considered to be for Good Reason if you resign as President and Chief Executive Officer (whether or not you resign as a Director and, if Chairman of the Board, as Chairman of the Board) upon ninety (90) days' prior written notice within ninety (90) days after the occurrence of one of the following events: (i) your removal, dismissal or failure to be re-elected as President or Chief Executive Officer (other than on account of your termination for some other reason) or a de jure or de facto material reduction in your duties, title, responsibilities, authority, status, or reporting responsibilities (other than in connection with the appointment of a Chief Operating Officer or President who reports to you), unless you have previously consented in writing to such removal, dismissal or reduction (which consent may be given or withheld in your sole discretion); (ii) the failure to elect you, or your removal, dismissal or failure to be re-elected, as Chairman of the Board if the current Chairman of the Board ceases to serve as such; (iii) the failure of the Company to pay to you any amount due under this Agreement within ten (10) days after the later of its due date or your written demand for payment of such amount; (iv) any material breach by the Company of any provision of this Agreement which is not curred within thirty (30) days after your giving of written notice of such breach to the Company; (v) one year after a Change of Control, as defined in Exhibit A hereto, to the extent you are employed hereunder at that time; (vi) the relocation of the Company's principal executive office more than fifty (50) miles from the current location; or (vii) the failure of the Company to obtain and deliver to you a reasonably satisfactory written agreement from any successor to the Company as provided in paragraph 14(l).

(d) Upon an Involuntary Termination, you will become entitled to the benefits specified in paragraph 8 of this Agreement. In addition, you will be entitled to your Entitlements as calculated and paid in accordance with paragraph 5(c) above.

7. Removal for Cause.

- (a) Removal for Cause shall mean the termination of your duties as President, Chief Executive Officer and, if you are then serving in such capacity, Chairman of the Board, effected by the Board of Directors of the Company (after a Board of Directors meeting for which you had at least ten (10) days prior written notice and at which you had the opportunity to have counsel present to represent you in connection with issues concerning your removal for cause) by reason of any one or more of the following, which individually or in the aggregate has a material adverse effect on the aggregate business or affairs of the Company and any Related Entity:
 - (i) your gross neglect of your duties, your willful and continuing refusal to perform your duties (other than, in any such case, because of a reasonably documented mental or physical illness), your refusal to obey any lawful order of the Board of Directors, or any material breach by you of any provision of paragraphs 11 or 12 of this Agreement, which, in any of the foregoing events, continues for more than thirty (30) days following your receipt of written notice from the Board of Directors that describes such breach or other event
 - (ii) your willful misconduct with respect to the business or affairs of the Company or of any Related Entity
 - (iii) your conviction of, or your plea of nolo contendere to, a misdemeanor involving embezzlement or fraud or other offense involving money or other property of the Company (other than a good faith dispute over expense account items), any criminal violation of the Securities Act of 1933 or the Securities Exchange Act of 1934, or any felony, provided your rights of appeal with respect to such matter have either lapsed or been exercised
- (b) Upon your Removal for Cause, you will be entitled to your Entitlements as calculated and paid in accordance with paragraph 5(c) above. In such case, no amounts will be payable to you under paragraph 8 of this Agreement for any reason whatsoever.
- (c) In the event of your voluntary termination in accordance with paragraph 4(e), you shall receive the same amounts as if you were Removed for Cause plus the Stock Option Treatment (as set forth in paragraph 8(f)).

8. Severance Benefits.

- (a) Subject to paragraphs 8(b) and 8(e), upon an Involuntary Termination, you will become entitled to the following severance benefits:
 - (i) The Company will pay you an amount equal to one and one-quarter (1-1/4) times the sum of (x) your Base Salary in effect (or, if improperly reduced, required to be in effect) at the time of your Involuntary Termination and (y) the average of the annual bonuses paid or payable to you during the three (3) completed fiscal years prior to your Involuntary Termination; and such payment shall made to you in lump sum on the date specified in paragraph 8(g) below.
 - (ii) With respect to medical and dental coverage, you shall be required to pay the applicable COBRA premium for you and your dependents, or to obtain covering for you and your dependents under substitute arrangements, for eighteen (18) months, and you shall be reimbursed monthly by the Company for such amount, and to the extent you incur tax that you would not have incurred as an active employee as a result of the aforementioned coverage, you shall receive from the Company, subject to paragraph 14(o)(i), an additional gross-up payment in the amount necessary so that you will have no additional cost for receiving such items or any additional payment. The Company shall continue to provide you and your eligible dependents, upon the same terms and conditions (except for the requirement of your continued employment), with life insurance at a level of coverage comparable to the coverage in effect for you at the time of your Involuntary Termination for the eighteen (18) month period following your Involuntary Termination.
- (b) Notwithstanding paragraph 8(a), upon your Involuntary Termination within three (3) years after a Change of Control, as defined in Exhibit A hereto, or within three (3) months prior thereto in anticipation of a Change of Control, you will become entitled to the following severance benefits in lieu of the amounts under paragraph 8(a) above:
 - (i) The Company will make a lump sum payment to you at on the date specified in paragraph 8(g) below of an amount equal to three (3) times the sum of (x) your Base Salary in effect (or, if improperly reduced, required to be in effect) at the time of your Involuntary Termination and (y) the average of the annual bonuses paid or payable to you during the three (3) completed fiscal years prior to your Involuntary Termination or, if higher, the three (3) completed fiscal years prior to the Change of Control.
 - (ii) Any bonus, vacation pay or other compensation accrued or earned under law or in accordance with the Company's policies applicable to you but not yet paid and any incurred but unreimbursed business expenses for the period prior to termination shall be payable, subject to paragraph 14(o)(i), in accordance with the Company's policies and the terms of the applicable plan

- (iii) With respect to medical and dental coverage, you shall be required to pay the applicable COBRA premium for you and your dependents, or to obtain covering for you and your dependents under substitute arrangements, for the thirty-six (36) month period following your Involuntary Termination, and you shall be reimbursed monthly by the Company for such amount, and to the extent you incur tax that you would not have incurred as an active employee as a result of the aforementioned coverage, you shall receive from the Company, subject to paragraph 14(o)(i), an additional gross-up payment in the amount necessary so that you will have no additional cost for receiving such items or any additional payment. The Company shall continue to provide you and your eligible dependents, upon the same terms and conditions (except for the requirement of your continued employment), with life insurance at a level of coverage comparable to the coverage in effect for you at the time of your Involuntary Termination for the thirty-six (36) month period following your Involuntary Termination.
- (iv) All stock options, whether heretofore or hereafter, granted to you shall become fully vested and immediately exercisable and, if the basis were an action in anticipation of the Change of Control, the option shall remain exercisable (unless the original terms would otherwise end) at least through the Change of Control
- (c) Each of your outstanding loans from the Company will become due and payable in accordance with their existing terms and provisions, and none of these loans will be forgiven or otherwise canceled in whole or in part.
- (d) The Company agrees that if your employment with the Company is terminated during the Employment Term for any reason whatsoever, you are not required to seek other employment or to attempt in any way to reduce any amounts payable to you by the Company pursuant to this Agreement. Further, the amount of any payment or benefit provided for in this Agreement shall not be reduced by any compensation earned by you or benefit provided to you as the result of employment by another employer or otherwise. In addition, the amounts payable hereunder shall not be subject to setoff, counterclaim, recoupment, defense or other right which the Company may have against you or others, except upon obtaining by the Company of a final nonappealable judgment against you.
- (e) In the event that you have received or commenced receipt of any payments or other rights under paragraphs 5(a) or 8(a), you shall not be entitled to any additional payments or rights under paragraphs 5(a), 8(a), or 8(b) with respect to any subsequent occurrence which might otherwise give rise to such payments or rights under such paragraphs, except as specifically provided with regard to paragraph 8(b).
- (f) Notwithstanding anything to the contrary in this Agreement or any other agreement between you and the Company, the Company agrees that if your employment with the Company terminates during the Employment Term for any reason (other than a Removal for Cause), including a termination of employment pursuant to paragraphs 4(a), 4(b), 4 (c) and 4(e), (i) all of your stock options and other equity awards shall continue to vest in accordance with the terms of the applicable grant agreement notwithstanding the employment termination, (ii) you (or your executors or administrators of your estate, in the case of your death) shall be entitled to exercise any of your stock options at any time during the original term of such options, and (iii) all agreements relating to your stock options or other equity shall be deemed amended to the extent inconsistent with the foregoing (such continued vesting and exercisability, the "Stock Option Treatment").

- (g) Any amounts payable and benefits or additional rights provided pursuant to paragraphs 8(a) or 8(b) beyond Entitlements ("Release Conditioned Amounts") shall be payable only if you deliver to the Company a release of all claims that you have or may have (and you do not revoke the release within the revocation period) within sixty (60) days after your termination in a form substantially in the form of Exhibit B hereto. Release Conditioned Amounts shall be paid to you in a lump sum, or shall commence if in installments, on the sixtieth (60th) day following your date of termination, with any missed installment payments paid in a lump sum on such date.
- 9. <u>Excise Tax</u>. In the event that you become entitled to payments and/or benefits which would constitute "parachute payments" within the meaning of Section 280G(b)(2) of the Internal Revenue Code of 1986, as amended, (the "Code"), the provisions of Exhibit C shall apply.
- 10. Proprietary Information and Inventions. You understand and acknowledge that:
 - (a) The Company is and will be engaged in a continuous program of research, design, development, production, and marketing with respect to its business.
 - (b) Your employment by the Company creates a relationship of confidence and trust between the Company and you with respect to certain information relating to the business and affairs of the Company or applicable to the business of any client, customer, consultant, partner, external collaborator, or service provider of the Company, which may be made known to you by the Company or by any client, customer, consultant, partner, external collaborator, or service provider of the Company, or learned by you during the period of your affiliation with the Company.
 - (c) The Company will possess information created, discovered, or developed by, or otherwise become known to, the Company (including, without limitation, information created, discovered, developed, or made known to you during the Employment Term) or in which property rights have been or may be assigned or otherwise conveyed to the Company (whether or not the information has commercial value in the business in which the Company is or proposes to be engaged) and is treated by the Company as confidential. All this information is "Proprietary Information," which includes, but is not limited to, systems, processes, formulae, data, functional specifications, computer software, programs and displays, know-how, improvements, discoveries, inventions, developments, designs, techniques, marketing plans, strategies, forecasts, new and proposed products, unpublished financial statements, budgets, projections, licenses, prices, costs, and customer, external collaborator, partner, client, and supplier lists, and any and all intellectual properties. The foregoing, however, shall not cover information generally known in the industry or which hereafter become generally known in the industry.

11. Ownership of Proprietary Information and Inventions.

- (a) All Proprietary Information shall be the sole property of the Company and its assigns, and the Company and its assigns will be the sole owners of all inventions, patents, copyrights, trademarks, and other rights in connection therewith. You hereby assign to the Company any right you may have or acquire in such Proprietary Information. At all times, you will keep in strictest confidence and trust all Proprietary Information and you will not use or disclose any Proprietary Information without the written consent of the Company.
- (b) If your employment with the Company is terminated for any reason, you will deliver to the Company all documents, notes, drawings, specifications, computer software, data, inventions, organisms, and other materials of any nature pertaining to any Proprietary Information, and will not take any of the foregoing, or any reproduction of any of the foregoing, that is embodied in any tangible medium of expression. This shall not limit you from retaining your personal phone directories and rolodexes.
- (c) You will promptly disclose to the Company (or any persons designated by it) all discoveries, developments, designs, improvements, inventions, formulae, processes, techniques, computer software, strategies, know-how, and data, whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by you, either alone or jointly with others, during your employment by the Company, which result from carrying out your responsibilities to the Company, or result from the use of premises or property owned, leased, or contracted for by the Company (all such discoveries, developments, designs, improvements, inventions, formulae, processes, techniques, computer software, know-how, and data are referred to in this Agreement as Inventions). You will also promptly disclose to the Company, and the Company agrees to receive all such disclosures in confidence, all other discoveries, developments, designs, improvements, inventions, formulae, processes, techniques, computer software, strategies, know-how, and data, whether or not patentable or registrable under copyright or similar statutes, made or conceived or reduced to practice or learned by you, either alone or jointly with others, during your employment by the Company for the purpose of determining whether they are Inventions, as that term is used in this Agreement. At all times during your employment by the Company you will use your reasonable business efforts to avoid conflicts of interest involving potential rights and claims of the Company and of third parties to Inventions, including those that might arise by virtue of your affiliation with a university or other medical institution concurrently with your employment by the Company and will take all action reasonably necessary and or desirable to minimize the probability of any such conflicts of interest and to maximize the likelihood that any Inventions made, conceived or developed or reduced to practice by you (alone or jointly with others) during your empl

(d) All Inventions shall be the sole property of the Company and its assigns, and the Company and its assigns shall be the sole owner of all patents, copyrights, trademarks, and other rights in connection therewith. You hereby assign to the Company any rights you may have or acquire in such Inventions. You will assist the Company in every proper way as to all such Inventions (but at the Company's expense) to obtain and from time to time enforce patents, copyrights, trademarks, and other rights and protections on and enforcing such Inventions, as the Company may desire, together with any assignments thereof to the Company or persons designated by it. Your obligation to assist the Company in obtaining and enforcing patents, copyrights, trademarks, and other rights and protections relating to such Inventions in any and all countries shall continue beyond the Employment Term. If the Company is unable, after reasonable effort, to secure your signature on any document or documents needed to apply for or prosecute any patent, copyright, or other right or protection relating to an Invention, for any other reason whatsoever, you hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as your agent and attorney-in-fact, to act for and on your behalf to execute and file any such application or applications and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights, or similar protections thereon with the same legal force and effect as if executed by you and you hereby ratify, affirm, and approve all such lawfully permitted acts accordingly.

12. Restricted Covenant.

(a) You are aware that the services you perform for the Company are of a special, unique character. You also acknowledge your possession and future possession of Proprietary Information and the highly competitive nature of the business of the Company. Accordingly, you agree that, for the consideration set forth in this Agreement, you will not, without the written permission of the Company pursuant to Board of Directors authorization, during your employment under this Agreement and, if your employment ends as a result of your voluntary termination of employment pursuant to paragraph 4(e), for a period of one (1) year thereafter (six (6) months, in the event of any such termination after the occurrence of a Change of Control): (i) directly or indirectly engage or become interested or involved in any Competitive Business (as defined in subparagraph (b) below), whether such engagement, interest, or involvement shall be as an employer, officer, director, owner shareholder, employee, partner, consultant, or in any other capacity or relationship; provided, however, that this shall not preclude a passive investment of less than one (1%) of the stock of any publicly traded company; or (ii) materially assist others in engaging in any Competitive Business in the manner described in the foregoing clause (i); provided, further, that this shall not preclude you from providing investment banking services to or on behalf of an entity after your termination of employment that might otherwise be a Competitive Business so long as such services are to arrange a purchase, sale or other business combination for or with such entity or to arrange financing for such entity (including, without limitation, obtaining a bank loan for such entity or participating in the sale of the debt or equity securities of such entity).

You understand that this provision is not meant to prevent you from earning a living or fostering your career. It does intend, however, to prevent Competitive Businesses from gaining any unfair advantage from your knowledge of Proprietary Information. You understand that by making any other employer aware of this provision, that employer can take such action as to avoid your breach of this provision and to indemnify you in the event of a breach.

- (b) The term "Competitive Business" means:
 - (i) For the period commencing on the date of this Agreement and ending on the date of your termination of employment any business or activity that is substantially the same as any business or activity of the Company as conducted by the Company or any Related Entity during such period; and
 - (ii) For the period thereafter, any business or activity described in subparagraph (i) above to the extent that on the date of your termination of employment such business or activity represents at least 10% of the research and development budget of the Company for the fiscal year in which your termination occurs; provided, however, that any business or activity of the Company shall be deemed to have been conducted by the Company at the time of your termination of employment if the Company has undertaken steps to commence such business or activity prior to your termination of employment. Notwithstanding the foregoing, the provisions of this paragraph shall not operate to preclude your employment with (or providing consulting services to) any company that has a market capitalization at the time of your termination of employment of at least \$500 million.
- 13. <u>Litigation Support</u>. Subject to your other commitments, following the Employment Term, you shall make yourself reasonably available to cooperate (but only truthfully) with the Company and provide information as to matters with which you were personally involved, or have information on, while you were an officer of the Company and which are or become the subject of litigation or other dispute.

14. General Provisions.

- (a) <u>Death</u>. Should you die before receipt of any or all severance payments to which you became entitled under paragraph 8, then the balance of the payments to which you are entitled shall continue to be paid in accordance with the terms hereof to the executors or administrators of your estate.
- (b) <u>General Creditor Status</u>. The amounts to which you may become entitled hereunder shall be paid, when due, from the general assets of the Company, and no trust fund, escrow arrangements, or other segregated account shall be established as a funding vehicle for such payment. Accordingly, your right (or the right of the executors or administrators of your estate) to receive such benefits shall at all times be that of a general creditor of the Company and shall have no priority over the claims of other general creditors.
- (c) <u>Indemnification</u>. During the Employment Term and thereafter, the Company shall indemnify you and hold you harmless to the fullest extent permitted by law against any judgments, fines, amounts paid in settlement and reasonable expenses (including reasonable attorneys' fees), and advance amounts necessary to pay the foregoing at the earliest time and to the fullest extent permitted by law, in connection with any claim, action or proceeding (whether civil or criminal) against you as a result of you serving as an officer or Director of the Company or in any capacity at the request of the Company in or with regard to any other entity, employee benefit plan or enterprise. This indemnification is in addition to and not in lieu of any other indemnification rights you may otherwise have.
- (d) Remedies. Your obligations under paragraphs 11 or 12 of this Agreement will survive termination of your employment by the Company. You acknowledge that a remedy at law for any breach or threatened breach of such provisions would be inadequate and therefore agree that the Company may be entitled to injunctive relief and any other available rights and remedies in case of any such breach or threatened breach; provided, however, that nothing contained in this subparagraph (d) will be construed as prohibiting the Company from pursuing any other remedies available for any such breach or threatened breach.
- (e) <u>Interpretation</u>. This Agreement shall be interpreted under the laws of the State of New York without regard to conflict of law provisions thereof.
- (f) Notices. Any notice which a party is required or may desire to give under this Agreement will be given by personal delivery, air courier, or registered or certified mail, return receipt requested, addressed to you at the address of record with the Company and addressed to the Secretary of the Company at its principal office, or at such other place as either party may from time to time designate in writing given as aforesaid. The date of delivery of any notice or communication will be deemed to be (i) the date of delivery thereof, in the case of personal delivery; (ii) the day after the date when dispatched, in the case of air courier; and (iii) the date of receipt, in the case of mailing.

- (g) <u>Waivers</u>. If either party shall waive any breach of any provision of this Agreement, he or it will not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.
- (h) <u>Headings</u>. The paragraph headings of this Agreement are for convenience only and will not be deemed to affect the meaning of the Agreement.
- (i) <u>Superseding</u>. This Agreement supersedes all prior agreements between you and the Company relating to the subject of your personal services and severance benefits, including the letter agreement dated September 14, 1993, which is hereby terminated. The provisions of this Agreement may only be amended by written instrument signed by you and a member of the Board of Directors.
- (j) <u>No Guarantee of Employment or Service</u>. Nothing in this Agreement is intended to provide you with any right to continue in the service of the Company for any period of specific duration, nor, except as specifically provided herein, to provide the Company with any right to require you to continue in the service of the Company.
- (k) <u>Amendment or Termination</u>. This Agreement may not be amended or terminated orally, but only by a writing executed by the party to be charged.
- (l) Assignment. None of the benefits to which you may become entitled hereunder may be assigned, transferred, pledged, or otherwise encumbered by you, and to the maximum extent permissible under law, such benefits will not be subject to the claims of your creditors or to levy, attachment, execution, or other legal process. This Agreement shall be binding upon and inure to the benefit of the Company, its successors and permitted assigns and your executors and heirs, provided that the Company may not assign the Agreement except in connection with a sale of all or substantially all of its assets and then only if said acquiror assumes in a writing delivered to you the obligations of the Company hereunder.
- (m) Costs of Collection. In the event either party collects any part or all of the payments provided for hereunder or otherwise successfully enforces the terms of this Agreement by or through a lawyer or lawyers, the losing party shall pay all costs of such collection or enforcement, including reasonable legal fees and other fees and expenses which the successful party may incur plus interest ("Costs"); provided, however, that the Company shall not be entitled to recover any Costs from you unless an arbitrator determines that your action to recover any payment or to enforce the terms of this Agreement was not grounded on a reasonable good faith interpretation of the Agreement or that the action was undertaken for the primary purpose of harassing the Company. Interest shall be calculated at the prime rate as announced from time to time by Citibank, N.A. on all or any part of any amount to be paid to you hereunder that is not paid when due. The prime rate for each calendar quarter shall be the prime rate in effect on the first day of the calendar quarter. Any amounts due and payable to you on a favorable award of the arbitrator, pursuant to this paragraph 14(m) and paragraph 14(n), shall be paid within sixty (60) days following the date the arbitrator's decision becomes final.

- (n) Arbitration. Any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration, conducted before a panel of three (3) arbitrators in New York, New York, in accordance with the rules of the American Arbitration Association then in effect, and judgment may be entered on the arbitrators' award in any court having jurisdiction. The Company shall pay all costs of the American Arbitrator Association and the arbitrator. The decision upon arbitration shall be final and binding upon both you and the Company. Notwithstanding the foregoing, you shall be entitled to seek specific performance from a court of your right to be paid until the date of termination during the pendency of any dispute or controversy arising under or in connection with this Agreement and the Company shall have the right to obtain injunctive relief from a court pursuant to subparagraph (d) above.
- (o) Section 409A. It is the intention of the parties hereto that the provisions of this Agreement comply with or be exempt from Section 409A of the Code and the regulations and guidance promulgated thereunder ("Section 409A") and that the Agreement shall be construed in accordance with such intention. Without limiting the generality of the foregoing, the Company and you agree as follows:
 - (i) Reimbursements payable to you as a result of the operation of paragraph 3(c), paragraph 3(d), paragraph 3(f) (other than the "Grandfathered Reimbursements"), paragraph 3(g), paragraph 3(h), paragraph 5, paragraph 8 (including paragraphs 8(b) (iii) and 8(f)), paragraph 14(c) or paragraph 14(m) hereof, or any other provision in this Agreement regarding reimbursement, shall be paid to you within sixty (60) days following the date upon which you become entitled to the reimbursement (or such earlier date specified in this Agreement), but in no event later than the end of the calendar year following the year in which the expenses to be reimbursed are incurred (or, in the case of payments under paragraph 14(m), the year following the year in which you become entitled to reimbursement). Tax gross-up payments (and related reimbursements) payable to you as a result of the operation of paragraph 3(f), paragraph 5(b), paragraph 8(f), paragraph 9 or Exhibit C hereof, or any other provision in this Agreement regarding tax gross-up payments, shall be paid to you within sixty (60) days following the date upon which the tax resulting in the gross-up is paid, but in no event later than the end of the calendar year following the year in which the tax resulting in the gross-up is paid. With regard to such reimbursements and payments under this paragraph or elsewhere in the Agreement, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits shall not be subject to liquidation or exchange for another benefit, and (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year, provided that the foregoing clause (ii) shall not be violated without regard to expenses reimbursed under any arrangement covered by Section 105(b) of the Code solely because such expenses are subject to a limit related to the period the arrangement is in effect.

- (ii) Notwithstanding anything to the contrary herein, if you are a "specified employee" (within the meaning of Section 409A(a)(2)(B)(i) of the Code) with respect to the Company, (1) any amounts (or benefits) otherwise payable to or in respect of you under this Agreement pursuant to your termination of employment with the Company, which are deferred compensation under Section 409A, shall be delayed for a period of six months following such termination (or until death if earlier), so that taxes are not imposed on you pursuant to the operation of Section 409A, and shall be paid on first business day following the expiration such six month period and (2) any payments and benefits not required to be so delayed shall be paid or provided in accordance with this Agreement.
- (iii) For purposes of amounts under this Agreement which are subject to Section 409A, your employment with the Company will not be treated as terminated unless and until such termination of employment constitutes a "separation from service" for purposes of Section 409A.
- (iv) For purposes of Section 409A, to the extent that any payment payable under the Agreement is to be paid in installments, each such payment shall be treated as a separate identified payment for purposes of Section 409A. To the extent that the Agreement provides for a payment to be made on or before a specified date, the decision with respect to when to make such payment within the specified period shall be made in the sole discretion of the Company.
- (v) The Company shall gross you up for any taxes, interest or penalties incurred by you under Section 409A as a result of any payments or benefits hereunder or otherwise due from the Company in such a manner that you will have no after tax cost as a result thereof, as soon as practicable but in no event later than the last day of the calendar year following the calendar year in which such tax, interest or penalty is paid. You agree to reasonably cooperate with the Company in order to avoid the imposition of such taxes, it being understood that such cooperation shall not require you to forgo receipt or receive a reduced amount of payments or benefits due hereunder.

Please indicate your acceptance by signing the enclosed copy of this letter and returning it to the Company.				
Very truly yours,				
REGENERON PHARMACEUTICALS, INC.				
/s/ Arthur F. Ryan Chairman of the Compensation Committee of the Board of Directors				
AGREED TO AND ACCEPTED BY: LEONARD S. SCHLEIFER, M.D., Ph.D.				
/s/ Leonard Schleifer 18				
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EXHIBIT A

CHANGE OF CONTROL

For purposes of this Agreement, "Change of Control" shall be deemed to have occurred if the event set forth in any one of the following paragraphs shall have occurred:

- (i) any "Person" (as defined in Section 3(a)(9) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as modified and used in Sections 13(d) and 14(d) thereof, except that such term shall not include (1) the Company, (2) a trustee or other fiduciary holding securities under an employee benefit plan of the Company, (3) an underwriter temporarily holding securities pursuant to an offering of such securities, or (4) a corporation owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their ownership of stock of the Company) is or becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person any securities acquired directly from the Company) representing 20% or more of the Company's then outstanding securities, excluding any Person who is an officer or director of the Company or who becomes such a Beneficial Owner in connection with a transaction described in clause (A) of paragraph (iii) below; or
- (ii) the following individuals cease for any reason to constitute a majority of the number of directors then serving: individuals who, on the date hereof, constitute the Board of Directors and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including but not limited to a consent solicitation, relating to the election of directors of the Company) whose appointment or election by the Board of Directors or nomination for election by the Company's shareholders was approved or recommended by a vote of at least two-thirds (2/3) of the directors then still in office who either were directors on the date hereof or whose appointment, election or nomination for election was previously so approved or recommended; or
- (iii) there is consummated a merger or consolidation of the Company with any other corporation other than (A) a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) at least 60% of the combined voting power of the voting securities of the Company or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (B) a merger or consolidation effected to implement a recapitalization of the Company (or similar transaction) in which no Person is or becomes the Beneficial Owner, directly or indirectly, of securities of the Company (not including in the securities Beneficially Owned by such Person any securities acquired directly from the Company) representing 20% or more of the combined voting power of the Company's then outstanding securities; or
- (iv) the shareholders of the Company approve a plan of complete liquidation or dissolution of the Company or there is consummated an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets, other than a sale or disposition by the Company of all or substantially all of the Company's assets to an entity at least 75% of the combined voting power of the voting securities of which are owned by Persons in substantially the same proportions as their ownership of the Company immediately prior to such sale.

EXHIBIT B

FORM OF RELEASE

To: Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591-6707 Attention: [General Counsel]

- 1. Termination. (a) I hereby acknowledge that my employment with Regeneron Pharmaceuticals, Inc. (the "Company") [will terminate] [has terminated] on, (the "Termination Date") pursuant to provisions of paragraphs 8 of my employment agreement dated as of December 20, 2002 with the Company (the "Employment Agreement"), that the Company will not have an obligation to rehire me or to consider me for reemployment after the Termination Date and that my employment with the Company is permanently and irrevocably severed.
- (b) I hereby confirm my resignation from my position as President and Chief Executive Officer of the Company and that I will not be eligible for any benefits or compensation after the Termination Date, other than as specifically provided hereunder and in paragraphs 3 and 8 of the Employment Agreement [or in any capacity as a director of the Company]. In addition, effective as of the Termination Date, I hereby resign from all offices, directorships, trusteeships, committee memberships and fiduciary capacities held with, or on behalf of, the Company or any of its affiliates [other than as a director]. These resignations will become irrevocable on the Effective Date of this Agreement, as defined in Section 6 below.
- 2. Consideration. I acknowledge that this General Release is being executed in accordance with paragraph 8(g) of the Employment Agreement.
- 3. General Release. (a) For and in consideration of the payments to be made and the promises set forth under the Employment Agreement, I, for myself and for my heirs, dependents, executors, administrators, trustees, legal representatives and assigns (collectively referred to as "Releasors"), hereby forever release, waive and discharge the Company, its affiliates, employee benefit and/or pension plans or funds, insurers, successors and assigns, and all of its or their past, present and/or future directors, officers, trustees, agents, members, partners, counsel, employees, fiduciaries, administrators, representatives, successors and assigns, whether acting on behalf of the Company or its affiliates or in their individual capacities (collectively referred to as "Releasees"), from any and all claims, demands, causes of action, fees and liabilities of any kind whatsoever, whether known or unknown, which Releasors ever had, now have, or hereafter may claim to have against Releasees by reason of any actual or alleged act, omission, transaction, practice, policy, procedure, conduct, occurrence, or other matter up to and including the date of my execution of this General Release, in connection with, or in any way related to or arising out of, my employment, service as a director, service as a trustee, service as a fiduciary or termination of any of the foregoing with the Company.

- (b) Without limiting the generality of the foregoing, this General Release is intended and shall release the Releasees from any and all claims, whether known or unknown, which Releasors ever had, now have, or may hereafter claim to have against the Releasees including, but not limited to, (i) any claim of discrimination or retaliation under the Age Discrimination in Employment Act ("ADEA"), Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act ("ADA"), the Employee Retirement Income Security Act of 1974 or the Family and Medical Leave Act; (ii) any claim under the New York State Human Rights Law and the New York City Administrative Code; (iii) any other claim (whether based on federal, state or local law, statutory or decisional) relating to or arising out of my employment, the terms and conditions of such employment and/or any of the events relating directly or indirectly to or surrounding the termination of such employment, including, but not limited, breach of contract (express or implied), wrongful discharge, tortious interference, detrimental reliance, defamation, emotional distress or compensatory or punitive damages; and (iv) any claim for attorney's fees, costs, disbursements and the like.
- (c) I further acknowledge and agree that by virtue of the foregoing, I have waived all relief available to me (including without limitation, monetary damages, equitable relief and reinstatement) under any of the claims and/or causes of action waived in Sections 3(a) and (b) above. Therefore I agree that I will not seek or accept any award or settlement from any source or proceeding (including, but not limited to, any proceeding brought by any other person or by any government agency) with respect to any claim or right waived in this General Release. I further agree, to the maximum extent permitted by law, that I will not sue or commence any proceeding (judicial or administrative), or participate in any action, suit or proceeding (unless compelled by legal process or court order), against the Company (or any of its affiliates), with respect to any claim released by Sections 3(a) and (b) above, other than a claim contesting the validity of the release under applicable provisions of the ADEA. I also warrant and represent that as of the date I sign this Agreement, I have not taken or engaged in any of the acts described in the foregoing sentences. I understand that this release has neither the purpose nor intent of interfering with my protected right to file a charge with or participate in an investigation or proceeding pursuant to the statutes administered and enforced by the EEOC, specifically: the ADEA, the Equal Pay Act, Title VII of the Civil Rights Act of 1964 and the ADA. I may have to recover money or other relief in any lawsuit or proceeding brought by me or by an agency or third party, including the EEOC, on my behalf. If, notwithstanding the foregoing promises and understandings, I violate this Section 3(c), I shall be required, to the maximum extent permitted by law, to indemnify and hold harmless the Company (and its affiliates) from and against any and all demands, assessments, judgments, costs, damages, losses and liabilities, and attorneys' fees and other expenses which result from, or are incident
- (d) Notwithstanding anything herein to the contrary, the sole matters to which the release and covenants in this Section 3 do not apply are: (i) my rights of indemnification and directors and officers liability insurance coverage which I was entitled immediately prior to the Termination Date under the Company's By-laws or otherwise with regard to my service as an officer and director of the Company (including, without limitation, under paragraph 14(c) of the Employment Agreement); (ii) my rights under any tax-qualified pension or tax deferred annuity plan or claims for accrued vested benefits under any other employee benefit plan, program, policy or arrangement maintained by the Company or under COBRA; (iii) my rights under the provisions of the Employment Agreement which are intended to survive termination of employment (including claims to payments, benefits or entitlements specifically payable or provided under the Employment Agreement); or (iv) my rights as a stockholder or as a director of the Company.

- 4. Governing Law; Enforceability. The interpretation of this General Release will be construed and enforced in accordance with the laws of the State of New York without regard to that state's principles of conflicts of law. If, at any time after the execution of this General Release, any provision of this General Release will be held to be illegal or unenforceable by a court of competent jurisdiction, solely such provision will be of no force or effect.
- 5. Acknowledgement. I acknowledge that I have been advised by the Company in writing to consult, and I have consulted, independent legal counsel of my choice before signing this General Release. I further acknowledge that I have had the opportunity to consult independent legal counsel and to consider the terms of this General Release for a period of at least 21 days. I further acknowledge that I have carefully read this General Release in its entirety; that I have had an adequate opportunity to consider it and to consult with any advisors of my choice about it; that I have consulted with independent legal counsel of my choice who has answered to my satisfaction all questions I had regarding this General Release; that I understand all the terms of this General Release and their significance; that I am legally competent to execute this Agreement; that I have not relied on any statements or explanations made by the Company, any agent of the Company or its counsel; that I knowingly and voluntarily assent to all the terms and conditions contained herein; and that I am signing this General Release voluntarily and of my own free will.
- 6. Effective Date. I further acknowledge that this General Release will not become effective until the eighth day following my execution of this General Release (the "Effective Date"), and that I may at any time prior to the Effective Date revoke this General Release by delivering written notice of revocation to the Company, at 777 Old Saw Mill River Road, Tarrytown, New York 10591-6707, to the attention of the [General Counsel]. In the event that I revoke this General Release prior to the eighth day after its execution, this General Release will automatically be null and void.
- 7. **Surviv**al. The provisions in the Employment Agreement which are intended to survive termination of employment hall survive and continue in full force and effect.

Acknowledged and Agreed: REGENERON PHARMACEUTICALS, INC.

EXHIBIT C

GOLDEN PARACHUTE PROVISION

(a) (i) In the event that you shall become entitled to payments and/or benefits provided by this Agreement or any other amounts in the "nature of compensation" (whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement with the Company, any person whose actions result in a change of ownership or effective control covered by Section 280G(b)(2) of the Code or any person affiliated with the Company or such person) as a result of such change in ownership or effective control (collectively the "Company Payments"), and such Company Payments will be subject to the tax (the "Excise Tax") imposed by Section 4999 of the Code (and any similar tax that may hereafter be imposed by any taxing authority) the Company shall pay to you at the time specified in subsection (d) below (x) an additional amount (the "Gross-up Payment") such that the net amount retained by you, after deduction of any Excise Tax on the Company Payments and any U.S. federal, state, and for local income or payroll tax upon the Gross-up Payment provided for by this paragraph (a), but before deduction for any U.S. federal, state, and local income or payroll tax on the Company Payments, shall be equal to the Company Payments and (y) an amount equal to the product of any deductions disallowed for federal, state or local income tax purposes because of the inclusion of the Gross-Up Payment in your adjusted gross income multiplied by your actual applicable marginal rate of federal, state or local income taxation, respectively, for the calendar year in which the Gross-Up Payment is to be made.

(ii) Notwithstanding the foregoing, if it shall be determined that you are entitled to a Gross-Up Payment, but that if the Company Payments (other than that portion valued under Q&A 24(c) of the proposed regulations under Section 280G of the Code(the "Stock Vesting Value")) (the "Cash Payments") are reduced by the amount necessary such that the receipt of the Company Payments would not give rise to any Excise Tax (the "Reduced Payment") and the Reduced Payment (other than the Stock Vesting Value) would not be less than 90% of the Cash Payment, then no Gross-Up Payment shall be made to you and the Cash Payments, in the aggregate, shall be reduced to the Reduced Payments (other than the Stock Vesting Value). If the Reduced Payments is to be effective, payments shall be reduced as mutually agreed between the Company and you or, in the event the parties cannot agree, in the following order (1) any lump sum severance based on a multiple of Base Salary or annual bonus, (2) any other cash amounts payable to you and (3) any benefits valued as parachute payments.

(iii) In the event that the Internal Revenue Service or court ultimately makes a determination that the excess parachute payments plus the base amount is an amount other than as determined initially, an appropriate adjustment shall be made with regard to the Gross-Up Payment or Reduced Payment, as applicable to reflect the final determination and the resulting impact on whether (ii) applies.

- (b) For purposes of determining whether any of the Company Payments and Gross-up Payments (collectively the "Total Payments") will be subject to the Excise Tax and the amount of such Excise Tax, (x) the Total Payments shall be treated as "parachute payments" within the meaning of Section 280G(b) (2) of the Code, and all "parachute payments" in excess of the "base amount" (as defined under Section 280G(b) (3) of the Code) shall be treated as subject to the Excise Tax, unless and except to the extent that, in the opinion, delivered to the Company and you at a level of more likely than not, of the Company's independent certified public accountants appointed prior to any change in ownership (as defined under Section 280G(b)(2) of the Code) or tax counsel selected by such accountants (the "Accountants") such Total Payments (in whole or in part) either do not constitute "parachute payments," represent reasonable compensation for services actually rendered within the meaning of Section 280G(b)(4) of the Code in excess of the "base amount" or are otherwise not subject to the Excise Tax, and (y) the value of any non-cash benefits or any deferred payment or benefit shall be determined by the Accountants in accordance with the principles of Section 280G of the Code. In the event that the Accountants are serving (or decline to serve) as accountant or auditor for the individual, entity or group effecting the Change of Control, you may appoint another nationally recognized accounting firm or law firm to make the determinations hereunder (which accounting firm or law firm shall then be referred to as the "Accountants" hereunder). All determinations hereunder shall be made by the Accountants which shall provide detailed supporting calculations both to the Company and you at such time as it is requested by the Company or you. If the Accountants determine that payments under this Agreement must be reduced pursuant to this paragraph, they shall furnish you with a written opinion to such effect. The determination of the Accountant
- (c) For purposes of determining the amount of the Gross-up Payment, you shall be deemed to pay U.S. federal income taxes at actual rate of U.S. federal income taxation in the calendar year in which the Gross-up Payment is to be made and state and local income taxes at the rate of taxation in the state and locality of your residence for the calendar year in which the Company Payment is to be made, net of the reduction in U.S. federal income taxes which could be obtained from deduction of such state and local taxes if paid in such year. In the event that the Excise Tax is subsequently determined by the Accountants to be less than the amount taken into account hereunder at the time the Gross-up Payment is made, you shall repay to the Company, at the time that the amount of such reduction in Excise Tax is finally determined, the portion of the prior Gross-up Payment attributable to such reduction (plus the portion of the Gross-up Payment attributable to the Excise Tax and U.S. federal, state and local income tax imposed on the portion of the Gross-up Payment being repaid by you if such repayment results in a reduction in Excise Tax or a U.S. federal, state and local income tax deduction), plus interest on the amount of such repayment at the rate provided in Section 1274(b)(2)(B) of the Code. Notwithstanding the foregoing, in the event any portion of the Gross-up Payment thereof (and related amounts) shall not be required until actual refund or credit of such portion has been made to you, and interest payable to the Company shall not exceed the interest received or credited to you by such tax authority for the period it held such portion. Furthermore, to the extent the foregoing provision shall be deemed to create a loan of a personal nature in violation of Section 402 of the Sarbanes-Oxley Act of 2002, the provision for repayment shall be null and void. You and the Company shall mutually agree upon the course of action to be pursued (and the method of allocating the expense thereof) if your claim for refund or cred

In the event that the Excise Tax is later determined by the Accountant or the Internal Revenue Service to exceed the amount taken into account hereunder at the time the Gross-up Payment is made (including by reason of any payment the existence or amount of which cannot be determined at the time of the Gross-up Payment), the Company shall make an additional Gross-up Payment in respect of such excess (plus any interest or penalties payable with respect to such excess) at the time that the amount of such excess is finally determined.

- (d) The Gross-up Payment or portion thereof provided for in subsection (c) above shall be paid not later than the thirtieth (30th) day following an event occurring which subjects you to the Excise Tax; provided, however, that if the amount of such Gross-up Payment or portion thereof cannot be finally determined on or before such day, the Company shall pay to you on such day an estimate, as determined in good faith by the Accountant, of the minimum amount of such payments and shall pay the remainder of such payments (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code), subject to further payments pursuant to subsection (c) hereof, as soon as the amount thereof can reasonably be determined, but in no event later than the ninetieth day after the occurrence of the event subjecting you to the Excise Tax. In the event that the amount of the estimated payments exceeds the amount subsequently determined to have been due, such excess shall constitute a loan by the Company to you, payable on the fifth day after demand by the Company (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code), provided that, to the extent the foregoing provision shall be deemed to create a loan of a personal nature in violation of Section 402 of the Sarbanes-Oxley Act of 2002, the provision for repayment shall be null and void.
- (e) In the event of any controversy with the Internal Revenue Service (or other taxing authority) with regard to the Excise Tax, you shall permit the Company to control issues related to the Excise Tax (at its expense), provided that such issues do not potentially materially adversely affect you, but you shall control any other issues. In the event the issues are interrelated, you and the Company shall in good faith cooperate so as not to jeopardize resolution of either issue, but if the parties cannot agree you shall make the final determination with regard to the issues. In the event of any conference with any taxing authority as to the Excise Tax or associated income taxes, you shall permit the representative of the Company to accompany you, and you and your representative shall cooperate with the Company and its representative.
- (f) The Company shall be responsible for all charges of the Accountant.
- (g) The Company and you shall promptly deliver to each other copies of any written communications, and summaries of any verbal communications, with any taxing authority regarding the Excise Tax covered by this Exhibit C.
- (h) Any Gross-Up Payments hereunder shall be paid in the time and manner set forth in Section 14(o)(i) and (ii) of the Agreement.

REGENERON PHARMACEUTICALS. INC.

CHANGE IN CONTROL SEVERANCE PLAN

As amended and restated, effective November 14, 2008

INTRODUCTION

The purposes of this Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan (this "Plan") are (i) to help the Company (as defined below) retain key employees of the Company, (ii) to help maintain the focus of such employees on the business of the Company and to mitigate the distractions caused by the possibility that the Company may be the target of an acquisition; and (iii) to provide certain benefits to such employees in the event their employment is terminated (or constructively terminated) after, or in contemplation of, a change in control. The possibility of such terminations and the uncertainty it creates may result in the loss or distraction of key employees of the Company to the detriment of the Company and its shareholders.

The Company's Board of Directors (the "Board") considers the retention of key employees and the avoidance of such loss and distraction to be essential to protecting and enhancing the best interests of the Company and it shareholders. The Board also believes that when a change in control is perceived as imminent, or is occurring, the Board should be able to receive and rely on disinterested service from employees regarding the best interests of the Company and its shareholders without concern that employees might be distracted or concerned by the personal uncertainties and risks created by a change in control.

Accordingly, in order to accomplish the above purposes, the Board has caused the Company to adopt this Plan, as amended and restated effective November 14, 2008 (the "Effective Date").

- 1. <u>Definitions</u>. For the purpose of this Plan the foregoing terms shall have the following meanings:
- (a) "Anticipatory Termination" means a termination of an Eligible Executive's employment by the Company without Cause or by an Eligible Executive for Good Reason that occurs after a tender offer is announced for the Company or after material discussions have occurred with a possible acquirer with regard to a Transaction (as defined in the definition of "Change in Control" below), provided, that such offer or discussions have not terminated.
- (b) "Average Bonus" shall mean the average amount in each of the Company's last three (3) completed fiscal years prior to the termination of employment (or if higher the last three (3) completed fiscal years prior to the Change in Control) awarded to an Eligible Executive as an annual bonus for such years (or if not employed on the last day of three prior completed fiscal years, the average over those fiscal years when employed on the last day of a fiscal year or, if no such dates, the average of the Average Bonus of all Eligible Executives in the Eligible Executive's Group; provided, that any bonus awarded to an Eligible Executive for a fiscal year during which he or she was employed for only a portion of the year shall be annualized to reflect a full year's bonus for such year).
- (c) "<u>Bonus</u>" shall mean the product of (i) the Eligible Executive's annual base salary rate for the year in which the Date of Termination occurs (which is calculated immediately prior to any reduction in base salary (if any) if such termination is by the Eligible Executive for Good Reason) multiplied by (ii) the average of the percentages that bonuses represented of base salary for the fiscal years utilized to determine Average Bonus.
- (d) "Cause" shall mean, as to each Eligible Executive, (i) the Eligible Executive's willful misconduct involving the Company or its assets, business or employees or in the performance of his or her duties which is materially injurious to the Company (in a manner which would affect the Company economically or as to its reputation); (ii) the Eligible Executive's indictment for, or conviction of, or pleading guilty or nolo contendre to, a felony (provided that for this purpose, a felony shall cover any action or inaction that is a felony or crime under federal, state or local law in the United States (collectively, "U.S. law") and any action or inaction which takes place outside of the United States, if it would be a felony under U.S. law); (iii) the Eligible Executive's continued and substantial failure to attempt in good faith to perform his or her duties with the Company (other than failure resulting from the Eligible Executive's incapacity due to physical or mental illness or injury), which failure has continued for a period of at least ten (10) days after written notice thereof from the Company; (iv) the Eligible Executive's breach of any material provisions of any written agreement with the Company, which breach, if curable, is not cured within ten (10) days after written notice thereof from the Company; or (v) the Eligible Executive's failure to attempt in good faith to promptly follow a written direction of the Board or a more senior officer, provided that the failure shall not be considered "Cause" if the Eligible Executive, in good faith, believes that such direction, or implementation thereof, is illegal or inconsistent with the Company's Code of Conduct and he or she promptly so notifies the Chairman of the Board in writing. No act or failure to act by an Eligible Executive shall be deemed to be "willful" if the Eligible Executive believed in good faith that such action or non-action was in, or not opposed to, the best interests of the Company.

- (e) A "Change in Control" shall mean the occurrence of any of the following events: (i) any "Person" (as defined in Section 3(a) (9) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as modified and used in Sections 13(d) and 14(d) thereof, except that such term shall not include (1) the Company, (2) a trustee or other fiduciary holding securities under an employee benefit plan of the Company, (3) an underwriter temporarily holding securities pursuant to an offering of such securities, or (4) a corporation owned, directly or indirectly, by the shareholders of the Company in substantially the same proportions as their ownership of stock of the Company) is or becomes the "Beneficial Owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing thirty-five percent (35%) or more of the Company's then outstanding securities, excluding any Person who is an officer or director of the Company or who becomes such a Beneficial Owner in connection with a transaction described in clause (A) of subsection (iii) below; (ii) the following individuals cease for any reason to constitute a majority of the number of directors then serving; individuals who, on the Effective Date, constitute the Board and any new director (other than a director whose initial assumption of office is in connection with an actual or threatened election contest, including but not limited to a consent solicitation, relating to the election of directors of the Company) whose appointment or election by the Board or nomination for election by the Company's shareholders was approved or recommended by a vote of at least two-thirds (2/3) of the directors then still in office who either were directors on the Effective Date or whose appointment, election or nomination for election was previously so approved or recommended; (iii) there is consummated a merger or consolidation of the Company outstanding immediately prior to such merger or consolidation continuing to represent (ei
 - (f) "Code" shall mean the Internal Revenue Code of 1986, as amended.
 - (g) "Committee" shall mean the Compensation Committee of the Board.
- (h) "Company" shall mean Regeneron Pharmaceuticals, Inc. and any successor thereto; <u>provided</u>, that for the purposes of this Plan, other than any obligation to make payments or provide benefits hereunder and as to the definition of Change in Control, "Company" shall also include all of the Company's subsidiaries (as defined in Code Section 424(f)).
- (i) "<u>Disability</u>" shall mean, as to each Eligible Executive, the Eligible Executive's failure to have performed his or her material duties and responsibilities as a result of physical or mental illness or injury for more than one hundred eighty (180) days during a three hundred sixty-five (365) day period.

- (j) "Eligible Executives" shall mean Group 1 Executives and Group 2 Executives.
- (k) "Equity Grant" shall mean any stock option, restricted stock award, or other equity grant under the Company's long-term incentive plans.
- (l) "Good Reason" shall mean, as to each Eligible Executive, a termination (including, if applicable, by retirement in accordance with Company policy) by the Eligible Executive and effected by a written notice given within ninety (90) days after the occurrence of the Good Reason event. For purposes of this Agreement, "Good Reason" shall mean, as to each Eligible Executive, the occurrence of any of the following events without the Eligible Executive's express written consent which event is not cured within thirty (30) days after written notice thereof from the Eligible Executive to the Company: (i) any material diminution in the Eligible Executive's position, duties, responsibilities, title or authority, or the assignment to the Eligible Executive of duties and responsibilities materially inconsistent with his or her position, except in connection with the Eligible Executive's termination for Cause or as a result of death, or temporarily as a result of the Eligible Executive's incapacity or other absence for an extended period; (ii) any material breach by the Company of any material provision of any written agreement with the Eligible Executive or failure to timely pay any compensation obligation to the Eligible Executive; (iii) a reduction in the Eligible Executive's annual base salary or target bonus opportunity (if any); (iv) a relocation of the Eligible Executive's principal business location to an area outside of a fifty (50) mile radius of the Eligible Executive's current principal business location or (v) a failure by the Company to comply with this Plan.
- (m) "Group 1 Executive" shall mean an officer or other executive who has been designated by the Committee as a Group 1 Executive in accordance with Section 2 below.
- (n) "Group 2 Executive" shall mean an officer or other executive who has been designated by the Committee as a Group 2 Executive in accordance with Section 2 below.
 - (o) "Severance Multiplier" shall mean one for Group 1 Executives and two for Group 2 Executives.
- (p) A termination "<u>without Cause</u>" shall mean a termination of an Eligible Executive's employment by the Company other than for a termination for Cause or due to Disability.

- 2. <u>Eligible Executives</u>. Eligible Executives shall consist of those officers and other executives of the Company as the Committee in its sole discretion designates in writing to participate in the Plan. At the time the Committee designates an employee as an Eligible Executive, the Committee shall also designate whether such Eligible Executive is a Group 1 Executive or a Group 2 Executive. The Committee may, in its sole discretion, terminate an employee's participation in the Plan as an Eligible Executive by providing not less than one (1) year's prior written notice to the employee (a "Plan Participation Termination Notice") at any time following the two (2) year anniversary of the Effective Date; <u>provided</u>, that no Plan Participation Termination Notice shall be effective after a Change in Control (whether sent before or after). The Committee may designate additional Eligible Executives or change the designation of any Group 1 Executive to a Group 2 Executive at any time in its sole discretion.
 - 3. <u>Termination of Employment in Connection with a Change in Control</u>. Subject to the provisions of Section 24 hereof:
- (a) If (i) a Change in Control occurs and an Eligible Executive's employment with the Company is terminated by the Company without Cause or by the Eligible Executive for Good Reason at any time within two (2) years after the Change in Control or (ii) there was an Anticipatory Termination and the Change in Control has taken place within one hundred eighty (180) days thereafter, such Eligible Executive shall be entitled to the amounts provided in Section 4 upon such termination or, if an Anticipatory Termination, upon the Change in Control (less any severance benefits previously paid or provided by the Company).
- (b) In the event of an Anticipatory Termination, if any Equity Grants in the name of the applicable Eligible Executive would vest as a result of the Anticipatory Termination had it occurred after the Change in Control (or the Equity Grant otherwise would have vested pursuant to tist terms on or prior to the Change in Control if not for the Anticipatory Termination), any such Equity Grant that otherwise would be forfeited shall not be forfeited pending a determination of whether or not a Change in Control occurs within one hundred eighty (180) days thereafter (the "Determination Period"), but during the Determination Period no unvested Equity Grant shall vest or be exercisable and no dividends shall be payable unless and until the Change in Control takes place during the Determination Period. If a Change in Control occurs during the Determination Period, then the Equity Grants that would have vested during the Determination Period absent the Anticipatory Termination and any Equity Grants that would vest on the Change in Control or, upon a without Cause or Good Reason termination within two (2) years thereafter, shall become vested upon the Change in Control and the exercise period of all Equity Grants that are subject to exercise conditions shall be extended, to the extent applicable, to the later of (i) the permitted exercise dates after the Anticipatory Termination provided in the plan or grant assuming the Change in Control had happened immediately prior to the Anticipatory Termination and (ii) the date which is thirty (30) days following the first date after such Change in Control in which shares of the Company could be traded by the Eligible Executive on the applicable market under Code Section 409A without such Equity Grant being deemed subject to the additional tax under Code Section 409A, and (y) in no event beyond the initial expiration date of the grant. In the event an Equity Grant would expire after an Anticipatory Termination and prior to it becoming exercisable (including as a result of a Change in

- 4. Compensation on Change in Control Termination. (a) If, pursuant to Section 3, an Eligible Executive is entitled to amounts and benefits under this Section 4, such Eligible Executive shall receive the following payments and benefits from the Company:
- (i) (A) any base salary, bonus, paid time off or other compensation accrued or earned under law or in accordance with the Company's policies and practices applicable to the Eligible Executive but not yet paid; (B) subject to submission of appropriate documentation, any incurred but unreimbursed business expenses for the period prior to the Eligible Executive's termination payable in accordance with the Company's policies and practices; and (C) any other amounts or vested benefits due under the then applicable employee benefit (including without limitation any Supplemental Executive Retirement Plan), equity or incentive plans of the Company then in effect, applicable to the Eligible Executive (including, without limitation, the Company's 401(k) Savings Plan) as shall be determined and paid in accordance with such plans;
- (ii) subject to Section 4(b) and Section 8 hereof, within ten (10) days after the satisfaction of the requirements of Section 8 hereof (or, if such termination occurred prior to a Change in Control, within ten (10) days after the latter of the aforesaid date or the Change in Control), a lump sum payment equal to the product of (A) the Severance Multiplier times (B) the sum of (x) the Eligible Executive's annual base salary rate (which is calculated immediately prior to any reduction in base salary (if any) if such termination is by the Eligible Executive for Good Reason) and (y) the Eligible Executive's Average Bonus;
- (iii) subject to Section 4(b) and Section 8 hereof, within ten (10) days after the satisfaction of the requirements of Section 8 hereof (or, if such termination occurred prior to a Change in Control, within ten (10) days after the latter of the aforesaid date or the Change in Control), a pro rata Bonus payment for the year in which the Eligible Executive is terminated based on the portion of the year the Eligible Executive was employed;
- (iv) to the extent not paid pursuant to Section 4(a)(i)(A) above, any earned but unpaid bonus for a previously completed fiscal year of the Company; provided that such bonus shall be paid to the Eligible Executive in the year following the completed fiscal year of the Company when other executives of the Company receive their bonuses (but not later than 2 % months following the completion of such fiscal year);
- (v) subject to Section 4(b) and Section 8 hereof, continued coverage pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA"), or otherwise, under the Company health plans in which the Eligible Executive and his/her dependents participated immediately prior to the Eligible Executive's Date of Termination, or materially equivalent plans thereto (the "Health Plans"), for the Eligible Executive and the Eligible Executive's dependents until the earlier of (A) (x) one (1) year following the Date of Termination applicable to the Eligible Executive is a Group 1 Executive, or (y) eighteen (18) months following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 2 Executive, and (B) the Eligible Executive's becoming eligible to participate in the health plan of another employer; provided, that the Eligible Executive timely elects such coverage and pays the same premium amount for such coverage as the Eligible Executive would pay if an active employee immediately prior to the Change in Control (the "Existing Premium Amount"); and further provided that such coverage shall cease to the extent that the providing of such coverage would violate applicable law. Furthermore, to the extent that the applicable coverage period in this Section 4(a)(v) can not be provided under the Company's policies or, if the providing of such coverage would result in taxation of the benefits under Code Section 105(h) (or a successor provision), the Company shall make payments to the Eligible Executive of the premiums it had been paying for such coverage for the Eligible Executive (but on a fully taxed grossed-up basis). In addition, if a Group 2 Executive has not become eligible to participate in the health plan of another employer by the date immediately following the expiration of the eighteen (18) month period referred to in the preceding sentence, the Company shall make a monthly payment to the Eligible Executive of the monthly premium it had been paying for such coverage f

- (vi) subject to Section 4(b) and Section 8 hereof, continued coverage (at Company expense to the same extent as payments were made by the Company while the Eligible Executive was an active employee) in all welfare benefit plans (other then those covered by (v) above) and financial/tax advisory and preparatory services that the Eligible Executive participated in prior to his/her Date of Termination for (x) one (1) year following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 1 Executive, or (y) two (2) years following the Date of Termination applicable to the Eligible Executive if the Eligible Executive is a Group 2 Executive. All such coverage shall be provided in a manner such that it either (i) does not provide for a "deferral of compensation" within the meaning of Code Section 409A or (ii) complies with the requirements of Code Section 409A. Payment to an Eligible Executive of a lump sum amount equal to the premium payable for such coverage shall only be permitted if such payment may be made without violating the requirements of Code Section 409A.
- (b) Severance payments and benefits pursuant to Section 4(a)(ii), (iii) or (iv) hereof are intended to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4). Nevertheless, if the Company determines in good faith that any payment provided under such sections or otherwise under Section 4(a) would cause a violation of Code Section 409A if paid within the first six (6) months after termination of an Eligible Executive's employment, such amount(s) shall not be paid to such Eligible Executive during such six (6) month period but shall instead be paid or provided to such Eligible Executive immediately after the end of such six (6) month period, in a lump sum (without interest). Thereafter, payments to such Eligible Executive shall be made in accordance with the Company's normal payroll practices. In the event that continuation of any benefit would in the good faith judgment of the Company cause a violation of Code Section 409A if provided at Company cost during the first six (6) months after the Date of Termination of an Eligible Executive, if the Eligible Executive wants such benefit continuation, he/she shall pay to the Company the full cost therefor during such six (6) month period and the Company shall reimburse him/her for such cost in a lump sum payment immediately after the end of such six (6) month period.
- 5. Excise Tax. In the event that an Eligible Executive shall become entitled to payments and/or benefits provided by this Plan or any other amounts in the "nature of compensation" (whether pursuant to the terms of this Plan or any other plan, arrangement or agreement with the Company, including, without limitation, an award agreement under an equity compensation plan, any Person whose actions result in a change of ownership or effective control covered by Section 280G(b)(2) of the Code or any person affiliated with the Company or such person) as a result of a Change in Control (collectively the "Company Payments"), and if such Company Payments will be subject to the tax (the "Excise Tax") imposed by Section 4999 of the Code (and any similar tax that may hereafter be imposed by any taxing authority) the amounts of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Eligible Executive to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Eligible Executive (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Eligible Executive minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. The Eligible Executive may elect which payments and benefits shall be reduced to accomplish the foregoing, but, if the Eligible Executive does not make such an election, the first benefit to be reduced is acceleration of vesting of any stock option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur, and the second benefit to be reduced shall be any cash payments under this Plan.
- (a) For purposes of determining whether any of the Company Payments will be subject to the Excise Tax and the amount of such Excise Tax, (x) the Company Payments shall be treated as "parachute payments" within the meaning of Section 280G(b)(2) of the Code, and all "parachute payments" in excess of the "base amount" (as defined under Code Section 280G(b)(3) of the Code) shall be treated as subject to the Excise Tax, unless and except to the extent that, in the opinion of the Company's independent certified public accountants appointed prior to any change in ownership (as defined under Code Section 280G(b)(2)) or tax counsel selected by such accountants (the "Accountants") such Company Payments (in whole or in part) either do not constitute "parachute payments," including giving effect to the recalculation of stock options in accordance with Treasury Regulation Section 1.280G-1 Q/A33, represent reasonable compensation for services actually rendered within the meaning of Section 280G(b)(4) of the Code in excess of the "base amount" or are otherwise not subject to the Excise Tax, and (y) the value of any non-cash benefits or any deferred payment or benefit shall be determined by the Accountants in accordance with the principles of Section 280G of the Code. To the extent permitted under Revenue Procedure 2003-68, the value determination shall be recalculated to the extent it would be beneficial to the Eligible Executive, at the request of the Eligible Executive.

- (b) For purposes of making the calculation hereunder, the Eligible Executive shall be deemed to pay U.S. federal income taxes at the highest marginal rate of U.S. federal income taxation in effect in the calendar year in which the Company Payments are to be made and state and local income taxes at the highest marginal rate of taxation in the state and locality of the Eligible Executive's residence in effect for the calendar year in which the Company Payments are to be made, net of the maximum reduction in U.S. federal income taxes which could be obtained from deduction of such state and local taxes if paid in such year.
- (c) In the event of any controversy with the Internal Revenue Service (or other taxing authority) with regard to the Excise Tax, the Eligible Executive shall permit the Company to control issues related to the Excise Tax (at its expense), provided that such issues do not potentially materially adversely affect the Eligible Executive, but the Eligible Executive shall control any other issues. In the event the issues are interrelated, the Eligible Executive and the Company shall in good faith cooperate so as not to jeopardize resolution of either issue, but if the parties cannot agree the Eligible Executive shall make the final determination with regard to the issues. In the event of any conference with any taxing authority as to the Excise Tax or associated income taxes, the Eligible Executive shall permit the representative of the Company to accompany the Eligible Executive, and the Eligible Executive and the Eligible Executive's representative shall cooperate with the Company and its representative.
 - (d) The Company shall be responsible for all charges of the Accountants.
- (e) The Company and the Eligible Executive shall promptly deliver to each other copies of any written communications, and summaries of any verbal communications, with any taxing authority regarding the Excise Tax.
- 6. Notice of Termination. After a Change in Control, any purported termination of an Eligible Executive's employment (other than by reason of death) shall be communicated by written Notice of Termination from the Company to the Eligible Executive or from the Eligible Executive to the Company, as the case may be, in accordance with Section 19. For purposes of this Plan, a "Notice of Termination" shall mean a notice which shall set forth in reasonable detail the facts and circumstances claimed to provide a basis for termination of an Eligible Executive's employment. Further, a Notice of Termination for Cause after a Change in Control is required to include a copy of a resolution duly adopted by the affirmative vote of not less than two-thirds (2/3) of the entire membership of the Board (at a meeting of the Board which was called and held for the purpose of considering such termination and at which the Eligible Executive had the right to attend and speak) finding that, in the good faith opinion of the Board, the Eligible Executive has engaged in conduct set forth in the definition of Cause herein, and specifying the particulars thereof in detail.
- 7. <u>Date of Termination</u>. "<u>Date of Termination</u>," with respect to any purported termination of an Eligible Executive's employment after a Change in Control, shall mean the date specified in the Notice of Termination (or, in the case of a termination by the Company, if no date is specified, the date which is ten (10) days from the date of such Notice of Termination) and, in the case of a termination by an Eligible Executive for Good Reason, shall be thirty (30) days from the date such Notice of Termination is given.
- 8. Acceptance and Release. Any and all amounts payable and benefits or additional rights provided pursuant to Sections 4 (a)(ii), (iii), (v) and (vi) above shall only be payable if the Eligible Executive executes and delivers to the Company within forty five (45) days following the Date of Termination an Acceptance Form and Release in the form attached hereto as Appendix B discharging all claims of the Eligible Executive which may have occurred up to the Date of Termination applicable to the Eligible Executive (with such changes therein as may be necessary to make it valid and encompassing under applicable law). Notwithstanding anything herein to the contrary, if an Eligible Executive materially breaches any of the provisions of Section 10 of this Plan, the Company may cease all payments and benefits due to such Eligible Executive thereafter under Sections 4(a) (ii), (iii), (v) and (vi) above (other than as required by law).

9. No Duty to Mitigate/Set-off. The Company agrees that the Eligible Executive shall not be required to seek other employment or to attempt in any way to reduce any amounts payable to the Eligible Executive by the Company pursuant to this Plan. Further, other than as set forth in Section 4(a)(v)(B), the amount of any payment or benefit provided for in this Plan shall not be reduced by any compensation earned by an Eligible Executive or benefit provided to an Eligible Executive as the result of employment by another employer, unemployment insurance payments or otherwise. Except as otherwise provided herein and apart from any disagreement between an Eligible Executive and the Company concerning interpretation of this Plan or any term or provision hereof, the Company's obligations to make the payments provided for in this Plan and otherwise to perform its obligations hereunder shall not be affected by any circumstances, including without limitation, any set-off, counterclaim, recoupment, defense or other right which the Company may have against an Eligible Executive. The amounts due under Section 4 are inclusive, and in lieu of, any amounts payable under any other salary continuation or cash severance arrangement of the Company and to the extent paid or provided under any other such arrangement shall be offset against the amount due hereunder.

10. Confidentiality, Non-Solicitation and Cooperation.

- (a) In consideration of participating in this Plan, by the execution and delivery to the Committee of an Acknowledgement and Agreement to Restrictive Covenants set forth on Appendix A attached hereto, if the Eligible Executive is employed by the Company at the time of a Change in Control or has been terminated in an Anticipatory Termination within one hundred eighty (180) days prior thereto, each Eligible Executive agrees to the following agreements:
- (i) during the Eligible Executive's employment with the Company and thereafter, the Eligible Executive agrees not to, directly or indirectly, for any reason whatsoever, communicate or disclose to any unauthorized person, firm or corporation, or use for the Eligible Executive's own account, without the prior written consent of the Board or the Chief Executive Officer of the Company (the "CEO"), any proprietary processes, trade secrets or other confidential data or information of the Company and its related and affiliated companies concerning their businesses or affairs, accounts, products, services or customers, it being understood, however, that the obligations of this Section 10(a) shall not apply to the extent that the aforesaid matters (i) are disclosed in circumstances in which the Eligible Executive is legally required to do so, provided that the Eligible Executive gives the Company prompt written notice of receipt of notice of any legal proceedings so as the Company has the opportunity to obtain a protective order, or (ii) become known to and available for use by the public other than by the Eligible Executive's wrongful act or omission;
- (ii) during the Eligible Executive's employment with the Company and thereafter, the Eligible Executive agrees to fully cooperate with the Company or its counsel in connection with any matter, investigation, proceeding or litigation regarding any matter in which the Eligible Executive was involved during the Eligible Executive's employment with the Company or to which the Eligible Executive has knowledge based on the Eligible Executive's employment with the Company; and

(iii) during the Eligible Executive's employment with the Company and for the one (1) year period thereafter, if the Eligible Executive is receiving the amounts and benefits provided under Section 4, the Eligible Executive agrees that he or she will not individually or on behalf of any other person, firm, corporation or other entity (actions of such other person, firm, corporation or other entity not being attributable to the Eligible Executive unless he or she is personally involved therewith), solicit, induce, hire or retain any employee of the Company (or any person who had been such an employee in the prior three (3) months) to leave the employ of the Company and to accept employment or retention as an independent contractor with, or render services to or with any other person, firm, corporation or other entity unaffiliated with the Company or take any action to assist or aid any other person, firm, corporation or other entity in identifying, soliciting, hiring or retaining any such employee; provided, the Eligible Executive may serve as a reference after the Eligible Executive is no longer employed by the Company, but not with regard to any entity with which the Eligible Executive is affiliated or from which the Eligible Executive is receiving compensation and this provision shall not be violated by general advertising not specifically targeted at employees of the Company.

- (b) Because the Company's remedies at law for a breach or threatened breach of any of the provisions of this Section 10 would be inadequate, in the event of such a breach or threatened breach by an Eligible Executive, in addition to any remedies at law, the Company shall be entitled to seek equitable relief in the form of specific performance, a temporary restraining order, a temporary or permanent injunction or any other equitable remedy which may then be available.
- (c) If it is determined by a court of competent jurisdiction that any restriction in this Section 10 is excessive in duration or scope or is unreasonable or unenforceable, such restriction may be modified or amended by the court to render it enforceable to the maximum extent permitted.
- (d) The agreements set forth in this Section 10 are in addition to any other activity limitations an Eligible Executive is subject to under any other agreement between the Eligible Executive and the Company or any other plan or arrangement of the Company applicable to the Eligible Executive.

11. <u>Service with Subsidiaries</u>. For purposes of this Plan, employment by a subsidiary or a parent of the Company shall be deemed to be employment by the Company and references to the Company shall include all such entities, except that the payment obligation hereunder shall be solely that of the Company. A Change in Control, however, as used in this Plan, shall refer only to a Change in Control of the Company.

12. Liability Insurance; Indemnification.

If an Eligible Executive is receiving the payments and benefits under Section 4, then:

- (a) the Company shall continue to cover such Eligible Executive, or cause the Eligible Executive to be covered, under any director and officer insurance maintained after the Change in Control for directors and officers of the Company (whether by the Company or another entity) at the highest level so maintained for any other past or active director or officer with regard to any action or omission of the Eligible Executive while an officer or director of the Company. Such coverage shall continue for any period during which the Eligible Executive may have any liability for the aforesaid actions or omissions; and
- (b) following a Change in Control, the Company shall, with regard to matters related to such Eligible Executive's period of employment with the Company, indemnify the Eligible Executive to the fullest extent permitted or authorized by the Company's bylaws against any claims, suits, judgments, expenses (including reasonable attorney fees), with advancement of legal fees and disbursements to the fullest extent permitted by law, arising from, out of, or in connection with the Eligible Executive's services as an officer or director of the Company, as an officer or director of any affiliate for which the Eligible Executive was required to serve as such by the Company or as a fiduciary of any benefit plan of the Company or any affiliate.
- 13. <u>Funding</u>. This Plan shall be funded out of the general assets of the Company as and when benefits are payable under this Plan. To the extent that any Eligible Executive acquires a right to receive payments under this Plan, such right shall not be secured by any assets of the Company or any of its affiliated companies. The Eligible Executives shall be general creditors of the Company. Any assignment, lien or other encumbrance by an Eligible Executive of the amounts and benefits provided under this Plan shall be null and void. If the Company decides in its sole discretion to establish any advance accrued reserve on its books against the future expense of benefits payable hereunder, or if the Company decides in its sole discretion to fund a trust under this Plan, such reserve or trust shall not under any circumstances be deemed to be an asset of this Plan.

14. Administration of this Plan.

- (a) The general administration of this Plan on behalf of the Company (as "Plan Administrator" under Section 3(16)(A) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA")) shall be placed with the Committee.
- (b) The Company may, in its sole discretion, pay or reimburse the members of the Committee for all reasonable expenses incurred in connection with their duties hereunder.
- (c) Decisions of the Committee shall be made by a majority of its members attending a meeting at which a quorum is present (which meeting may be held telephonically), or by written action in accordance with applicable law. Subject to the terms of this Plan and provided that the Committee acts in good faith, the Committee shall have complete authority to determine an Eligible Executive's participation and benefits under this Plan, to interpret and construe, in its sole discretion, the provisions of this Plan, and to make decisions in all disputes involving the rights of any person interested in this Plan. All decisions by the Committee shall be made in the Committee's sole discretion and shall be final and binding on all persons having or claiming any interest in this Plan. Notwithstanding the foregoing, all decisions of the Committee after a Change in Control shall be reviewable on a *de novo* basis by an arbitrator or court , as applicable.

- (d) The Committee may delegate any and all of its powers and responsibilities hereunder to other persons by formal resolution filed with and accepted by the Board. Any such delegation shall not be effective until it is accepted by the Board and the persons designated and may be rescinded at any time by written notice from the Committee to the person to whom the delegation is made.
- (e) The Committee may employ such legal counsel, accountants and other persons as may be required in carrying out its work in connection with this Plan.
- (f) The Committee shall maintain such accounts and records regarding the fiscal and other transactions of this Plan and such other data as may be required to carry out its functions under this Plan and to comply with all applicable laws.
- (g) The Company shall be the Plan Administrator for the purposes of any applicable law and shall be responsible for the preparation and filing of any required returns, reports, statements or other filings with appropriate governmental agencies. The Company shall also be responsible for the preparation and delivery of information to persons entitled to such information under any applicable law.
- (h) The Company shall indemnify, to the full extent permitted by law and its Certificate of Incorporation and By-laws (but only to the extent not directly covered by insurance) its officers and directors, (and any employee involved in carrying out the functions of the Company under this Plan), each member of the Committee, and any person designated pursuant to Section 14 (d) above, against any expenses, including amounts paid in settlement of a liability, which are reasonably incurred in connection with any legal action to which such person is a party by reason of his or her duties or responsibilities with respect to this Plan, except with regard to matters as to which he or she shall be adjudged in such action to be liable for gross negligence, willful misconduct or fraud in the performance of his or her duties.
- 15. <u>ERISA Provisions (Including Claims Procedures)</u>. This Plan is intended to be a "top hat" welfare benefit plan within the meaning of U.S. Department of Labor Regulation Section 2520.104-24. Administrative provisions about this Plan are contained in Appendix C hereto. This Plan document, including the Appendices hereto, shall constitute the Plan document and shall be distributed to Eligible Executives in this form.
- 16. Employee Benefit Plans. The amounts and benefits specified in Section 4 hereof shall not be paid to any Eligible Executive as an employee and no Eligible Executive shall be eligible to participate in employee benefit plans maintained by the Company following the Date of Termination applicable to such Eligible Executive except as specifically provided herein or in such benefit plan(s). Amounts paid pursuant to Section 4 shall not be taken into account for purposes of determining contributions to or calculating accrued benefits under the employee benefit plans maintained by the Company, except for accrued amounts that would be so taken into account pursuant to the terms of the applicable plan.

- 17. Successors; Binding Agreement. In addition to any obligations imposed by law upon any successor to the Company, the Company will require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company to expressly assume and agree in writing to be obligated to make the payments and provide the benefits under this Plan in the same manner and to the same extent that the Company would have been obligated under this Plan if no such succession had taken place. This Plan shall inure to the benefit of and be enforceable by each Eligible Executive's personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. If an Eligible Executive shall die while any amount would still be payable to such Eligible Executive hereunder, all such amounts, unless otherwise provided herein, shall be paid in accordance with the terms of this Plan to the executors, personal representatives or administrators of such Eligible Executive's estate as if the Eligible Executive had continued to live. No rights or obligations hereunder may be assigned by an Eligible Executive.
- 18. Amendment and Termination. This Plan shall continue until terminated by the Company in accordance with this Section 18, but the Plan shall cover only the first Change in Control occurring hereafter. The Company reserves the right to amend or terminate, in whole or in part, any or all of the provisions of this Plan by action of the Board or the Committee at any time and for any reason prior to a Change in Control, provided that in no event shall any amendment which reduces an Eligible Executive's right to payment and/or benefits under this Plan or any termination of this Plan be effective as to any Eligible Executive then participating in this Plan prior to the one (1) year anniversary such amendment or Plan termination is adopted by the Board or the Committee, and provided further that no such amendment or termination that is not effective prior to a Change in Control shall be effective after a Change in Control.
- 19. <u>Notices</u>. Any notice or other communication required or permitted under this Plan shall be in writing and shall be delivered personally, or sent by registered mail, postage prepaid. Any such notice shall be deemed given when so delivered personally, or, if mailed, five (5) days after the date of deposit in the United States mails,
 - (i) If to the Company, to: Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 Attention: Chief Executive Officer
 - (ii) If to an Eligible Executive, to his or her last shown address on the books of the Company.

20. <u>Separability</u>. If any provisions of this Plan (including the appendices hereto) shall be declared to be invalid or unenforceable, in whole or in part, (by a court of competent jurisdiction) such invalidity or unenforceability shall not affect the validity of the remaining provisions of this Plan (including the appendices hereto).

21. Legal Fees.

- (a) In the event the Company does not make the payments due hereunder on a timely basis (as determined by an arbitrator) and the matter is arbitrated pursuant to Section 22 below, if the Eligible Executive prevails in such arbitration, the Company shall pay all costs of such arbitration, including reasonable legal fees and other reasonable fees and expenses which the Eligible Executive may incur (on a tax grossed up basis, to the extent such amounts are taxable to the Eligible Executive).
- (b) The Company shall pay to the Eligible Executive interest at the prime lending rate (as reported from time to time by <u>The Wall Street Journal</u>) on all or any part of any amount to be paid to Eligible Executive hereunder that is not paid when due. The prime rate for each calendar quarter shall be the prime rate in effect on the first day of the calendar quarter.
- 22. <u>Arbitration</u>. Any dispute or controversy arising under or in connection with this Plan shall be settled exclusively by arbitration conducted in the City of New York in the State of New York under the Commercial Arbitration Rules then prevailing of the American Arbitration Association and such submission shall request the American Arbitration Association to: (i) appoint an arbitrator experienced and knowledgeable concerning the matter then in dispute; (ii) require the testimony to be transcribed; (iii) require the award to be accompanied by findings of fact and the statement for reasons for the decision; and (iv) request the matter to be handled by and in accordance with the expedited procedures provided for in the Commercial Arbitration Rules. The determination of the arbitrators, which shall be based upon a de novo interpretation of this Plan, shall be final and binding and judgment may be entered on the arbitrators' award in any court having jurisdiction. The Company shall pay all costs of the American Arbitration Association and the arbitrator.
- 23. Withholding. The Company shall have the right to make such provisions as it deems necessary or appropriate to satisfy any obligations it reasonably believes it may have to withhold federal, state or local income or other taxes incurred by reason of payments pursuant to this Plan. In lieu thereof, the Company shall have the right to withhold the amounts of such taxes from any other sums due or to become due from the Company to an Eligible Executive upon such terms and conditions as the Committee may prescribe.
- 24. <u>Code Section 409A</u>. This Plan is intended to comply with the applicable requirements of Code Section 409A and shall be limited, construed, interpreted and administered in accordance with such intent. The Company reserves the right to amend the provisions of this Plan at any time in order to avoid the imposition of the additional tax under Code Section 409A on any payments to be made hereunder. The Company shall indemnify the Eligible Executives for any taxes, interest or penalties incurred under Code Section 409A as a result of any payments or benefits hereunder in such a manner that the Eligible Executive will have no after tax cost as a result thereof. Without limiting the generality of the foregoing:

- (a) For purposes of this Plan, the employment of Eligible Executives with the Company will not be treated as terminated unless and until such termination of employment constitutes a "separation from service" for purposes of Section 409A of the Code.
- (b) The Acceptance Form and Release described in Section 8 hereof shall be provided to the Eligible Executive and shall be required to be executed by the Eligible Executive in a time period which will not result in severance payments made to the Eligible Executive hereunder failing to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4). Severance payments pursuant to Section 4(a) hereof are intended to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b)(4).
- (c) If the provisions of Section 3(b) are applicable to an equity or equity-based award subject to the provisions of Section 409A of the Code, payment of such awards shall be made, if provided for in Section 3(b), in a time period which will not result in such payments failing to qualify as a short-term deferral for purposes of Treasury Regulation Section 1.409A-1(b) (4).
- (d) To the extent necessary to comply with the provisions of Section 409A of the Code and the guidance issued thereunder (A) reimbursements or tax gross-up payments to an Eligible Executive pursuant to Section 4, Section 12, Section 21, this Section 24 or otherwise hereunder shall be made not later than the end of the calendar year following the year in which the reimbursable expense is incurred or tax subject to a gross-up provision is paid by the Eligible Executive, as applicable, and shall otherwise be made in a manner that complies with the requirements of Treasury Regulation Section 1.409A-3(i)(l)(iv).
- 25. Non-Exclusivity of Rights. Nothing in this Plan shall prevent or limit an Eligible Executive's continuing or future participation in any benefit, bonus, incentive, equity or other plan or program provided by the Company for which the Eligible Executive may qualify, nor shall anything herein (except Section 8) limit or otherwise prejudice such rights as the Eligible Executive may have under any other currently existing plan, agreement as to employment, or termination from employment with the Company or any other contractual or statutory entitlements. Amounts that are vested benefits or those which an Eligible Executive is otherwise entitled to receive under any other plan or program of the Company, at or subsequent to the Termination Date applicable to such Eligible Executive, shall be payable in accordance with such other plan or program, except as otherwise specifically provided herein. With the exception of the provisions in this Agreement regarding vesting and exercisability of Equity Grants following an Anticipatory Termination, nothing in this Plan will affect any term or provision of any stock option award between an Eligible Executive and the Company and the rights set forth in this Plan are in addition to, and not in lieu of, the terms of any such award agreements. Notwithstanding the foregoing, an Eligible Executive shall not be entitled to received duplicative severance payments and benefits and, to the extent that an Eligible Executive is entitled to severance payments and benefits under any other plan or agreement, such Eligible Executive shall be entitled to the greater of the payments and benefits thereunder or hereunder but not under both plans or agreements.

- 26. At Will Employment. This Plan does not constitute a contract of employment and, subject to any other agreement between an Eligible Executive and the Company, the Company reserves the right to terminate an Eligible Executive's employment at any time with or without reason or notice (unless otherwise prohibited by law), subject to the payment and other provisions hereof.
- 27. <u>Governing Law</u>. The construction, interpretation and administration of this Plan shall be governed by ERISA. To the extent not so governed, it shall be construed, interpreted, and governed in accordance with the laws of the State of New York without reference to rules relating to conflicts of law.

IN WITNESS WHEREOF, this amended and restated Plan has been adopted effective as of November 14, 2008, and Regeneron Pharmaceuticals, Inc. has caused this instrument to be signed by its officer or representative duly authorized on this 14^{th} day of November 2008.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski

Name: Stuart Kolinski

Title: Senior Vice President & General Counsel

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Appendix A

FORM OF

ACKNOWLEDGEMENT AND AGREEMENT TO RESTRICTIVE COVENANTS

The Compensation Committee Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591

Reference is hereby made to the Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, as amended and restated effective November 14, 2008 (the "Plan"). Any capitalized term used but not defined herein shall have the meaning ascribed to such term in the Plan.

In consideration of participation in the Plan as an Eligible Executive, the undersigned hereby acknowledges and agrees that if the undersigned is employed by the Company at the time of a Change in Control or has been terminated in an Anticipatory Termination within one hundred eighty (180) days prior thereto, the undersigned shall be bound by the restrictive covenants and agreements set forth in Section 10 of the Plan.
[Name of Eligible Executive]
Effective Date:

Appendix B

ACCEPTANCE FORM AND RELEASE

Release

- 1. I agree and acknowledge that the payments and other benefits provided pursuant to the Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan ("Plan"), as amended and restated effective November 14, 2008 and my rights under any equity grant (i) are in full discharge of any and all liabilities and obligations of the Company to me, monetarily or with respect to employee benefits or otherwise, including but not limited to any and all obligations arising under any alleged written or oral employment agreement, policy, plan or procedure of the Company and/or any alleged understanding or arrangement between me and the Company; and (ii) exceed any payment, benefit, or other thing of value to which I might otherwise be entitled under any policy, plan or procedure of the Company and/or any agreement between me and the Company.
- 2. In consideration for the payments and benefits to be provided to me pursuant to the Plan, I forever release and discharge the Company from any and all claims. This includes claims that are not specified in this Acceptance Form and Release (this "Release"), claims of which I am not currently aware, claims under: (i) the Age Discrimination in Employment Act, as amended; (ii) Title VII of the Civil Rights Act of 1964, as amended; (iii) the Americans with Disabilities Act, as amended; (iv) the Employee Retirement Income Security Act of 1974, as amended (excluding claims for accrued, vested benefits under any employee benefit pension plan of the Company in accordance with the terms and conditions of such plan and applicable law); (v) the Workers' Adjustment and Retraining Notification Act; (vi) the Family and Medical Leave Act; (vii) any claim under the New York State Human Rights Law and the New York City Administrative Code; (viii) any other claim (whether based on federal, state, or local law, statutory or decisional) relating to or arising out of my employment, the terms and conditions of such employment, the separation of such employment, and/or any of the events relating directly or indirectly to or surrounding the separation of that employment, including, but not limited to, breach of contract (express or implied), wrongful discharge, detrimental reliance, defamation, emotional distress or compensatory or punitive damages; and (ix) any claim for attorneys' fees, costs, disbursements and/or the like. Notwithstanding anything herein to the contrary, the sole matters to which this Release does not apply are (i) the rights of indemnification and directors and officers liability insurance coverage to which I was entitled immediately prior to my termination; (ii) my rights under any tax-qualified pension plan or claims for accrued vested benefits under any other employee benefit plan, policy or arrangement maintained by the Company or under the Consolidated Omnibus Budget Reconciliation Act of 1985; and (iii) my
- 3. This Release applies to me and to anyone who succeeds to my rights, such as my heirs, executors, administrators of my estate, trustees, and assigns. This Release is for the benefit of (i) the Company, (ii) any related corporation or entity, (iii) any director, officer, employee, or agent of the Company or of any such related corporation or entity, or (iv) any person, corporation or entity who or that succeeds to the rights of the Company or of any such person, corporation or entity.

- 4. I acknowledge that I: (a) have carefully read in their entirety the Plan, this Release [and the information attached as Appendix I provided pursuant to the Older Workers Benefit Protection Act]; (b) have had an opportunity to consider fully for at least [twenty-one (21)] [forty-five (45)] days the terms of the Plan, this Release [and information attached as Appendix I]; (c) have been advised by the Company in writing to consult with an attorney of my choosing in connection with the Plan, this Release [and the information attached as Appendix I]; (d) fully understand the significance of all of the terms and conditions of the Plan, Release [and the information attached as Appendix I], and have discussed them with my independent legal counsel, or have had a reasonable opportunity to do so; (e) have had answered to my satisfaction any questions I have asked with regard to the meaning and significance of any of the provisions of the Plan, this Release [and the information attached as Appendix I]; and (f) am signing this Release voluntarily and of my own free will and assent to all the terms and conditions contained herein and contained in the Plan and the Release.
- 5. I understand that I will have [twenty-one (21)] [forty-five (45)] days from the date of receipt of this Release [and information attached as Appendix I] to consider the terms and conditions of those documents. I may execute and thereby accept this Release by signing and sending it to _______, After executing this Release and returning it to _______, I shall have seven (7) days (the "Revocation Period") to revoke this Release by indicating my desire to do so in writing delivered by no later than 5:00 p.m. on the seventh (7th) day following the date I sign and return this Release. The effective date of this Release shall be the eighth (8th) day following my signing and return of this Release. If the last day of the Revocation Period falls on a Saturday, Sunday or holiday, the last day of the Revocation Period will be deemed to be the next business day. In the event I do not accept this Release, or in the event I revoke this Release during the Revocation Period, my rights under the Plan, this Release, including but not limited to my rights to receive payments and other benefits from the Company, shall be deemed automatically null and void.

Print Name:	Date:
Employ	ee
Signature:	
Employe	ee
STATE OF NEW YORK)) ss:
COUNTY OF) 55.
On this day of person described and who same.	, before me personally came to be known and known to me to be the o executed the foregoing Release, and (s)he duly acknowledged to me that (s)he executed the
Notary Public	
	3

ACCEPTANCE FORM AND RELEASE

Acceptance Form:

I have read the Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, as amended and restated effective November 14, 2008 ("Plan") and the accompanying Release [and the information attached as Appendix I] and hereby accept the benefits provided under the Plan, subject to the terms and conditions set forth in the Plan and the Release.

Print Name:	Date:
Employee	
Signature:Employee	
STATE OF NEW YORK	
COUNTY OF) ss: .)
On this day of person described and who e same.	, before me personally came to be known and known to me to be the xecuted the foregoing Release, and (s)he duly acknowledged to me that (s)he executed the
Notary Public	

APPENDIX C

PROVISIONS RELATING TO ERISA

A. Claims Procedure

- 1. Any claim by an Eligible Executive with respect to eligibility, participation, contributions, benefits or other aspects of the operation of the Plan shall be made in writing to a person designated by the Committee from time to time for such purpose. If the designated person receiving a claim believes, following consultation with the Chairman of the Committee, that the claim should be denied, he or she shall notify the Eligible Executive in writing of the denial of the claim within ninety (90) days after his or her receipt thereof. This period may be extended an additional ninety (90) days in special circumstances and, in such event, the Eligible Executive shall be notified in writing of the extension, the special circumstances requiring the extension of time and the date by which the Committee expects to make a determination with respect to the claim. If the extension is required due to the Eligible Executive's failure to submit information necessary to decide the claim, the period for making the determination will be tolled from the date on which the extension notice is sent until the date on which the Eligible Executive responds to the Plan's request for information.
- 2. If a claim is denied in whole or in part, or any adverse benefit determination is made with respect to the claim, the Eligible Executive will be provided with a written notice setting forth (a) the specific reason or reasons for the denial making reference to the pertinent provisions of the Plan or of Plan documents on which the denial is based, (b) a description of any additional material or information necessary to perfect or evaluate the claim, and explain why such material or information, if any, is necessary, and (c) inform the Eligible Executive of his or her right, pursuant to Paragraph A(1) of this Appendix, to request review of the decision. The notice shall also provide an explanation of the Plan's claims review procedure and the limits applicable to such procedure, as well as a statement of the Eligible Executive's right to bring a civil action under Section 502(a) of ERISA following an adverse benefit determination on review. If an Eligible Executive is not notified (of the denial or an extension) within ninety (90) days from the date the Eligible Executive notifies the Plan Administrator, the Eligible Executive may request a review of the application as if the claim had been denied.
- 3. An Eligible Executive may appeal the denial of a claim by submitting a written request for review to the Committee, within sixty (60) days after written notification of denial is received. Such period may be extended by the Committee for good cause shown. The claim will then be reviewed by the Committee. In connection with this appeal, the Eligible Executive (or his or her duly authorized representative) may (a) be provided, upon written request and free of charge, with reasonable access to (and copies of) all documents, records, and other information relevant to the claim; and (b) submit to the Committee written comments, documents, records, and other information related to the claim. If the Committee deems it appropriate, it may hold a hearing as to a claim. If a hearing is held, the Eligible Executive shall be entitled to be represented by counsel.
- 4. The review by the Committee will take into account all comments, documents, records, and other information the Eligible Executive submits relating to the claim. The Committee will make a final written decision on a claim review, in most cases within sixty (60) days after receipt of a request for a review. In some cases, the claim may take more time to review, and an additional processing period of up to sixty (60) days may be required. If that happens, the Eligible Executive will receive a written notice of that fact, which will also indicate the special circumstances requiring the extension of time and the date by which the Committee expects to make a determination with respect to the claim. If the extension is required due to the Eligible Executive's failure to submit information necessary to decide the claim, the period for making the determination will be tolled from the date on which the extension notice is sent to the Eligible Executive until the date on which the Eligible Executive responds to the Plan's request for information.

5. The Committee decision on the claim for review will be communicated to the Eligible Executive in writing. If an adverse benefit determination is made with respect to the claim, the notice will include (a) the specific reason(s) for any adverse benefit determination, with references to the specific Plan provisions on which the determination is based; (b) a statement that the Eligible Executive is entitled to receive, upon request and free of charge, reasonable access to (and copies of) all documents, records and other information relevant to the claim; and (c) a statement of the Eligible Executive's right to bring a civil action under Section 502(a) of ERISA. An Eligible Executive may not start a lawsuit to obtain benefits until after he or she has requested a review and a final decision has been reached on review, or until the appropriate time frame described above has elapsed since the Eligible Executive filed a request for review and you have not received a final decision or notice that an extension will be necessary to reach a final decision. The law also permits the Eligible Executive to pursue his or her remedies under section 502(a) of ERISA without exhausting these appeal procedures if the Plan has failed to follow them.

B. Plan Interpretation and Benefit Determination

- 1. The Committee (or, where applicable, any duly authorized delegee of the Committee) shall have the exclusive right, power, and authority, in its sole and absolute discretion, to administer, apply and interpret the Plan and any other documents, and to decide all factual and legal matters arising in connection with the operation or administration of the Plan.
- 2. Without limiting the generality of the foregoing paragraph, the Committee (or, where applicable, any duly authorized delegee of the Committee) shall have the sole and absolute discretionary authority to:
- (a) take all actions and make all decisions (including factual decisions) with respect to the eligibility for, and the amount of, benefits payable under the Plan;
 - (b) formulate, interpret and apply rules, regulations and policies necessary to administer the Plan;
- (c) decide questions, including legal or factual questions, relating to the calculation and payment of benefits, and all other determinations made, under the Plan;
- (d) resolve and/or clarify any factual or other ambiguities, inconsistencies and omissions arising under this Plan or other Plan documents; and
 - (e) process, and approve or deny, benefit claims and rule on any benefit exclusions.

All determinations made by the Committee (or, where applicable, any duly authorized delegee of the Committee) with respect to any matter arising under the Plan shall be final and binding on the Company, Eligible Executive, beneficiary, and all other parties affected thereby. Notwithstanding the foregoing, all decisions of the Committee after a Change in Control shall be reviewable on a *de novo* basis by an arbitrator or court, as applicable.

Regeneron Pharmaceuticals, Inc. Computation of Ratio of Earnings to Combined Fixed Charges (Dollars in thousands)

_	2004	2005	2006	2007	2008 (B)
Earmogs		2000	2000	2007	
Income (loss) from continuing operations					
before income (loss) from equity investee	\$41,565	\$ (95,456)	\$(103,150)	\$(105,600)	\$ (82,710)
Fixed charges	14.060	13.687	13.643	ψ(103,000) 13.708	\$ (02,710) \$ 11.261
Amortization of capitalized interest	78	78	73	23	20
	10	10	13	۷۵	20
Interest capitalized					
					<u></u>
Adjusted earnings	\$55,703	\$(81,691)	\$ (89,434)	\$ (91,869)	\$ (71,429)
Fixed charges					
Interest expense	\$12,175	\$ 12,046	\$ 12,043	\$ 12,043	\$ 7,752
Interest capitalized					
Assumed interest component of rental charges	1,885	1,641	1,600	1,665	3,509
Total fixed charges	\$14,060	\$ 13,687	\$ 13,643	\$ 13.708	\$ 11.261
				_	
Ratio of earnings to fixed charges	3.96	(A)	(A)	(A)	(A)

- (A) Due to the registrant's losses for the years ended December 31, 2005, 2006, 2007, and 2008 the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.
- (B) During the year ended December 31, 2008, the registrant repurchased \$82.5 million and repaid the remaining \$117.5 million of its convertible senior subordinate notes. As of December 31, 2008, the registrant therefore does not have any registered debt outstanding.

•	2005	2006	2007	2008 (B)
Coverage deficiency	\$ 05,379	\$103.077	\$105.577	RRD AGA

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-50480, 333-85330, 333-97176, 333-33891, 333-80663, 333-61132, 333-97375, 333-119257 and 333-151941) and on Form S-3 (No. 333-121225) of Regeneron Pharmaceuticals, Inc., of our report dated February 26, 2009 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

PricewaterhouseCoopers LLP

New York, New York February 26, 2009

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Leonard S. Schleifer, certify that:
- 1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2009 By: /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

- 1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2009

By: /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and Assistant
Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2008 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer February 26, 2009

/s/ Murray A. Goldberg

Murray A. Goldberg Chief Financial Officer February 26, 2009

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-K

Filing Date: 2/17/2011

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

21.10				
(Mark C	one)			
X	ANNUAL REPORT PU	URSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHAN	GE ACT OF 1934
		For the	fiscal year ended December 31, 201	0
			OR	
	TRANSITION REPOR	RT PURSUANT TO SECTION 13 O	R 15(d) OF THE SECURITIES EXC	HANGE ACT OF 1934
		For the t	ransition period from to	_
		Со	mmission File Number 0-19034	
			PHARMACEUTIC	CALS, INC.
		New York		<u>13-3444607</u>
	(State	e or other jurisdiction of		(I.R.S. Employer
	incor	poration or organization)		Identification No)
		River Road, Tarrytown, NewYork of principal executive offices)		10591-6707 (Zip code)
			(914) 347-7000	
		(Registr	rant's telephone number, including area code)	
		Securities regi	stered pursuant to Section 12(b) of	the Act:
		Title of each class		Name of each exchange on which registered
	Common Stoo	ck - par value \$.001 per share		NASDAQ Global Select Market
		Securities registe	red pursuant to section 12(g) of the	Act: None
Indica	te by check mark if the registrant	is a well-known seasoned issuer, as defined in	Rule 405 of the Securities Act. Yes ☑ No □]
Indica	ite by check mark if the registrant	t is not required to file reports pursuant to Section	on 13 or 15(d) of the Act. Yes 🗖 No 🗹	
	-	gistrant (1) has filed all reports required to be fi tts), and (2) has been subject to such filing requ	· · · · ·	hange Act of 1934 during the preceding 12 months (or for such shorter period tha
	-	· · · · · · · · · · · · · · · · · · ·	-	eractive Data File required to be submitted and posted pursuant to Rule 405 or
			rter period that the registrant was required to sub	
			alation S-K (§229.405 of this chapter) is not con 10-K or any amendment to this Form 10-K.	tained herein, and will not be contained, to the best of registrant's knowledge, in
Indica	•	ristrant is a large accelerated filer, an accelerated	·	ing company. See the definitions of "large accelerated filer", "accelerated filer" and
Large	accelerated filer 🗹	Accelerated filer	Non-accelerated filer □	Smaller reporting company □
Indica	ite by check mark whether the res	gistrant is a shell company (as defined in Rule 1	2b-2 of the Exchange Act). Yes □ No ☑	
The a	nggregate market value of the co	-		ted by reference to the closing sales price of the stock on NASDAQ on June 30
		ach of the registrant's classes of common stock	as of February 11, 2011:	
	<u>(</u>	Class of Common Stock		Number of Shares

DOCUMENTS INCORPORATED BY REFERENCE:

Class A Stock, \$.001 par value

Common Stock, \$.001 par value

2,182,036

87,777,008

PART I

ITEM 1. BUSINESS

This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the nature, timing, and possible success and therapeutic applications of our product candidates and research programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates, the commercial success of our marketed product, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

General

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have 11 product candidates in clinical development, including three that are in late-stage, (Phase 3). All of these product candidates were discovered in our research laboratories. Our late-stage programs are VEGF Trap-Eye (aflibercept ophthalmic solution), which is being developed using intraocular delivery for the treatment of serious eye diseases; ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs include the following fully human antibodies, which are being developed in collaboration with sanofi-aventis:

- REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9) for low-density lipoprotein (LDL) cholesterol reduction;
- REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and ankylosing spondylitis;
- REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis and asthma;
- REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology,
- REGN910, an antibody to Angiopoietin-2 (ANG2), another novel angiogenesis target, which is being developed in oncology;
- REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain (currently on clinical hold); and
- REGN728 and REGN846, two antibodies in clinical development against undisclosed targets.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, to combine that foundation with our clinical development and manufacturing capabilities, and to continue to expand our commercialization capabilities in anticipation of possible regulatory approval and launch of one or more of our late-stage product candidates. Our long-term objective is to build a successful, integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*TM technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene®* technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune®*) and cell line expression technologies (*VelociMab®*) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune®*. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® - CAPS

Net product sales of ARCALYST® in 2010 were \$25.3 million, which included \$20.5 million of ARCALYST® net product sales made in 2010 and \$4.8 million of previously deferred net product sales, as described below under Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations – Results of Operations." In 2009, we recognized \$18.4 million of ARCALYST® net product sales.

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST® is available for prescription in the United States for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We, together with our ex-U.S. collaborator Bayer HealthCare LLC, are evaluating VEGF Trap-Eye in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), and choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia. We and Bayer HealthCare conducted a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME) and are discussing plans to initiate Phase 3 studies in DME. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), compared VEGF Trap-Eye and Lucentis® (ranibizumab injection), a registered trademark of Genentech, Inc. Lucentis® is an anti-angiogenic agent approved for use and the current standard of care in wet AMD. VIEW 1 was conducted in North America and VIEW 2 was conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials both evaluated VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly loading doses), compared with Lucentis® dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents is being evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks.

The primary endpoint of these non-inferiority studies was the proportion of patients treated with VEGF Trap-Eye who maintain visual acuity at the end of one year compared to patients dosed monthly with Lucentis. Visual acuity is defined as the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, a standard research tool for measuring visual acuity. Maintenance of vision is defined as losing

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fewer than three lines (equivalent to 15 letters) on the ETDRS chart. Secondary endpoints included the mean change from baseline in visual acuity as measured by ETDRS, the proportion of patients who gained at least 15 letters of vision at week 52, and the amount of fluid under the retina.

We and Bayer HealthCare announced week 52 results from the VIEW 1 and VIEW 2 studies in November 2010. In these studies, all regimens of VEGF Trap-Eye, including VEGF Trap-Eye dosed every two months, successfully met the primary endpoint of statistical non-inferiority compared to Lucentis® dosed every month. In the North American VIEW 1 study, 96% of patients receiving VEGF Trap-Eye 0.5 mg monthly, 95% of patients receiving VEGF Trap-Eye 2.0 mg monthly, and 95% of patients receiving VEGF Trap-Eye 2.0 mg every two months achieved maintenance of vision compared to 94% of patients receiving VEGF Trap-Eye 2.0 mg monthly, and 96% of patients receiving VEGF Trap-Eye 2.0 mg monthly, and 96% of patients receiving VEGF Trap-Eye 2.0 mg every two months achieved maintenance of vision compared to 94% of patients receiving Lucentis® 0.5 mg dosed every month.

A generally favorable safety profile was observed for both VEGF Trap-Eye and Lucentis®. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD; the most frequently reported events were falls, pneumonia, myocardial infarction, atrial fibrillation, breast cancer, and acute coronary syndrome. There were no notable differences among the study arms.

Based on these positive results, we plan to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In addition, Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe.

VEGF Trap-Eye is also in Phase 3 development for the treatment of CRVO, another cause of visual impairment. We are leading the COPERNICUS (COntrolled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study, and Bayer HealthCare is leading the GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study. Patients in both studies receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2.0 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients are dosed on a PRN basis for another six months. All patients are eligible for rescue laser treatment.

We and Bayer HealthCare announced in December 2010 that in the COPERNICUS study, VEGF Trap-Eye met the primary endpoint of a statistically significant improvement in visual acuity at six months compared to sham injections. In this trial, 56.1% of patients receiving VEGF Trap-Eye gained at least 15 letters of vision from baseline, compared to 12.3% of patients receiving sham injections (p<0.0001). Patients receiving VEGF Trap-Eye on average gained 17.3 letters of vision, compared to a mean loss of 4.0 letters with sham injections (p<0.001), a secondary endpoint.

In the COPERNICUS study, VEGF Trap-Eye was generally well tolerated. The most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were uncommon (3.5%) and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. There were no deaths among the 114 patients treated with VEGF Trap-Eye and two (2.7%) in the 73 patients treated with sham injections.

GALILEO study data are expected in the first half of 2011.

The Phase 2 DME study, known as DA VINCI (<u>DME And VEGF Trap-Eye</u>: <u>IN</u>vestigation of <u>Clinical Impact</u>), was a double-masked, randomized, controlled trial that evaluated four different dosing regimens of VEGF Trap-Eye versus focal laser treatment. In February 2010, we and Bayer HealthCare announced that treatment with VEGF Trap-Eye demonstrated a statistically significant improvement in visual acuity compared to focal laser therapy at 24 weeks, the primary endpoint of the study. Visual acuity was measured by the mean number of letters gained.

Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 (p< 0.01 for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported. The adverse events reported were those typically associated with intravitreal injections or the underlying disease.

In December 2010, we and Bayer HealthCare reported that the mean visual acuity gains seen in the DA VINCI study at 24 weeks were maintained or numerically improved up to completion of the study at week 52 in all VEGF Trap-Eye study groups, including the group receiving a 2.0 mg dose every two months. At week 52, all VEGF Trap-Eye dose groups reported mean gains in visual acuity of 9.7 to 13.1 letters, compared to a mean loss of 1.3 letters for patients receiving focal laser therapy (p<0.01 for each VEGF Trap-Eye dose group versus focal laser). VEGF Trap-Eye was generally well tolerated during the study and no patients experienced ocular drug-related serious adverse events. There were no patients with non-ocular serious adverse events judged by investigators to be drug-related during the first six months of the study and one in the second six months. The most common adverse events reported were those typically associated with intravitreal injections or the underlying disease. The most frequent ocular adverse events reported among patients receiving VEGF Trap-Eye were conjunctival hemorrhage, eye pain, ocular redness (hyperemia), and increased intraocular pressure. The incidence of non-ocular serious adverse events was generally well balanced between all treatment arms. There were six deaths (3.4%) among the 175 patients treated with VEGF Trap-Eye and one (2.3%) in the 44 patients treated with focal laser over 12 months. Based on these positive results, Regeneron and Bayer HealthCare are discussing plans to initiate Phase 3 studies of VEGF Trap-Eye in DME.

In January 2011, we and Bayer HealthCare initiated a new Phase 3 clinical trial in Asia in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of VEGF Trap-Eye in patients with CNV of the retina as a result of pathologic myopia. The study, which will enroll approximately 250 patients, has started in Japan and is scheduled to run until June 2013.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We have received \$60 million in development milestone payments and can earn up to \$50 million in future milestone payments related to marketing approvals of VEGF Trap-Eye in major market countries outside the United States. We can also earn up to \$135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

2. ARCALYST® - Inflammatory Diseases

ARCALYST® is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly allopurinol, is prescribed to eliminate the urate crystals and prevent them from reforming. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We are conducting a Phase 3 clinical development program with ARCALYST® in gout patients initiating uric acid-lowering therapy. The program currently consists of PRE-SURGE 1 (PREvention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, and RE-SURGE (REview of Safety Utilizing Rilonacept in Gout Exacerbations), each of which are described below.

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In June 2010, we announced that results from PRE-SURGE 1, a North America-based double-blind, placebo-controlled study, showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period. Patients initiating uric acid-lowering therapy who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, p<0.0001). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, p<0.0001).

All secondary endpoints of the study were highly positive (p<0.001 vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88% (3.7% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo, p<0.0001). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST® 160 mg, 18.8% with ARCALYST® 80 mg, and 46.8% with placebo, p<0.001).

A total of 241 patients were randomized in PRE-SURGE 1. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Adverse events that occurred at a frequency of at least 5% in any study group were: injection site reaction (19.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 7.6% with placebo), lower respiratory tract infection (0% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 2.5% with placebo), musculoskeletal pain/discomfort (6.2% with ARCALYST® 160 mg, 7.5% with ARCALYST® 80 mg, and 8.9% with placebo), and headache, (3.7% with ARCALYST® 160 mg, 6.3% with ARCALYST® 80 mg, and 1.3% with placebo).

In addition, in June 2010, we reported results from a placebo-controlled, Phase 3 study evaluating pain in patients presenting with an acute gout flare. The results of this study showed that there was no significant benefit from combining ARCALYST® with indomethacin (a non-steroidal anti-inflammatory drug (NSAID) considered the standard of care), as measured by the primary study endpoint, which was the average intensity of gout pain from 24 to 72 hours after initiation of treatment.

There are two ongoing studies in the Phase 3 program with ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy. The global PRE-SURGE 2 study, which has a similar trial design as PRE-SURGE 1, is evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. The global RE-SURGE study is evaluating the safety of ARCALYST® versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. PRE-SURGE 2 and RE-SURGE are fully enrolled, and we expect to have initial data from both studies during the first quarter of 2011. We own worldwide rights to ARCALYST®.

3. Aflibercept - Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A), VEGF-B, and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PIGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are conducting three randomized, double-blind Phase 3 trials, all of which are fully enrolled, that are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (VELOUR) is evaluating aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd-line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel/prednisone. In addition, a Phase 2 study (AFFIRM) of aflibercept in 1st-line metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin) is also fully enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a pre-specified number of events have occurred in each trial. In September 2010, we and sanofi-aventis announced that, following a planned interim analysis, the VELOUR study's IDMC recommended that the VELOUR study continue to completion as planned, with no modifications due to efficacy or safety concerns. Both sanofi-aventis and our management and staff remain blinded to the interim study results. Final results from the VITAL and VELOUR studies are anticipated in the first half of 2011. Based on projected event rates, an interim analysis of the VENICE study is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012. Initial data from the AFFIRM study are anticipated in the second half of 2011.

Aflibercept Collaboration with sanofi-aventis

We and sanofi-aventis globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

4. REGN727 (PCSK9 Antibody) for LDL cholesterol reduction

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 is a naturally occurring secreted protein that also modulates LDL cholesterol levels through its interaction with the LDL receptor. In a landmark study published in the *New England Journal of Medicine* in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL cholesterol, but also a significant reduction in the risk of coronary heart disease. We used our *VelocImmune*® technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to robustly lower LDL cholesterol.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from this Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. No serious adverse events and no dose limiting toxicities have been reported. Dose escalation is ongoing in both studies.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested at that time, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean additional reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities were reported. Dose escalation in this study is ongoing. In early 2011, we initiated Phase 2 studies of REGN727 in patients with hypercholesterolemia. REGN727 is being developed in collaboration with sanofi-aventis.

5. REGN88 (IL-6R Antibody) for inflammatory diseases

IL-6 is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to IL-6R, Actemra® (tocilizumab), a registered trademark of Genentech, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune®* technology that has completed Phase 1 studies, the results of which were presented at the annual meetings of the European League Against Rheumatism (EULAR) in June 2010 and the American College of Rheumatology in October 2010. REGN88 was well tolerated by patients with rheumatoid arthritis, and no dose-limiting toxicities were reported. Treatment with REGN88 resulted in dose-related reductions in biomarkers of inflammation. REGN88 is currently in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients, and initial Phase 2 results are expected in 2011. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN668 (IL-4R Antibody) for allergic and immune conditions

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis.

REGN668 is a fully human monoclonal antibody generated using our *VelocImmune*® technology that is designed to bind to IL-4R. A Phase 1 trial of REGN668 in healthy volunteers has been completed. A Phase 1b study in patients with atopic dermatitis is underway and a Phase 2 study in asthma is planned. REGN668 is being developed in collaboration with sanofi-aventis.

7. REGN421 (Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Dll4, inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune*® technology. REGN421, which is being developed in collaboration with sanofi-aventis, is in Phase 1 clinical development.

8. REGN910 (ANG2 Antibody) for oncology

In the fourth quarter of 2010, we initiated a phase 1 study in the oncology setting of REGN910, an antibody that specifically blocks ANG2. The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, ANG2 is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. REGN910 is being developed for cancer indications in collaboration with sanofi-aventis.

9. REGN475 (NGF Antibody) for pain

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune*® technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF. REGN475 is being developed in collaboration with sanofi-aventis.

In May 2010, we announced an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks.

The primary endpoint of this study was safety, and REGN475 was generally well tolerated through 16 weeks. Serious treatment emergent adverse events were rare and balanced between placebo and drug arms with three events (5.5%) in the placebo group and four events (2.5%) in the combined REGN475 groups. The most frequent adverse events reported among patients receiving REGN475 included sensory abnormalities, arthralgias, hyper/hypo-reflexia, peripheral edema, and injection site reactions. The types and frequencies of adverse events reported were similar to those previously reported from other investigational studies involving an anti-NGF antibody.

In the first interim efficacy analysis, REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 8 weeks following a single intravenous infusion (p<0.01). In July 2010, we reported that REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 16 weeks following a second intravenous infusion at week 8 (p<0.01). Pain was measured by the Numeric Rating Scale (NRS), as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) pain and function subscales.

Analysis of efficacy data from a Phase 2 trial in the acute setting of nerve root compression induced pain (acute sciatica) suggested that REGN475 therapy would not be effective in that setting. Studies in burn pain, vertebral compression fracture, and pancreatitis pain have been terminated due to low enrollment.

In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients. REGN475 is being developed in collaboration with sanofi-aventis.

10. REGN728 and REGN846

In the fourth quarter of 2010, clinical trials began with two additional antibodies that are part of the sanofi-aventis collaboration, REGN728 and REGN846. The targets of these antibodies have not been disclosed.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. $VelociSuite^{TM}$ is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuiteTM

VelociSuite™ consists of VelocImmune®, VelociGene®, VelociMouse®, and VelociMab® The VelocImmune® mouse platform is utilized to produce fully human monoclonal antibodies. VelocImmune® was generated by exploiting our VelociGene® technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. VelocImmune® mice can be

used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. VelocImmune and our entire $VelociSuite^{TM}$ offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the VelocImmune technology to produce our next generation of drug candidates for preclinical and clinical development.

Our VelociGene® platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knockout models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, VelociGene® offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, VelociGene® allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse*® technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse*® technology are suitable for direct phenotyping or other studies. We have also developed our *VelociMab*® platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune*® human monoclonal antibodies.

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. In connection with the execution of the discovery agreement in 2007, we received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis. Pursuant to the collaboration, sanofi-aventis is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified through discovery research under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with sanofi-aventis generally funding these costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017.

Under the amended discovery agreement, sanofi-aventis agreed to fund up to \$160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria were not satisfied. Sanofi-aventis has an option to extend the discovery program for up to an additional three years after 2017 for further antibody development and preclinical activities. Pursuant to the collaboration, sanofi-aventis is also obligated to fund up to \$30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities.

In 2010, as we scaled up our capacity to conduct antibody discovery activities, sanofi-aventis funded \$137.7 million of our preclinical research under the expanded collaboration. The balance between that amount and \$160 million, or \$22.3 million, has been added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement. During 2010, sanofi-aventis also funded \$138.3 million of our costs for clinical development of antibodies under the license agreement.

From the collaboration's inception in November 2007 through December 31, 2010, sanofi-aventis has funded a total of \$312.7 million of our costs under the discovery agreement and a total of \$263.0 million of our development costs under the license agreement, or a total of \$575.7 million in funding for our antibody research and development activities during this approximate three-year period.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Under this agreement, sanofi-aventis is required to pay us a minimum of \$21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

AstraZeneca UK Limited. In February 2007, we entered into a six-year, non-exclusive license agreement with AstraZeneca UK Limited to allow AstraZeneca to utilize our *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million annual, non-refundable payment to us in each of the first quarters of 2007, 2008, 2009, and 2010. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement, effective in February 2011, thereby canceling its obligation to make either of the final two annual payments. We remain entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by MedImmune using our *VelocImmune*® technology.

Astellas Pharma Inc. In March 2007, we entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million annual, non-refundable payment to us in each of the second quarters of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a \$165.0 million up-front payment to us in August 2010. In addition, Astellas will make a \$130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our VelocImmune® technology.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis Pharma AG (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1B antibody. The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed \$1.5 billion. Canakinumab is marketed for the treatment of CAPS, has completed Phase 3 development for gout, and is in earlier stage development for atherosclerosis and other inflammatory diseases. While our royalties under this agreement

could be significant if canakinumab is approved and successfully commercialized for additional disease indications, to date these royalties have been minimal. Accordingly, we are unable to predict whether these royalties will ever contribute materially to our results of operations or financial condition.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received \$21.6 million from the grant's inception through December 31, 2010 and are entitled to receive an additional \$3.7 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

Sales and Marketing

We have established a small commercial organization to support sales of ARCALYST® for the treatment of CAPS in the United States. We have no sales or distribution personnel and distribute the product through third party service providers. We currently have no sales, marketing, commercial, or distribution organization outside the United States. We are currently expanding our commercial capabilities and increasing the number of commercial personnel in preparation for the potential commercialization of VEGF Trap-Eye and our other late-stage product candidates.

Manufacturing

Our manufacturing facilities are located in Rensselaer, New York and consist of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space. We currently have approximately 54,000 liters of cell culture capacity at these facilities. At December 31, 2010, we employed 356 people at our Rensselaer facilities. There were no impairment losses associated with long-lived assets at these facilities as of December 31, 2010.

Among the conditions for regulatory marketing approval of a medicine is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to the good manufacturing practice (GMP) regulations of the health authority. In complying with standards set forth in these regulations, manufacturers must continue to expend time, money, and effort in the areas of production and quality control to ensure full technical compliance. Manufacturing establishments, both foreign and domestic, are also subject to inspections by or under the authority of the FDA and by other national, federal, state, and local agencies. If our manufacturing facilities fail to comply with FDA and other regulatory requirements, we will be required to suspend manufacturing. This would likely have a material adverse effect on our financial condition, results of operations, and cash flow.

Competition

We face substantial competition from pharmaceutical, biotechnology, and chemical companies (see Item 1A. "Risk Factors – Risks Related to Commercialization of Products – Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for and may be marketing products with a similar mechanism of action, or may enter the marketplace with better or lower cost drugs."). Our competitors include Genentech/Roche, Novartis, Pfizer Inc., Bayer HealthCare, Onyx Pharmaceuticals, Inc., Eli Lilly and Company, Abbott Laboratories, sanofi-aventis, Merck & Co., Inc., Amgen Inc., AstraZeneca, BristolMyersSquibb, Johnson and Johnson, GlaxoSmithKline, and others. Many of our competitors have substantially greater research, preclinical, and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Competition from smaller competitors may also be or become more significant if those competitors acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we are able to commercialize additional product candidates, one or more of our competitors may have brought a competitive product to market earlier than us or may have obtained

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or obtain patent protection that dominates or adversely affects our activities or products. Our ability to compete will depend, to a great extent, on how fast we can develop safe and effective product candidates, complete clinical testing and approval processes, and supply commercial quantities of the product to the market. Competition among product candidates approved for sale will also be based on efficacy, safety, reliability, availability, price, patent position, and other factors.

ARCALYST®. In 2009, Novartis received regulatory approval in the U.S. and Europe for canakinumab, a fully human anti-interleukin-IL1B antibody, for the treatment of CAPS. In January 2011, Novartis announced that it had submitted an application to the EMA for approval of canakinumab in gout. Novartis has also announced that it plans to submit to the FDA in the first quarter of 2011 an application for approval of canakinumab in gout. Canakinumab is also in development for atherosclerosis and a number of other inflammatory diseases. In addition, there are both small molecules and antibodies in development by other third parties that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Xoma Ltd., in collaboration with Servier, is developing an antibody to IL-1, and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. These drug candidates could offer competitive advantages over ARCALYST®. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST® for CAPS and delay or impair our ability to commercialize ARCALYST® for indications other than CAPS.

VEGF Trap-Eye. The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of wet AMD, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following retinal vein occlusion (RVO). Lucentis® was approved by the European Medicines Agency (EMA) for wet AMD in January 2007 and for the treatment of DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors as well as use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, DME, and RVO, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin® (bevacizumab). The relatively low cost of therapy with Avastin® in patients with wet AMD presents a significant competitive challenge in this indication. The National Eye Institute (NEI) initiated a Phase 3 trial to compare Lucentis® to Avastin® in the treatment of wet AMD. Data from this NEI study are expected to be published in 2011. Avastin® is also being evaluated in eye diseases in trials that have been initiated in the United Kingdom, Canada, Brazil, Mexico, Germany, Israel, and other areas.

Aflibercept. Many companies are developing therapeutic molecules designed to block the actions of VEGF specifically and angiogenesis in general. A variety of approaches have been employed, including antibodies to VEGF, antibodies to the VEGF receptor, small molecule antagonists to the VEGF receptor tyrosine kinase, and other anti-angiogenesis strategies. Many of these alternative approaches may offer competitive advantages to aflibercept in efficacy, side-effect profile, or method of delivery. Additionally, some of these molecules are either already approved for marketing or are at a more advanced stage of development than our product candidate.

In particular, Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and a number of pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are further along in development than aflibercept and may offer competitive advantages over our molecule. Pfizer, Onyx (together with its partner Bayer Healthcare), and GlaxoSmithKline are selling and marketing oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors.

Monoclonal Antibodies. Our early-stage clinical candidates in development are all fully human monoclonal antibodies which were generated using our VelocImmune® technology. Our antibody generation technologies and early-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, AstraZeneca, Amgen, Biogen Idec, Inc., Novartis, Genentech/Roche, Bristol-Myers Squib, Abbott, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences. As noted above, AstraZeneca and Astellas have licensed our *VelocImmune*® technology as part of their internal antibody development programs.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor Ortho Biotech, Inc. and Bristol-Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, Inc., has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against IL-4 in clinical development. Amgen previously had an antibody against IL-4R in clinical development for the treatment of asthma. We believe that several companies, including Amgen and Pfizer, have development programs for antibodies against PCSK9. Amgen, Pfizer, and AstraZeneca have development programs underway for antibodies against ANG2.

Other Areas. Many pharmaceutical and biotechnology companies are attempting to discover new therapeutics for indications in which we invest substantial time and resources. In these and related areas, intellectual property rights have been sought and certain rights have been granted to competitors and potential competitors of ours, and we may be at a substantial competitive disadvantage in such areas as a result of, among other things, our lack of experience, trained personnel, and expertise. A number of corporate and academic competitors are involved in the discovery and development of novel therapeutics that are the focus of other research or development programs we are now conducting. These competitors include Amgen and Genentech, as well as many others. Many firms and entities are engaged in research and development in the areas of cytokines, interleukins, angiogenesis, and muscle conditions. Some of these competitors are currently conducting advanced preclinical and clinical research programs in these areas. These and other competitors may have established substantial intellectual property and other competitive advantages.

If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our operations or future prospects.

We also compete with academic institutions, governmental agencies, and other public or private research organizations, which conduct research, seek patent protection, and establish collaborative arrangements for the development and marketing of products that would provide royalties or other consideration for use of their technology. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties or other consideration for use of the technology they have developed. Products developed in this manner may compete directly with products we develop. We also compete with others in acquiring technology from these institutions, agencies, and organizations.

Patents, Trademarks, and Trade Secrets

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties (see Item 1A. "Risk Factors – Risks Related to Intellectual Property – We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights."). Our policy is to file patent applications to protect technology, inventions, and improvements that we consider important to our business and operations. As of December 31, 2010, we held an ownership interest in a total of approximately 170 issued patents in the United States and approximately 590 issued patents in foreign countries with respect to our products and technologies. In addition, we hold an ownership interest in hundreds of patent applications in the United States and foreign countries.

Our patent portfolio includes granted patents and pending patent applications covering our *VelociSuite*TM technologies, including our *VelocImmune*® mouse platform which produces fully human monoclonal antibodies. Our issued patents covering these technologies generally expire between 2020 and 2030. However, we continue to file patent applications directed to improvements to these technology platforms.

Our patent portfolio also includes issued patents and pending applications relating to our marketed product, ARCALYST®, and our product candidates in clinical development. These patents cover the proteins and DNA encoding the proteins, manufacturing patents, method of use patents, and pharmaceutical compositions, as well as

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various methods of using the products. For each of ARCALYST® and our late-stage product candidates, aflibercept and VEGF Trap-Eye, these patents generally expire between 2020 and 2028. However, the projected patent terms may be subject to extension based on potential patent term extensions in countries where such extensions are available.

We also are the nonexclusive licensee of a number of additional patents and patent applications. In July 2008 we entered into an Amended and Restated Non-Exclusive License Agreement with Cellectis S.A. pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to this agreement, we agreed to pay Cellectis a low, single-digit royalty based on any future revenue received by us from any future licenses or sales of our *VelociGene®* or *Velocimmune®* products or services. No royalties are payable to Cellectis on any revenue from commercial sales of antibodies from our *Velocimmune®* technology, including antibodies developed under our collaboration with sanofi-aventis. We also have non-exclusive license agreements with Amgen and other organizations for patent rights related to ARCALYST®. In exchange for these licenses, we pay a mid-single digit royalty on net sales of ARCALYST®.

Patent law relating to the patentability and scope of claims in the biotechnology field is evolving and our patent rights are subject to this additional uncertainty. The degree of patent protection that will be afforded to our products in the United States and other important commercial markets is uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, and governments in these countries. There is no certainty that our existing patents or others, if obtained, will provide us protection from competition or provide commercial benefit.

Others may independently develop similar products or processes to those developed by us, duplicate any of our products or processes or, if patents are issued to us, design around any products and processes covered by our patents. We expect to continue, when appropriate, to file product and process applications with respect to our inventions. However, we may not file any such applications or, if filed, the patents may not be issued. Patents issued to or licensed by us may be infringed by the products or processes of others.

Defense and enforcement of our intellectual property rights is expensive and time consuming, even if the outcome is favorable to us. It is possible that patents issued or licensed to us will be successfully challenged, that a court may find that we are infringing validly issued patents of third parties, or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties (see Item 1A. "Risk Factors-Risks Related to Intellectual Property – We may be restricted in our development, manufacturing, and/or commercialization rights by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights").

Government Regulation

Regulation by government authorities in the United States and foreign countries is a significant factor in the research, development, manufacture, and marketing of ARCALYST® and our product candidates (see Item 1A. "Risk Factors – Regulatory and Litigation Risks – If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them."). All of our product candidates will require regulatory approval before they can be commercialized. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials and other pre-market approval requirements by the FDA and foreign authorities. Many aspects of the structure and substance of the FDA and foreign pharmaceutical regulatory practices have been reformed during recent years, and continued reform is under consideration in a number of jurisdictions. The ultimate outcome and impact of such reforms and potential reforms cannot be predicted.

The activities required before a product candidate may be marketed in the United States begin with preclinical tests. Preclinical tests include laboratory evaluations and animal studies to assess the potential safety and efficacy of the product candidate and its formulations. The results of these studies must be submitted to the FDA as part of an IND, which must be reviewed by the FDA before proposed clinical testing can begin. Typically, clinical testing involves a three-phase process. In Phase 1, trials are conducted with a small number of subjects to determine the early safety profile of the product candidate. In Phase 2, clinical trials are conducted with subjects afflicted with a specific disease or disorder to provide enough data to evaluate the preliminary safety, tolerability, and efficacy of different potential doses of the product candidate. In Phase 3, large-scale clinical trials are conducted with patients afflicted with the specific disease or disorder in order to provide enough data to understand the efficacy and safety profile of the product candidate, as required by the FDA. The results of the preclinical and clinical testing of a biologic product

candidate are then submitted to the FDA in the form of a BLA for evaluation to determine whether the product candidate may be approved for commercial sale. In responding to a BLA, the FDA may grant marketing approval, request additional information, or deny the application.

Any approval required by the FDA for any of our product candidates may not be obtained on a timely basis, or at all. The designation of a clinical trial as being of a particular phase is not necessarily indicative that such a trial will be sufficient to satisfy the parameters of a particular phase, and a clinical trial may contain elements of more than one phase notwithstanding the designation of the trial as being of a particular phase. The results of preclinical studies or early stage clinical trials may not predict long-term safety or efficacy of our compounds when they are tested or used more broadly in humans.

Approval of a product candidate by comparable regulatory authorities in foreign countries is generally required prior to commencement of marketing of the product in those countries. The approval procedure varies among countries and may involve additional testing, and the time required to obtain such approval may differ from that required for FDA approval.

Various federal, state, and foreign statutes and regulations also govern or influence the research, manufacture, safety, labeling, storage, record keeping, marketing, transport, and other aspects of pharmaceutical product candidates. The lengthy process of seeking these approvals and the compliance with applicable statutes and regulations require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could adversely affect the manufacturing or marketing of our products and our ability to receive product or royalty revenue.

In addition to the foregoing, our present and future business will be subject to regulation under the United States Atomic Energy Act, the Clean Air Act, the Clean Water Act, the Comprehensive Environmental Response, Compensation and Liability Act, the National Environmental Policy Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, national restrictions, and other current and potential future local, state, federal, and foreign regulations.

Business Segments

We manage our business as one segment which includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions and the development and commercialization of these discoveries. This segment also includes revenues and expenses related to (i) research and development activities conducted under our collaboration agreements with third parties and our grant from the NIH, (ii) ARCALYST® product sales for the treatment of CAPS, (iii) licensing agreements to utilize our *VelocImmune*® technology, and (iv) the supply of specified, ordered research materials using our *VelociGene*® technology platform.

Employees

As of December 31, 2010, we had 1,395 full-time employees, of whom 276 held a Ph.D. and/or M.D., or PharmD degree. We believe that we have been successful in attracting skilled and experienced personnel in a highly competitive environment; however, competition for these personnel is intense. None of our personnel are covered by collective bargaining agreements and our management considers its relations with our employees to be good.

Available Information

We make available free of charge on or through our Internet website (http://www.regeneron.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and, if applicable, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events

and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through December 31, 2010, we had a cumulative loss of \$1.0 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates, and to prepare for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of the product(s). We believe our existing capital resources, including the \$174.8 million net proceeds from our October 2010 public offering of Common Stock and the \$165.0 million up-front payment we received in August 2010 pursuant to our amended *VelocImmune*® technology license agreement with Astellas Pharma Inc., together with funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. Our expenses may increase for many reasons, including expenses in connection with the potential commercial launch of our products, expenses related to new clinical trials testing ARCALYST® or VEGF Trap-Eye, and expenses related to the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Should we require and be unable to raise sufficient funds to complete the development of our product candidates and also to successfully commercialize our late-stage product candidates if they obtain regulatory approval, we may face delay, reduction or elimination of our research and development or preclinical or clinical programs, and even if regulatory approval is obtained for such product candidates, they may never be successfully launched or become profitable, in which case our business, financial condition, or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of December 31, 2010, cash, cash equivalents, and marketable securities totaled \$626.9 million (including \$7.5 million of restricted cash and marketable securities) and represented 58% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities. We consider assets

classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled \$506.8 million at December 31, 2010, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of \$2.5 million, \$0.1 million, and \$0.1 million in 2008, 2009, and 2010, respectively. The current economic environment and the continued volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and ARCALYST® in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness.

Affibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd-line metastatic colorectal cancer, 1st-line androgen independent prostate cancer, and 2nd-line metastatic non-small cell lung cancer. Affibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that affibercept will be safe or effective in any of these cancer settings. In March 2010, Genentech, Inc. announced that a Phase 3 trial of its VEGF antagonist, Avastin®, in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of affibercept in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of CRVO. Although we reported positive Phase 3 trial results with VEGF Trap-Eye in wet AMD after one year of treatment, the trial will continue for an additional year and there is a risk that the results from the second year of the study could differ from the previously reported results, and such difference could delay or preclude regulatory approval. We also reported positive results in the first of two Phase 3 trials in the treatment of CRVO. The trial is continuing and there is a risk that the final results could differ from the previously reported results, and such final results could delay or preclude regulatory approval. There is also a risk that the results of the second Phase 3 trial in CRVO may demonstrate different results, and such results could delay or preclude regulatory approval. A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

ARCALYST® is in Phase 3 clinical trials for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Although we reported positive Phase 3 data from one trial in patients with gout initiating uric acid-lowering drug therapy, there is a risk that the results of the other ongoing trials of ARCALYST® in patients initiating

uric acid-lowering drug therapy will differ from the previously reported Phase 3 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to GCPs. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of IDMCs. These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating affibercept as a 1st-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times,

side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like VEGF Trap-Eye, which can cause injury to the eye and other complications. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), a registered trademark of Biovitrum, Enbrel® (etanercept), a registered trademark of Amgen and Pfizer, and Remicade® (infliximab) a registered trademark of Centocor, ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. Treatment with Kineret®, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® in gout or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

ARCALYST® and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of ARCALYST® were detected in patients with CAPS after treatment with ARCALYST®. Nineteen of 55 subjects (35%) who received ARCALYST® for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and possibly larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. We do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications. However, Genentech could seek to initiate a lawsuit or present a counterclaim for patent infringement in the declaratory judgment action we have filed, and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye or uses thereof. Genentech may be motivated to take such action(s) in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. We commenced in November 2010 a lawsuit against Genentech seeking a declaratory judgment that no activities relating to the Regeneron VEGF Trap infringe any valid claim of certain Genentech patents. It is possible that the court may decide to dismiss the action on procedural grounds or reach an adverse determination that would likely materially harm our business by requiring us to seek a license, which may not be available, or precluding the manufacture, further development, or sale of aflibercept or VEGF Trap-Eye, or resulting in a damage award. Similar patent actions may be taken in other countries, which could have similar or other adverse outcomes that would materially harm our business.

We are aware of patents and pending applications owned by Roche that claim antibodies to IL-6R and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to IL-6R, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST®, affibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS or VEGF Trap-Eye for the treatment of ophthalmologic disease, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST® and EMA approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST® or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates and/or in their commercial launch if they obtain regulatory approval, and a reduction in sales.

We and our third party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our marketed product and product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by patients who use ARCALYST® that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, known as off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business and financial results and condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states. In addition, as part of the federal Patient Protection and Affordable Care Act, or PPACA, pharmaceutical companies will be required to file reports with the federal government regarding payments made to healthcare professionals. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement actions, fines, and other penalties, and could receive adverse publicity, which would harm our business and financial results and condition.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Our business is subject to increasingly complex corporate governance, public disclosure, and accounting requirements and regulations that could adversely affect our business and financial results and condition.

We are subject to changing rules and regulations of various federal and state governmental authorities as well as the stock exchange on which our Common Stock is listed. These entities, including the Public Company Accounting Oversight Board (PCAOB), the SEC and the NASDAQ Global Market, have issued a significant number of new and increasingly complex requirements and regulations over the course of the last several years and continue to develop additional requirements and regulations in response to laws enacted by Congress, including the Sarbanes-Oxley Act of 2002 and, most recently, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that expressly authorized or required the SEC to adopt additional rules in these areas, such as shareholder approval of executive compensation (so-called "say on pay") and proxy access. On January 25, 2011, the SEC adopted final rules concerning "say on pay". Our efforts to comply with these requirements and regulations have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must

attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2010, which report is included in this Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a materially negative impact on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign cGMPs that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The PPACA potential regulations easing the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and financial condition, and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to \$1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN727, REGN88, REGN668, REGN421, REGN910, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research

and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofiaventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We currently have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as CROs, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance

with applicable GMPs, Good Laboratory Practices (GLPs), or GCP Standards, we could experience additional costs, delays, and difficulties in the manufacture or development of, or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST® for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for all our clinical trials or for commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services for our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may also be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

Our ability to manufacture our products may be impaired if any of our manufacturing activities are found to infringe third-party patents.

The ability for us to manufacture our products in our Rensselaer, New York facilities, or to utilize contract manufacturers to produce our products, depends on our ability to operate without infringing the patents or other intellectual property rights of third parties. Other parties may allege that our manufacturing activities infringe patents or other intellectual property rights. A judicial decision in favor of such third parties could preclude such manufacture of our products.

If any of our clinical programs are delayed or discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, or their clinical development is delayed, we may have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials at our manufacturing facilities in Rensselaer, New York. We would be unable to manufacture these materials if our Rensselaer facilities were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for the manufacture and formulation of ARCALYST® and of our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of ARCALYST® and our product candidates. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® or our product candidates for use in clinical trials or commercial supply, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacture and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or to enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST® for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates receive regulatory approval. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy if such products receive regulatory approval. Though we are currently actively pursuing establishing our own sales, marketing, and distribution organization in anticipation of filing for and receiving regulatory approval to market and sell in the United States VEGF Trap-Eye and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy, we may be unsuccessful in doing so, which would harm our business and adversely affect our future prospects.

There may be too few patients with CAPS to profitably commercialize ARCALYST® in this indication.

Our only approved product is ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009, we received European marketing authorization for rilonacept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST® in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for and may be marketing products with a similar mechanism of action or may enter the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin®, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer, Onyx Pharmaceuticals (together with its partner Bayer HealthCare), and GlaxoSmithKline are marketing and selling oral medications that target tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin®, and their extensive, ongoing clinical development plan for Avastin® in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis®, for the treatment of wet AMD, DME, and other eye indications. Lucentis® was approved by the FDA in June 2006 for the treatment of wet AMD and in June 2010 for the treatment of macular edema following RVO. Lucentis® was also approved by the EMA for wet AMD in January 2007 and for DME in January 2011. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME including those that act by blocking VEGF and VEGF receptors, as well as siRNAs that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, DME, and RVO, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin®.

The NEI and others are conducting long-term, controlled clinical trials comparing Lucentis® to Avastin® in the treatment of wet AMD. Data from these trials are expected in 2011. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis®, because doctors and patients have had significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin® in patients with wet AMD presents a significant competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel®, Remicade®, Humira® (adalimumab), a registered trademark of Abbott, and Simponi® (golimumab), a registered trademark of Centocor, and the IL-1 receptor antagonist Kineret®, and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® in other indications, and this is one of the reasons we discontinued the development of ARCALYST® in adult rheumatoid arthritis. In addition, even if ARCALYST® is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients have had significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST®, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of IL-1 or inhibit the signaling of IL-1. For example, Eli Lilly, Xoma (in collaboration with Servier), and Novartis are each developing antibodies to IL-1 and both Amgen and MedImmune are developing antibodies to the IL-1 receptor. In 2009, Novartis received regulatory approval in the U.S. and Europe for canakinumab, a fully human anti-interleukin-IL1ß antibody, for the treatment of CAPS. Canakinumab is also in development for atherosclerosis and a number of other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, canakinumab is dosed once every eight weeks compared to the onceweekly dosing regimen for ARCALYST®. The successful development and/or commercialization of these competing molecules could adversely affect sales of ARCALYST® for CAPS and delay or impair our ability to commercialize ARCALYST® for indications other than CAPS.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. In January 2011, Novartis announced that the results of two Phase 3 studies with canakinumab focused on reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout were positive. In addition, Novartis announced that it had submitted an application to the EMA for approval of canakinumab in gout. Novartis also announced that it plans to submit to the FDA in the first quarter of 2011 an application for approval of canakinumab in gout. Canakinumab is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST® in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other NSAIDs are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs will make it difficult for us to successfully commercialize ARCALYST® in these diseases.

Our early-stage clinical candidates in development are all fully human monoclonal antibodies, which were generated using our *VelocImmune®* technology. Our antibody generation technologies and early-stage clinical candidates face competition from many pharmaceutical and biotechnology companies using various technologies.

Numerous other companies are developing therapeutic antibody products. Companies such as Pfizer, Johnson & Johnson, AstraZeneca, Amgen, Biogen Idec, Novartis, Genentech/Roche, Bristol-Myers Squib, Abbott, and GlaxoSmithKline have generated therapeutic products that are currently in development or on the market that are derived from recombinant DNA that comprise human antibody sequences.

We are aware of several pharmaceutical and biotechnology companies actively engaged in the research and development of antibody products against targets that are also the targets of our early-stage product candidates. For example, Pfizer, Johnson & Johnson, and Abbott are developing antibody product candidates against NGF. Genentech/Roche is marketing an antibody against IL-6R (tocilizumab) for the treatment of rheumatoid arthritis, and several other companies, including Centocor Ortho Biotech and Bristol-Myers Squibb, have antibodies against IL-6 in clinical development for this disease. GlaxoSmithKline, in partnership with OncoMed Pharmaceuticals, has a Dll4 antibody in clinical development for the treatment of solid tumors. Aerovance has two formulations of a biologic directed against IL-4 in clinical development. Amgen previously had an antibody against IL-4R in clinical development for the treatment of asthma. We believe that several companies, including Amgen and Pfizer, have development programs for antibodies against PCSK9. Amgen, Pfizer, and AstraZeneca have development programs underway for antibodies against ANG2. If any of these or other competitors announces a successful clinical study involving a product that may be competitive with one of our product candidates or the grant of marketing approval by a regulatory agency for a competitive product, such developments may have an adverse effect on our operations or future prospects.

The successful commercialization of ARCALYST® and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including NSAIDs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely

affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. In particular, payers may impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® in the United States for the treatment of a group of rare genetic disorders called CAPS. We have received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST®. Physicians may not prescribe ARCALYST®, and CAPS patients may not be able to afford ARCALYST®, if third party payers do not agree to reimburse the cost of ARCALYST® therapy and this would adversely affect our ability to commercialize ARCALYST® profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the PPACA and a related reconciliation bill were enacted in the U.S. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers, our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material negative effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers and other key members of our senior management team. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. As we prepare for commercialization in the United States of our late-stage

product candidates should they receive regulatory approval, we will also be highly dependent on the expertise and services of members of our senior management leading these commercialization efforts. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary to continue to advance our business and achieve our strategic objectives.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our Common Stock by our executive officers, directors, or significant shareholders;
- · arrivals and departures of key personnel; and
- · general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of December 31, 2010, our four largest shareholders plus Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, beneficially owned 50.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2010. In September 2003, sanofi-aventis (then Aventis Pharmaceuticals Inc.) purchased 2,799,552 newly issued, unregistered shares of our Common Stock, and in December 2007 sanofi-aventis purchased an additional 12 million newly issued, unregistered shares of our Common Stock. Under our investor agreement, as amended, with sanofi-aventis, these shares may not be sold until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. In addition, in October 2010, sanofi-aventis purchased an additional 1,017,401 shares of Common Stock in our underwritten public offering. As of December 31, 2010, sanofi-aventis beneficially owned 15,816,953 shares of our Common Stock, representing approximately 18.1% of the shares of Common Stock then outstanding. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of December 31, 2010, holders of Class A Stock held 20.0% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of December 31, 2010:

- our current executive officers and directors beneficially owned 13.1% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2010, and 26.7% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of December 31, 2010; and
- our four largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 50.9% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of December 31, 2010. In addition, these five shareholders held 55.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of December 31, 2010.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and

• under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, as amended, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We conduct our research, development, manufacturing, and administrative activities at our owned and leased facilities. Under our main lease in Tarrytown, New York, as amended, we lease approximately 545,600 square feet of laboratory and office facilities, including approximately 401,600 square feet of space that we currently occupy and approximately 144,000 square feet of additional new space that we expect to occupy in early 2011. The term of the lease will expire in June 2024. The lease contains three renewal options to extend the term of the lease by five years each and early termination options on approximately 316,000 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Monthly lease payments on the new space commenced in January 2011 and charges for utilities, taxes, and operating expenses commenced in January 2010.

In December 2009, we entered into a separate agreement to lease approximately 6,600 square feet of laboratory and office space at our current Tarrytown location. The term of this lease will expire in August 2011 after which time we have the option to include this space in our main Tarrytown lease, as described above.

In October 2008, we entered into an operating sublease for approximately 14,100 square feet of office space in Bridgewater, New Jersey. The term of the lease expires in July 2011.

We own facilities in Rensselaer, New York, consisting of three buildings totaling approximately 395,500 square feet of research, manufacturing, office, and warehouse space.

The following table summarizes information regarding our current real property leases:

			Current Monthly	
	Square		Base Rental	Renewal Option
Location	Footage	Expiration	Charges ⁽¹⁾	Availahle
Tarrytown, New York	545,600	June 2024	\$1.767,600	Three 5-year terms
Tarrytown, New York	6,600	August 2011	\$ 21,900	Incorporate into main
				Tarrytown lease
Bridgewater, New Jersey(2)	14,100	July 2011	S 21700	None

Excludes additional charges for utilities, real estate taxes, and operating expenses, as defined.

(2) Relates to sublease in Bridgewater, New Jersey, as described above.

We believe that our existing owned and leased facilities are adequate for ongoing research, development, manufacturing, and administrative activities. In the future, we may lease, operate, or purchase additional facilities in which to conduct expanded research and development and manufacturing activities and support commercial operations.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition. On November 19, 2010, Regeneron filed a complaint against Genentech, Inc. in the United States District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint. The motion is currently pending. We may initiate similar actions in countries outside the United States.

ITEM 4. [REMOVED	AND RESERVED	
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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock is quoted on The NASDAQ Global Select Market under the symbol "REGN." Our Class A Stock, par value \$.001 per share, is not publicly quoted or traded.

The following table sets forth, for the periods indicated, the range of high and low sales prices for our Common Stock as reported by The NASDAQ Global Select Market:

	High	Low
2009		
First Quarter	\$20.08	\$11.81
Second Quarter	18.42	12.11
Third Quarter	23.49	16.05
Fourth Quarter	24.97	15.02
2010		
First Quarter	\$30.51	\$23.42
Second Charter	30.58	22.32
Third Quarter	27.53	20.45
Fourth Quarter	33.94	24.29

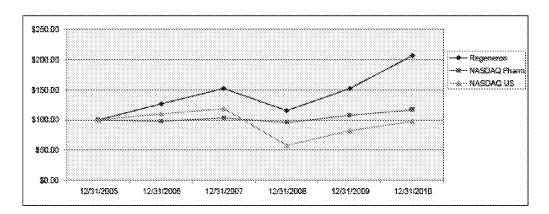
As of February 11, 2011, there were 432 shareholders of record of our Common Stock and 39 shareholders of record of our Class A Stock.

We have never paid cash dividends and do not anticipate paying any in the foreseeable future.

The information under the heading "Equity Compensation Plan Information" in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC is incorporated by reference into Item 12 of this Annual Report on Form 10-K.

STOCK PERFORMANCE GRAPH

Set forth below is a line graph comparing the cumulative total shareholder return on Regeneron's Common Stock with the cumulative total return of (i) The NASDAQ Pharmaceuticals Stocks Index and (ii) The NASDAQ Stock Market (U.S.) Index for the period from December 31, 2005 through December 31, 2010. The comparison assumes that \$100 was invested on December 31, 2005 in our Common Stock and in each of the foregoing indices. All values assume reinvestment of the pre-tax value of dividends paid by companies included in these indices. The historical stock price performance of our Common Stock shown in the graph below is not necessarily indicative of future stock price performance.



	12/31/2005	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010
Regeneron	\$100.00	\$126.23	\$151.89	511547	\$152.08	\$206.48
NASDAQ Pharm	100.00	97.88	102.94	95.78	107.62	116.66
NASDAQ US	100.00	109.84	119 14	57.41	82.53	97.94

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below for the years ended December 31, 2010, 2009, and 2008 and at December 31, 2010 and 2009 are derived from and should be read in conjunction with our audited financial statements, including the notes thereto, included elsewhere in this report. The selected financial data for the years ended December 31, 2007 and 2006 and at December 31, 2008, 2007, and 2006 are derived from our audited financial statements not included in this report.

		Year	Ended Decembe	r 31,	
	2010	2009	2008	2007	2006
		(In thousa	nds, except per sh	are data)	
Statement of Operations Data					
Revenues Callaboration revenue	S 386 725	\$314.457	\$185,138	\$ 87,648	\$ 47.763
Technology licensing	40.150	40.013	40.000	28,421	
Contract manufacturing	40,130	40,015	10,000	20,721	12,311
Net product sales	25,254	18,364	6,249	***************************************	•••••
Contract research and other	6.945	6,434	7,070	8,955	3,373
	459,074	379,268	238,457	125,024	63,447
Expenses					
Research and development	489,252	398,762	274,903	202,468	137,064
Contract manufacturing	(5.201	52.022	40.000	27.020	8,146
Selling, general, and administrative Cost of goods sold	65,201 2,093	52,923 1.686	48,880 923	37,929	25,892
LOS III SOLIIS SOII	556.546	453,371	324,706	240,397	171,102
Loss from aperations	(97,472)	(74,103)	(86,249)	(115.373)	(107.655)
Other income (expense)					··· <u>······</u> ··
Investment income	2 122	4,488	18,161	20.897	16,548
Interest expense	(9,118)	(2,337)	(7,752)	(12,043)	(12,043)
Loss on early extinguishment of debt			(938)		
	(6,996)	2,151	9,471	8,854	4,505
Net loss before income tax expense and cumulative effect of a change in accounting principle	AND ED	en ogn	(76,778)	cios sim	(103.120)
Income tax (benefit) expense	(104 468)	(71,952) (4,122)	2,351	(106,519)	(103,150)
Net loss before cumulative effect of a		(4,122)	2,331		
change in accounting principle	(104.468)	(67,830)	(79,129)	(106,519)	(103.150)
Cumulative effect of a change in accounting principle		······································	···	······································	···
related to share-based payments					813
Net lass	\$(104,468)	\$(67.830)	\$ (79.129)	<u>\$(106.519)</u>	\$(102.337)
Net loss per share, basic and diluted:		****************			
Net loss before cumulative effect of a					
change in accounting principle Cumulative effect of a change in accounting principle	\$ (1.26)	3 (133)	\$ (100)	3 (161)	\$ (1.78)
related to share-based payments					0.01
	S (1.26)	\$ (0.85)	S (100)	S (161)	S (177)
		·· <u>·····</u>	··· <u>······</u> /	· <u>·····</u>	:: <u></u>

		л	i becember 51,		
	2010	2009	2008	2007	2006
			In thousands)		
Balance Sheet Data					
Unrestricted and restricted cash, cash equivalents, and					
marketable securities (current and non-current)	\$ 626,939	\$390,010	\$527,461	\$846,279	\$522,859
Total assets	1.089,432	741,202	724,220	957.881	585.090
Notes payable (current and non-current)				200,000	200,000
Facility lease obligations (current and non-current)	160 030	109,022	54,182	21,623	
Capital lease obligations (current and non-current)	2,829				
Stockholders' equity	527.815	396,762	421,514	459,348	216.624

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older.

We have 11 product candidates in clinical development, including three that are in late-stage (Phase 3). All of these product candidates were discovered in our research laboratories. Our late-stage programs are VEGF Trap-Eye, which is being developed using intraocular delivery for the treatment of serious eye diseases; ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment; and affibercept, which is being developed in oncology in collaboration with sanofi-aventis. Our earlier stage clinical programs include the following fully human antibodies, which are being developed in collaboration with sanofi-aventis:

- REGN727, an antibody to PCSK9 for LDL cholesterol reduction;
- REGN88, an antibody to IL-6R, which is being developed in rheumatoid arthritis and ankylosing spondylitis;
- REGN668, an antibody to IL-4R, which is being developed in atopic dermatitis and asthma;
- REGN421, an antibody to Dll4, a novel angiogenesis target, which is being developed in oncology,
- REGN910, an antibody to ANG2, another novel angiogenesis target, which is being developed in oncology;
- REGN475, an antibody to NGF, which is being developed for the treatment of pain (currently on clinical hold); and
- REGN728 and REGN846, two antibodies in clinical development against undisclosed targets.

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

At December 31.

From inception on January 8, 1988 through December 31, 2010, we had a cumulative loss of \$1.0 billion, principally related to our research and development activities. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. We plan to submit a BLA to the FDA in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In addition, Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe. If we receive positive Phase 3 clinical trial results, we also expect to file for regulatory approval of ARCALYST® for the prevention of gout flares and of aflibercept in one or more oncology indications. We expect to incur substantial costs to prepare for potential commercialization of these late-stage product candidates and, if one or more of these product candidates receive regulatory approval, to fund the launch of the product(s). Thus, we expect to continue to incur substantial operating losses over at least the next few years related primarily to our research and development and commercialization activities. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, may expand and require additional resources. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the scope and progress of our research and development efforts, the progress of our efforts to commercialize our late-stage product candidates, the timing of certain expenses, and the amount of reimbursement that we receive from collaborators. We cannot predict whether or when our late-stage product candidates will receive regulatory approval or, if such approval is received, whether we will be able to successfully commercialize such product(s), or if we do commercialize such product(s), whether or when they may become profitable.

A primary driver of our expenses is our number of full-time employees. Our annual average headcount in 2010 was 1,249 compared with 980 in 2009 and 810 in 2008. In 2010, 2009, and 2008 our average headcount increased primarily to support our expanded research and development activities in connection with our antibody collaboration with sanofi-aventis. In 2011, we expect our average headcount to increase to approximately 1,600-1,650, primarily to support the further expansion of our research and development activities, especially in connection with our antibody collaboration with sanofi-aventis, and activities in connection with preparing for the potential commercialization of our late-stage product candidates.

Management of cash flow is extremely important as we continue our research and development activities and prepare for potential commercialization of our late-stage product candidates. Our principal sources of cash to-date have been from (i) sales of common equity, both in public offerings and to our collaborators, including sanofi-aventis, (ii) funding from our collaborators and licensees in the form of up-front and milestone payments, technology licensing payments, and payments for our research and development activities, and (iii) a private placement of convertible debt, which was repaid in full during 2008. The most significant use of our cash is for research and development activities, which include drug discovery, preclinical studies, clinical trials, and the manufacture of drug supplies for preclinical studies and clinical trials. We are reimbursed for a substantial portion of these research and development activities by our collaborators. A significant use of our cash will also be for activities in connection with preparing for the potential commercialization of our late-stage product candidates.

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The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2010 and 2011 to date were, and plans for the remainder of 2011 are, as follows:

Clinical Program	2010 and 2011 Events to Date	2011 Plans
VEGF Trap-Eye	 Reported positive 52-week results in the Phase 3 VIEW 1 and VIEW 2 trials in wet AMD Reported positive six-month results in the Phase 3 COPERNICUS trial in CRVO and completed patient enrollment in the Phase 3 GALILEO trial in CRVO Reported positive 24-week and 52-week results from the Phase 2 DME trial (DA VINCI) Initiated a Phase 3 trial in Asia in CNV of the retina as a result of pathologic myopia 	 File for regulatory approval of VEGF Trap-Eye in wet AMD in the first half of 2011 Report initial six-month data from GALILEO in the first half of 2011 Report two-year data from VIEW 1 and VIEW 2, and one-year data from COPERNICUS in the second half of 2011 If GALILEO is successful, file for regulatory approval of VEGF Trap-Eye in CRVO
ARCALYST®	Reported positive results from PRE-SURGE 1 and completed patient enrollment of PRE-SURGE 2 and RE-SURGE. PRE-SURGE 1 and 2 are Phase 3 studies that are evaluating ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy Reported that in a Phase 3 study evaluating ARCALYST in the treatment of pain during an acute gout flare, there was no significant benefit from combining ARCALYST with an NSAID versus an NSAID alone	 Report data from PRE-SURGE 2 and RE-SURGE in the first quarter of 2011 If PRE-SURGE 2 and RE-SURGE are successful file for regulatory approval of ARCALYST® for the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy by mid 2011
Aflibercept (VEGF Trap – Oncology)	 Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer (VITAL), prostate cancer (VENICE), and colorectal cancer (VELOUR) Completed patient enrollment in a Phase 2 1st-line study in metastatic colorectal cancer (AFFIRM) An IDMC conducted an interim analysis of VELOUR and recommended that the study continue to completion as planned with no modifications 	 Report data from VITAL and VELOUR in the first half of 2011 An IDMC is expected to conduct an interim analysis of VENICE in mid-2011 Report data from AFFIRM
REGN727 (PCSK9 Antibody)	 Reported proof-of-concept data from a Phase 1 study for LDL cholesterol reduction Initiated a Phase 2 program for LDL cholesterol reduction 	Report data from the Phase 2 program for LDL cholesterol reduction

Clinical Program	2010 and 2011 Events to Date	2011 Plans
REGN88 (IL-6R Antibody)	 Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis Initiated a Phase 2 dose-ranging study in ankylosing spondy litis Reported data from the Phase 1 program in rheumatoid arthritis 	 Report initial data in rheumatoid arthritis and in ankylosing spondylitis
REGN668 (IL-4R Antibody)	 Completed a Phase 1 study in healthy volunteers Initiated a Phase 1b program in atopic dermatitis 	• Initiate a Phase 2 program in asthma
REGN421 (Dll4 Antibody)	Continued patient enrollment in Phase 1 program	 Initiate a Phase 2 program in advanced malignancies
REGN910 (ANG2 Antibody)	Initiated a Phase 1 study in oncology	
REGN475 (NGF Antibody)	 Reported top-line results from Phase 2 studies in osteoarthritis of the knee and acute sciatica Phase 2 studies placed on clinical hold in December 2010 by the FDA due to adverse events seen with NGF antibodies under development at other pharmaceutical companies 	
REGN728 (target not disclosed)	Initiated clinical development in an undisclosed indication	
REGN846 (target not disclosed)	Initiated clinical development in an undisclosed indication	

Critical Accounting Policies and Use of Estimates

A summary of the significant accounting policies that impact us is provided in Note 2 to our Financial Statements, beginning on page F-7. The preparation of financial statements in accordance with accounting principles generally accepted in the United States of America (GAAP) requires management to make estimates and assumptions that affect reported amounts and related disclosures in the financial statements. Management considers an accounting estimate to be critical if:

- It requires an assumption (or assumptions) regarding a future outcome; and
- Changes in the estimate or the use of different assumptions to prepare the estimate could have a material effect on our results of operations or financial condition.

Management believes the current assumptions used to estimate amounts reflected in our financial statements are appropriate. However, if actual experience differs from the assumptions used in estimating amounts reflected in our financial statements, the resulting changes could have a material adverse effect on our results of operations, and in certain situations, could have a material adverse effect on our liquidity and financial condition. The critical accounting estimates that impact our financial statements are described below.

Revenue Recognition

Collaboration Revenue

We earn collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize our technology platforms. We currently have collaboration agreements with sanofi-aventis and Bayer HealthCare. The terms of collaboration agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

We enter into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. We may share the costs of research and development activities with our collaborator, such as in our VEGF Trap-Eye collaboration with Bayer HealthCare, or we may be reimbursed for all or a significant portion of the costs of our research and development activities, such as in our aflibercept and antibody collaborations with sanofi-aventis. We record our internal and third-party development costs associated with these collaborations as research and development expenses. When we are entitled to reimbursement of all or a portion of the research and development expenses that we incur under a collaboration, we record those reimbursable amounts as collaboration revenue proportionately as we recognize our expenses. If the collaboration is a cost-sharing arrangement in which both we and our collaborator perform development work and share costs, in periods when our collaborator incurs development expenses that benefit the collaboration and Regeneron, we also recognize, as additional research and development expense, the portion of the collaborator's development expenses that we are obligated to reimburse.

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, our estimated performance periods may change if development programs encounter delays or we and our collaborators decide to expand or contract our clinical plans for a drug candidate in various disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

Product Revenue

Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and we have no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distributor fees, and other sales-related deductions. We review our estimates of rebates payable each period and record any necessary adjustments in the current period's net product sales.

Clinical Trial Expenses

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as CROs, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by CROs. CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts with CROs are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue expense on an estimated cost-per-patient basis, based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the years ended December 31, 2010, 2009, or 2008.

Stock-based Employee Compensation

We recognize stock-based compensation expense for grants of stock option awards and restricted stock to employees and non-employee members of our board of directors under our long-term incentive plans based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period.

We use the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our historical exercise experience with previously issued employee and board of directors option grants. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The assumptions used in computing the fair value of option awards reflect our best estimates but involve uncertainties related to market and other conditions, many of which are outside of our control. Changes in any of these assumptions may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in future periods.

In addition, we have granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, we estimate that these options will vest, which is based on whether we consider the options' performance conditions to be probable of attainment. Our estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods. Changes in these estimates may materially affect the amount of stock-based compensation that we recognize in future periods related to performance-based options.

Marketable Securities

We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. We consider our marketable securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board (FASB). These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that may be charged against income.

On a quarterly basis, we review our portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. Such factors include the length of time and the extent to which market value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. With respect to debt securities, this review process also includes an evaluation of our intent to sell an individual debt security or our need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of our ability and intent to hold the securities until their full value can be recovered. This review is subjective and requires a high degree of judgment. For example, as a result of our quarterly reviews of our marketable securities portfolio, during 2010, 2009, and 2008 we recorded charges for other-than-temporary impairment of our marketable securities totaling \$0.1 million, \$0.1 million, and \$2.5 million, respectively.

Depreciation of Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. In some situations, the life of the asset may be extended or shortened if circumstances arise that would lead us to believe that the estimated life of the asset has changed. The life of leasehold improvements may change based on the extension of lease contracts with our landlords. Changes in the estimated lives of assets will result in an increase or decrease in the amount of depreciation recognized in future periods. For example, effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, were extended. The effect of this change in estimate was to lower depreciation expense by \$4.0 million and to lower our net loss per share by \$0.05 for the year ended December 31, 2010.

Results of Operations

Years Ended December 31, 2010 and 2009

Net Loss

Regeneron reported a net loss of \$104.5 million, or \$1.26 per share (basic and diluted), for the year ended December 31, 2010, compared to a net loss of \$67.8 million, or \$0.85 per share (basic and diluted) for 2009. The increase in our net loss in 2010 was principally due to higher research and development expenses, partly offset by higher collaboration revenue in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues in 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	\$311.3	\$247.2
Bayer HealthCare	75.4	67.3
Total collaboration revenue	386.7	314.5
Technology licensing revenue	40.2	40.0
Net product sales	25.3	18.4
Contract research and other revenue	6.9	64
Total revenue	\$459.1	\$379.3

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earned from sanofi-aventis, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

	Years	ended
	Decem	ber 31,
Sanofi-aventis Collaboration Revenue	2010	2009
(In millions)		
Affibercept		
Regeneron expense reimbursement	\$ 16.5	\$ 26.6
Recognition of deferred revenue related to up-front payments	9.0	9.9
Total aflibercept	26.4	36.5
Antibody		
Regeneron expense reimbursement	276.0	198.1
Recognition of deferred revenue related to up-front and other payments	73	9.9
Recognition of revenue related to VelociGene® agreement	1.6	2.7
Total antibody	284.9	210.7
Total sanofi-aventis collaboration revenue	\$311.3	\$247.2

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in 2010 compared to 2009, primarily due to lower costs related to internal research activities and manufacturing aflibercept clinical supplies. As of December 31, 2010, \$32.6 million of the original \$105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of \$137.7 million under the discovery agreement and \$138.3 million of development costs under the license agreement, compared to \$99.8 million and \$98.3 million, respectively, in 2009. The higher reimbursement amounts in 2010 compared to 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue related to sanofi-aventis' \$85.0 million up-front payment decreased in 2010 compared to 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to \$30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which \$23.4 million was received or receivable from sanofi-aventis as of December 31, 2010. Revenue related to these payments for such funding from sanofi-aventis is deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the recognition of the original \$85.0 million up-front payment. As of December 31, 2010, \$79.8 million of the sanofi-aventis payments was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. In 2010 and 2009, we recognized \$1.6 million and \$2.7 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron VEGF Trap-Eye development expenses, substantive performance milestone payments, and recognition of revenue related to a non-refundable \$75.0 million up-front payment received in October 2006 and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

	Years	ended
Bayer HealthCare Collahoration Revenue	Decem	ber 31,
(In millions)	2010	2009
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$45.5	\$37.4
Substantive performance milestone payments	20.0	20.0
Recognition of deferred revenue related to up-front and other nulestone payments	9.9	9.9
Total Bayer HealthCare collaboration revenue	\$75.4	\$67.3

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in 2010 compared to 2009 due to higher internal development activities and higher clinical development costs in connection with our Phase 3 COPERNICUS trial in CRVO. In the fourth quarter of 2010, we earned two \$10.0 million substantive milestone payments from Bayer HealthCare for achieving positive 52-week results in the VIEW 1 study and positive 6-month results in the COPERNICUS study. In July 2009, we earned a \$20.0 million substantive performance milestone payment from Bayer HealthCare in connection with the dosing of the first patient in the COPERNICUS study. In connection with the recognition of deferred revenue related to the \$75.0 million up-front payment and \$20.0 million milestone payment received in August 2007, as of December 31, 2010, \$47.0 million of these payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments were deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In both 2010 and 2009, we recognized \$40.0 million of technology licensing revenue related to these agreements. In addition, in connection with the amendment and extension of our license agreement with Astellas, in August 2010, we received a \$165.0 million up-front payment, which was deferred upon receipt and will be recognized as revenue ratably over a seven-year period beginning in mid-2011. As of December 31, 2010, \$176.6 million of these technology licensing payments was deferred and will be recognized as revenue in future periods.

Net Product Sales

In 2010 and 2009, we recognized as revenue \$25.3 million and \$18.4 million, respectively, of ARCALYST® net product sales for which both the right of return no longer existed and rebates could be reasonably estimated. The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had

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accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, \$4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower our net loss per share by \$0.06 in 2010. At December 31, 2010, there was no deferred revenue related to ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue in 2010 and 2009 included \$4.6 million and \$5.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to \$556.5 million in 2010 from \$453.4 million in 2009. Our average headcount in 2010 increased to 1,249 from 980 in 2009 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2010 and 2009 included a total of \$39.9 million and \$31.3 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the year	ended December 31	, 2010
	Expenses hefore inclusion of Non-cash	Non-cash	
	Compensation	Compensation	Expenses as
Expenses	Expense	Expense	Reported
(In millions)			
Research and development	5466.9	\$22.3	\$489.2
Selling, general, and administrative	47.6	17.6	65.2
Cost of goods sold	2.1		2.1
Total operating expenses	\$516.6	\$39.9	\$556.5
	For the year		
			2009
		ended December 31	, 2009
	Expenses hefore inclusion of Non-cash	ended December 31 Non-cash	, 2009
	Expenses hefore		Expenses as
Expenses	Expenses hefore inclusion of Non-cash	Non-cash	
Expenses (In millions)	Expenses hefore inclusion of Non-cash Compensation	Non-cash Compensation	Expenses as
	Expenses hefore inclusion of Non-cash Compensation	Non-cash Compensation	Expenses as
(In millions)	Expenses hefore inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
(In millions) Research and development	Expenses hefore inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported \$3398.8

The increase in total Non-cash Compensation Expense in 2010 was primarily attributable to (i) the recognition of higher expense in 2010 in connection with performance-based stock options that we estimate will vest, (ii) the increase in stock option awards in 2010, due in part to the increase in headcount, and (iii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2009 compared to December 2008.

Research and development expenses increased to \$489.2 million in 2010 from \$398.8 million in 2009. The following table summarizes the major categories of our research and development expenses in 2010 and 2009:

	Year I	Ended	
	Decem	ber 31,	Increase
Research and Development Expenses	2010	2009	(Decrease)
(In millions)			
Payroll and benefits())	\$131.7	\$ 99.9	531.8
Clinical trial expenses	106.9	111.6	(4.7)
Clinical manufacturing costs(2)	95.6	66.7	28.0
Research and other development costs	53.8	42.3	11.5
Occupancy and other operating costs	52.3	40.6	11.7
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses(3)	48.9	37.7	11.2
Total research and development expenses	\$489.2	\$398.8	\$90.4

- (1) Includes \$19.3 million and \$16.2 million of Non-cash Compensation Expense in 2010 and 2009, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$3.0 million and \$2.6 million of Non-cash Compensation Expense in 2010 and 2009, respectively.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® in gout, partly offset by higher costs related to our clinical development programs for VEGF Trap-Eye, principally in connection with our COPERNICUS trial in CRVO. Clinical manufacturing costs increased due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility and higher costs related to manufacturing clinical supplies of monoclonal antibodies, partly offset by lower costs related to manufacturing aflibercept clinical supplies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD which is being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	Year	ended	
	December 31,		Increase
Project Costs	2010	2009	(Decrease)
(In millions)			
ARCALYST®	\$ 56.8	\$ 677	\$(10.9)
VEGF Trap-Eye	138.5	109.8	28.7
Aflibercept	13.5	23.3	(9.8)
REGN88	25.0	36.9	(11.9)
REGN727	36.0	21.1	14.9
Other antibody candidates in clinical development	65.5	53.3	12.2
Other research programs & unallocated costs	153.9	86.7	67.2
Total research and development expenses	\$489.2	\$398.8	\$ 90.4

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a BLA must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST® and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$65.2 million in 2010 from \$52.9 million in 2009 due primarily to increases in compensation expense and recruitment costs, principally in connection with higher headcount in 2010, and an increase in Non-cash Compensation Expense for the reasons described above.

Cost of Goods Sold

Cost of goods sold in 2010 and 2009 was \$2.1 million and \$1.7 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies. To date, ARCALYST® shipments to our customers have primarily consisted of supplies of inventory manufactured and expensed as research and development costs prior to FDA approval in 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to \$2.1 million in 2010 from \$4.5 million in 2009, due primarily to lower yields on, and lower average balances of, cash and marketable securities.

Interest expense increased to \$9.1 million in 2010 from \$2.3 million in 2009. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York.

Income Tax Expense (Benefit)

In 2010, we did not recognize any income tax expense or benefit. In 2009, we recognized a \$4.1 million income tax benefit, consisting primarily of (i) \$2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allowed us to claim a refund of U.S. federal alternative minimum tax that we paid in 2008, and (ii) \$0.7 million resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

Years Ended December 31, 2009 and 2008

Net Loss

Regeneron reported a net loss of \$67.8 million, or \$0.85 per share (basic and diluted), for the year ended December 31, 2009, compared to a net loss of \$79.1 million, or \$1.00 per share (basic and diluted) for 2008. The decrease in our net loss in 2009 was principally due to higher collaboration revenue in connection with our antibody collaboration with sanofi-aventis, receipt of a \$20.0 million substantive performance milestone payment in connection with our VEGF Trap-Eye collaboration with Bayer HealthCare, and higher ARCALYST® sales, partly offset by higher research and development expenses, as detailed below.

Revenues

Revenues in 2009 and 2008 consist of the following:

(In millions)	2009	2008
Collaboration revenue		
Sanofi-aventis	\$247.2	\$154.0
Bayer HealthCare	67.3	31.2
Total collaboration revenue	314.5	185.2
Technology licensing revenue	40.0	40.0
Net product sales	18.4	6.3
Contract research and other revenue	6.4	7.0
Total revenue	\$379.3	\$238.5

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earned from sanofi-aventis, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the affibercept collaboration and \$85.0 million related to the antibody collaboration.

(In millions) Affibercept Regeneron expense reimbursement Recognition of deferred revenue related to up-front payments Total affibercept Regeneron expense reimbursement Regeneron expense reimbursement Regeneron expense reimbursement Recognition of deferred revenue related to up-front payment Recognition of revenue related to up-front payment Recognition of revenue related to VelociGene® agreement Total antibody 2009 2008 3 5 6 \$ 3 5.6 \$ 44.4 Antibody 2 7 1.2 Total antibody		Years	ended
Affibercept Regeneron expense reimbursement Recognition of deferred revenue related to up-front payments Total affibercept 36.5 44.4 Antibody Regeneron expense reimbursement Recognition of deferred revenue related to up-front payment Recognition of revenue related to VelociGene® agreement Total antibody Total antibody 219.7 109.6	Sanofi-aventis Collaboration Revenue	Decen	iber 31,
Regeneron expense reimbursement \$ 26.6 \$ 35.6 Recognition of deferred revenue related to up-front payments 99 \$ 8 Total affibercept 36.5 44.4 Antibody Regeneron expense reimbursement 198.1 97.9 Recognition of deferred revenue related to up-front payment 9.9 10.5 Recognition of revenue related to VelociGene® agreement 2.7 1.2 Total antibody 210.7 109.6	(In millions)	2009	2008
Recognition of deferred revenue related to up-front payments 9.9 8.8 Total affibercept 36.5 44.4 Antibody Regeneron expense reimbursement 198.1 97.9 Recognition of deferred revenue related to up-front payment 9.9 10.5 Recognition of revenue related to VelociGene® agreement 2.7 1.2 Total antibody 218.7 109.6	Affibercept		
Total aflibercept 36.5 44.4 Antibods Regeneron expense reimbursement 198.1 97.9 Recognition of deferred reconne related to up-front payment 9.9 19.5 Recognition of revenue related to VelociGene® agreement 2.7 1.2 Total antibody 219.7 199.6	Regeneron expense reimbursement	\$ 26.6	\$ 35.6
Antibody Regeneron expense reimbursement Recognition of deferred revenue related to up-front payment Recognition of revenue related to VelociGene® agreement Total antibody 198.1 97.9 19.5 19.5 19.6	Recognition of deferred revenue related to up-front payments	9.9	8.8
Regeneron expense reimbursement 198.1 97.9 Recognition of deferred revenue related to up-front payment 99.1 12.5 Recognition of revenue related to VelociGene® agreement 2.7 1.2 Total antibody 219.7 199.6	Total aflibercept	36.5	44.4
Recognition of deferred revenue related to up-front payment Recognition of revenue related to VelociGene® agreement 2.7 1.2 Fotal autibody 218.7 109.6	Antibody		
Recognition of revenue related to VelociGene® agreement 2.7 1.2 Total antibody 219.7 109.6	Regeneron expense reimbursement	198.1	97.9
Total antibody 210.7 109.6	Recognition of deferred revenue related to up-front payment	99	10.5
	Recognition of revenue related to VelociGene® agreement	2.7	1.2
Total sanofi-aventis collaboration revenue \$247.2 \$154.0	Total antibody	210.7	109.6
	Total sanofi-aventis collaboration revenue	\$247.2	\$154.0

Sanofi-aventis' reimbursement of our affibercept expenses decreased in 2009 compared to 2008, primarily due to lower costs related to internal research activities and manufacturing affibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front affibercept payments increased in 2009 compared to 2008 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of December 31, 2009, \$42.5 million of the original \$105.0 million of up-front payments related to affibercept was deferred and will be recognized as revenue in future periods.

In 2009, sanofi-aventis' reimbursement of our antibody expenses consisted of \$99.8 million under the discovery agreement and \$98.3 million of development costs under the license agreement, compared to \$72.2 million and \$25.7 million, respectively, in 2008. The higher reimbursement amounts in 2009 compared to 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement. Recognition of deferred revenue related to sanofi-aventis' \$85.0 million up-front payment decreased in 2009 compared to 2008 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. As of December 31, 2009, \$63.7 million of the original \$85.0 million up-front payment was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. In 2009 and 2008, we recognized \$2.7 million and \$1.2 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable \$75.0 million up-front payment received in October 2006 and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

	Years	ended
Bayer HealthCare Collaboration Revenue	Decem	ber 31,
(In millions)	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	53 7.4	\$18.8
Substantive performance milestone payment	20.0	
Recognition of deferred revenue related to up-front and other milestone payments	9.9	12.4
Total Bayer HealthCare collaboration revenue	\$67.3	\$31.2

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in 2009 compared to 2008. Under the terms of the collaboration, in 2009, all agreed-upon VEGF Trap-Eye development expenses incurred by Regeneron and Bayer HealthCare under a global development plan were shared equally. In 2008, the first \$70.0 million of agreed-upon VEGF Trap-Eye development expenses were shared equally, and we were solely responsible for up to the next \$30.0 million. During the fourth quarter of 2008, we were solely responsible for most of the collaboration's VEGF Trap-Eye development expenses, which reduced the amount of cost-sharing revenue we earned from Bayer HealthCare in 2008. In addition, cost-sharing revenue increased in 2009, compared to 2008, due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 DA VINCI trial in DME, and COPERNICUS trial in CRVO. In July 2009, we received \$20.0 million substantive performance milestone payment from Bayer HealthCare in connection with our COPERNICUS trial, which was recognized as collaboration revenue. Recognition of deferred revenue related to the up-front and August 2007 milestone payments from Bayer HealthCare decreased in 2009 from 2008 due to an extension of the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of December 31, 2009, \$56.8 million of these up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments were deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In both 2009 and 2008, we recognized \$40.0 million of technology licensing revenue related to these agreements.

Net Product Sales

In 2009 and 2008, we recognized as revenue \$18.4 million and \$6.3 million, respectively, of ARCALYST® net product sales for which both the right of return no longer existed and rebates could be reasonably estimated. At December 31, 2009, deferred revenue related to ARCALYST® net product sales totaled \$4.8 million.

Contract Research and Other Revenue

Contract research and other revenue in 2009 and 2008 included \$5.5 million and \$4.9 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to \$453.4 million in 2009 from \$324.7 million in 2008. Our average headcount in 2009 increased to 980 from 810 in 2008 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in 2009 and 2008 included a total of \$31.3 million and \$32.5 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the year ended December 51, 2009		
	Expenses before		
	inclusion of Non-casb	Non-casb	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported
Research and development	\$ 380.0	5 18 8	\$ 398.8
Selling, general, and administrative	40.4	12.5	52.9
Cost of goods sold	17		17
Total operating expenses	\$ 422.1	\$ 31.3	453.4

For the year ended December 31, 2000

	101 the jent that Detempts 51, 2000		
	Expenses before		
	inclusion of Non-casb	Non-casb	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported
Research and development	\$ 255.9	\$ 19 0	5 274 9
Selling, general, and administrative	35.4	13.5	48.9
Cast of goods sold	<u></u>		
Total operating expenses	\$ 292.2	\$ 32.5	\$ 324.7

The decrease in total Non-cash Compensation Expense in 2009 was primarily attributable to the lower fair market value of our Common Stock on the date of our annual employee option grants made in December 2008 as compared to the fair market value of annual employee option grants made in recent years prior to 2008.

Research and Development Expenses

Research and development expenses increased to \$398.8 million in 2009 from \$274.9 million in 2008. The following table summarizes the major categories of our research and development expenses in 2009 and 2008:

	Year E	nded	
Research and Development Expenses	Decemb	er 31,	
(In millions)	2009	2008	Increase
Payroll and benefits:0	\$ 99.9	\$ 817	5 18.2
Clinical trial expenses	111.6	49.3	62.3
Clinical manufacturing costs ⁽²⁾	66.7	53.8	12.9
Research and other development costs	42.3	29.6	12.7
Occupancy and other operating costs	406	30.5	10.1
Cost-sharing of Bayer HealthCare VEGF Trap-Eye development expenses(3)	37.7	30.0	7.7
Total research and development	5398.8	\$274.9	\$123.9

- 1) Includes \$16.2 million and \$16.7 million of Non-cash Compensation Expense in 2009 and 2008, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$2.6 million and \$2.3 million of Non-cash Compensation Expense in 2009 and 2008, respectively.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, DA VINCI trial in DME, and COPERNICUS trial in CRVO, (ii) ARCALYST®, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibody candidates, which are in earlier stage clinical development. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of ARCALYST® and monoclonal antibodies, partly offset by lower costs related to manufacturing aflibercept clinical supplies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

For the year ended December 31, 2008

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	Year e	nded	
Project Costs	Decemb	er 31,	Increase
(In millions)	2009	2008	(Decrease)
ARCALYST®	5 677	\$ 39.2	\$ 28.5
VEGF Trap-Eye	109.8	82.7	27.1
Affibercept	23.3	32.1	(8.8)
REGN88	36.9	21.4	15.5
Other antibody candidates in clinical development	74.4	27.4	47.0
Other research programs & unallocated costs	86.7	72.1	14.6
Total research and development expenses	\$398.9	\$274.9	\$123.9

For the reasons described above in Results of Operations for the years ended December 31, 2010 and 2009, under the caption "Research and Development Expenses", and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$52.9 million in 2009 from \$48.9 million in 2008. In 2009, we incurred (i) higher compensation expense, (ii) higher patent-related costs, (iii) higher facility-related costs due primarily to increases in administrative headcount, and (iv) higher patient assistance costs related to ARCALYST®. These increases were partly offset by (i) lower marketing costs related to ARCALYST®, (ii) a decrease in administrative recruitment costs, and (iii) lower professional fees related to various corporate matters.

Cost of Goods Sold

During 2008, we began recognizing revenue and cost of goods sold from net product sales of ARCALYST®. Cost of goods sold in 2009 and 2008 was \$1.7 million and \$0.9 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies. In 2009 and 2008, ARCALYST® shipments to our customers consisted of supplies of inventory manufactured and expensed as research and development costs prior to FDA approval in 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to \$4.5 million in 2009 from \$18.2 million in 2008, due primarily to lower yields on, and lower balances of, cash and marketable securities. In addition, in 2009 and 2008, deterioration in the credit quality of specific marketable securities in our investment portfolio subjected us to the risk of not being able to recover these securities' carrying values. As a result, in 2009 and 2008, we recognized charges of \$0.1 million and \$2.5 million, respectively, related to these securities, which we considered to be other than temporarily impaired. In 2009 and 2008, these charges were either wholly or partly offset by realized gains of \$0.2 million and \$1.2 million, respectively, on sales of marketable securities during the year.

Interest expense decreased to \$2.3 million in 2009 from \$7.8 million in 2008. Interest expense in 2009 was attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. Interest expense in 2008 related to \$200.0 million of 5.5% Convertible Senior Subordinated Notes until they were retired. During the second and third quarters of 2008, we repurchased a total of \$82.5 million in principal amount of these convertible notes for \$83.3 million. In connection with these repurchases, we recognized a \$0.9 million loss on early extinguishment of debt, representing the premium paid on the notes plus related unamortized debt issuance costs. The remaining \$117.5 million of convertible notes were repaid in full upon their maturity in October 2008.

Income Tax Expense (Benefit)

In 2009, we recognized a \$4.1 million income tax benefit, consisting primarily of (i) \$2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allowed us to claim a refund of U.S. federal alternative minimum tax that we paid in 2008, as described below, and (ii) \$0.7 million resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

In 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards that would otherwise have expired over the next several years, to offset income for tax purposes. As a result, we incurred and paid income tax expense of \$3.1 million, which relates to U.S. federal and New York State alternative minimum taxes and included \$0.2 million of interest and penalties. This expense was partly offset by a \$0.7 million income tax benefit, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed us to claim a refund for a portion of our unused pre-2006 research tax credits.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, and our technology licensing agreements, ARCALYST® product revenue, and investment income.

Sources and Uses of Cash for the Years Ended December 31, 2010, 2009, and 2008

At December 31, 2010, we had \$626.9 million in cash, cash equivalents, and marketable securities (including \$7.5 million of restricted cash and marketable securities) compared with \$390.0 million at December 31, 2009 (including \$1.6 million of restricted cash) and \$527.5 million (including \$1.7 million of restricted cash) at December 31, 2008. In October 2010, the Company completed an underwritten public offering of 6,325,000 shares of Common Stock and received net proceeds of \$174.8 million. Under the terms of our non-exclusive license agreements with AstraZeneca and Astellas, each company made \$20.0 million annual, non-refundable payments to us in each of 2010, 2009, and 2008. In addition, in connection with the July 2010 amendment and extension of our license agreement with Astellas, we received a \$165.0 million up-front payment from Astellas in August 2010. We also received, from Bayer HealthCare, a \$10.0 million milestone payment in December 2010 in connection with the VIEW 1 study, and a \$20.0 million milestone payment in July 2009 in connection with the COPERNICUS study.

Cash Provided by (Used in) Operations

Net cash provided by operations was \$96.3 million in 2010, compared with net cash used in operations of \$72.2 million in 2009 and \$89.1 million in 2008. Our net losses of \$104.5 million in 2010, \$67.8 million in 2009, and \$79.1 million in 2008 included \$39.9 million, \$31.3 million, and \$32.5 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of \$19.7 million, \$14.2 million, and \$11.3 million in 2010, 2009, and 2008, respectively.

At December 31, 2010, accounts receivable increased by \$27.5 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis and a \$10.0 million milestone payment receivable from Bayer HealthCare, which was earned in December 2010 in connection with the COPERNICUS study. Our deferred revenue at December 31, 2010 increased by \$158.2 million, compared to

end-of-year 2009, primarily due to (i) the receipt of the \$165.0 million up-front payment from Astellas, as described above, which was deferred and will be recognized ratably over the seven-year period commencing in mid-2011 and (ii) sanofi-aventis' funding of \$22.9 million of agreed-upon costs incurred by us during 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original \$85.0 million up-front payment received from sanofi-aventis. These increases were partly offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. Accounts payable, accrued expenses, and other liabilities increased \$7.6 million at December 31, 2010, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll-related expenses.

At December 31, 2009, accounts receivable increased by \$30.4 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Our deferred revenue at December 31, 2009 decreased by \$27.5 million, compared to end-of-year 2008, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. Accounts payable, accrued expenses, and other liabilities increased \$12.6 million at December 31, 2009, compared to end-of-year 2008, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for clinical-related expenses, which were partly offset by an \$8.6 million decrease in the cost-sharing payment due to Bayer HealthCare in connection with our VEGF Trap-Eye collaboration.

At December 31, 2008, accounts receivable increased by \$16.9 million, compared to end-of-year 2007, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Our deferred revenue at December 31, 2008 decreased by \$26.8 million, compared to end-of-year 2007, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by the deferral of \$4.0 million of ARCALYST® net product sales at December 31, 2008.

The majority of our cash expenditures in 2010, 2009, and 2008 were to fund research and development, primarily related to our clinical programs and our preclinical human monoclonal antibody programs. In 2008, we made interest payments totaling \$9.3 million on our convertible senior subordinated notes. The convertible notes were repaid in full in October 2008.

Cash (Used in) Provided by Investing Activities

Net cash used in investing activities was \$434.2 million in 2010, compared with net cash provided by investing activities of \$146,000 in 2009 and \$30.8 million in 2008. In 2010, purchases of marketable securities exceeded sales or maturities by \$335.6 million. In 2009 and 2008, sales or maturities of marketable securities exceeded purchases by \$97.4 million and \$65.7 million, respectively. Capital expenditures in 2010, 2009, and 2008 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December 2006 Tarrytown, New York lease, as described below.

Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was \$243.3 million in 2010 and \$31.4 million in 2009, respectively, and net cash used in financing activities was \$192.9 million in 2008. In October 2010, we completed an underwritten public offering of 6,325,000 shares of our Common Stock and received net proceeds of \$174.8 million. In addition, proceeds from issuances of our Common Stock in connection with exercises of stock options were \$22.0 million in 2010, \$8.6 million in 2009, and \$7.9 million in 2008. In 2010 and 2009, we received \$47.5 million and \$23.6 million, respectively, of tenant improvement reimbursements from our landlord in connection with our new Tarrytown facilities, which we are deemed to own in accordance with FASB authoritative guidance. In the second and third quarters of 2008, we repurchased \$82.5 million in principal amount of our convertible senior subordinated notes for \$83.3 million. The remaining \$117.5 million of convertible notes were repaid in full upon their maturity in October 2008.

Fair Value of Marketable Securities

At December 31, 2010 and 2009, we held marketable securities whose aggregate fair value totaled \$513.9 million and \$181.3 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	2010 2009		<u> </u>	
Investment type	Fair Value	Percent	Fair Value	Percent
Unrestricted				
U.S. government agency securities	\$434.4	85%	\$ 296	16%
U.S. Treasury securities			80.4	44%
U.S. government-guaranteed corporate bands	64.0	13%	48.7	27%
Equity securities	3.6	1%	5.4	3%
U.S. government guaranteed collateralized mortgage obligations	2.1		37	29%
Corporate bonds			10.3	6%
Other	1.6			
Mortgage-backed securities	1.1		3.2	2%
Total unrestricted marketable securities	506.8	999/4	181.3	100%
Restricted				
U.S. government agency securities	7.1	1%		
Total marketable securities	<u>§ 513.9</u>	100%	<u>\$181.3</u>	100%

In addition, at December 31, 2010 and 2009, we had \$113.0 million and \$208.7 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

We classify our investments using a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The three tiers are Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

The Company held one Level 3 marketable security, which had no fair value at December 31, 2010 and 2009, and whose fair value was \$0.1 million at December 31, 2008. This Level 3 security was valued using information provided by the Company's investment advisors and other sources, including quoted bid prices which took into consideration the securities' lack of liquidity. During the year ended December 31, 2009, the Company recorded charges for other-than-temporary impairment of this Level 3 marketable security totaling \$0.1 million; therefore, as of December 31, 2009, the fair value of this security had been written down to zero. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the years ended December 31, 2010 and 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the years ended December 31, 2010 and 2009.

Our methods for valuing our marketable securities are described in Note 2 to our financial statements included in this Annual Report on Form 10-K. With respect to valuations for pricing our Level 2 marketable securities, we consider quantitative and qualitative factors such as financial conditions and near term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. For valuations that we determine for our Level 3 marketable securities, we regularly monitor these securities and adjust their valuations as deemed appropriate based on the facts and circumstances.

Collaborations with sanofi-aventis

Aflibercept

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of aflibercept in all countries other than Japan, where we retained the exclusive right to develop and commercialize aflibercept. Sanofi-aventis made a non-refundable up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of our Common Stock for \$45.0 million.

In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude, from the scope of the collaboration, the development and commercialization of aflibercept for intraocular delivery to the eye. In connection with this amendment, sanofi-aventis made a \$25.0 million non-refundable payment to us.

In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a \$25.0 million non-refundable up-front payment to us, which was received in January 2006. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five aflibercept oncology indications in Japan.

We have agreed to manufacture clinical supplies of aflibercept at our plant in Rensselaer, New York. Sanofi-aventis has agreed to be responsible for providing commercial scale manufacturing capacity for aflibercept.

Under the collaboration agreement, as amended, agreed upon worldwide aflibercept development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of an aflibercept product for intraocular delivery to the eye predates the first commercial sale of an aflibercept product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs. Since inception of the collaboration agreement through December 31, 2010, we and sanofi-aventis have incurred \$707.3 million in agreed upon development expenses related to aflibercept. Currently, multiple clinical studies to evaluate aflibercept as both a single agent and in combination with other therapies in various cancer indications are ongoing.

Sanofi-aventis funded \$16.5 million, \$26.6 million, and \$35.6 million, respectively, of our aflibercept development costs in 2010, 2009, and 2008, of which \$3.9 million, \$3.6 million, and \$6.3 million, respectively, were included in accounts receivable as of December 31, 2010, 2009, and 2008. In addition, the up-front payments from sanofi-aventis of \$80.0 million in September 2003 and \$25.0 million in January 2006 were recorded to deferred revenue and are being recognized as contract research and development revenue over the period during which we expect to perform services. In 2010, 2009, and 2008, we recognized \$9.9 million, \$9.9 million, and \$8.8 million of revenue, respectively, related to these up-front payments.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of affibercept development expenses will terminate and we will retain all rights to affibercept.

Antibodies

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. In connection with the execution of the discovery agreement in 2007, we received a non-refundable up-front payment of \$85.0 million from sanofi-aventis. Pursuant to the collaboration, sanofi-aventis is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$175 million of research from the collaboration's inception through December 31, 2009. In November 2009, we and sanofi-aventis amended these collaboration agreements to expand and extend our antibody collaboration. Under the amended discovery agreement, sanofi-aventis agreed to fund up to \$160 million per year of our antibody discovery activities in 2010 through 2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria

were not satisfied. In 2010, as we scaled up our capacity to conduct antibody discovery activities, sanofi-aventis funded \$137.7 million of our preclinical research under the amended discovery agreement. The balance between that amount and \$160 million, or \$22.3 million, has been added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement. The amended discovery agreement will expire on December 31, 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified through discovery research under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Under the license agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by sanofi-aventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate (called Shared Phase 3 Trial Costs) are shared 80% by sanofi-aventis and 20% by us. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of \$341.0 million as of December 31, 2010) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and our share of the collaboration profits from commercialization of collaboration products. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the license agreement, we retain the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

We are obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the collaboration until commercial supplies of that drug candidate are being manufactured. In connection with the November 2009 amendment of the collaboration's discovery agreement, sanofi-aventis is funding up to \$30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which \$21.6 million had been received, and \$1.8 million was included in accounts receivable, at December 31, 2010.

In 2010, 2009, and 2008, sanofi-aventis funded \$137.7 million, \$99.8 million, and \$72.2 million, respectively, of our expenses under the collaboration's discovery agreement and \$138.3 million, \$98.3 million, and \$25.7 million, respectively, of our development costs under the license agreement. Of these amounts, \$73.4 million, \$57.9 million and \$25.5 million were included in accounts receivable as of December 31, 2010, 2009, and 2008, respectively. The \$85.0 million up-front payment received from sanofi-aventis in December 2007 was recorded to deferred revenue and is being recognized as collaboration revenue over the period during which we expect to perform services. In addition, reimbursements by sanofi-aventis of our costs to expand our manufacturing capacity are recorded to deferred revenue and recognized prospectively as collaboration revenue over the same period applicable to recognition of the \$85.0 million up-front payment. In 2010, 2009, and 2008, we recognized \$7.3 million, \$9.9 million, and \$10.5 million of revenue, respectively, related to these deferred payments.

In connection with the antibody collaboration, in August 2008, we entered into a separate agreement with sanofi-aventis to use our proprietary *VelociGene*® technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. The agreement provides for minimum annual order quantities for the term of the agreement, which extends through December 2012, for which we expect to receive payments totaling a minimum of \$21.5 million, of which \$9.2 million had been received as of December 31, 2010.

With respect to each antibody product which enters development under the license agreement, sanofi-aventis or we may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. We may also opt-out of the further development of an antibody product if we give notice to sanofi-

aventis within thirty days of the date that sanofi-aventis elects to jointly develop such antibody product under the license agreement. Each of the discovery agreement and the license agreement contains other termination provisions, including for material breach by the other party. Prior to December 31, 2017, sanofi-aventis has the right to terminate the amended discovery agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to us the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2017. Upon termination of the collaboration in its entirety, our obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate.

In December 2007, we sold sanofi-aventis 12 million newly issued, unregistered shares of Common Stock at an aggregate cash price of \$312.0 million, or \$26.00 per share of Common Stock. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with us. This agreement, which was amended in November 2009, contains certain demand rights, "stand-still provisions", and other restrictions, which are more fully described in Note 12 to our Financial Statements. In addition, in October 2010, sanofi-aventis purchased 1,017,401 shares of Common Stock in our underwritten public offering.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, VEGF Trap-Eye. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of \$75.0 million. In August 2007, we received a \$20.0 million milestone payment (which, for the purpose of revenue recognition, was not considered substantive) from Bayer HealthCare following dosing of the first patient in the VIEW 1 study of VEGF Trap-Eye in wet AMD. In July 2009, we received a \$20.0 million substantive performance milestone payment from Bayer HealthCare following dosing of the first patient in the COPERNICUS study of VEGF Trap-Eye in CRVO. In both December 2010 and January 2011, we received a \$10.0 million substantive milestone payment (for a total of \$20.0 million) from Bayer HealthCare for achieving positive 52-week results in the VIEW 1 study and positive 6-month results in the COPERNICUS study, respectively. We are eligible to receive up to \$50 million in future milestone payments related to marketing approvals of the VEGF Trap-Eye in major market countries outside the United States. We are also eligible to receive up to \$135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

We will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer HealthCare out of our share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$241.2 million at December 31, 2010) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and our share of the collaboration profits, or at a faster rate at our option. Within the United States, we are responsible for any future commercialization of VEGF Trap-Eye and retain exclusive rights to any future profits from such commercialization in the United States. To date, we and Bayer HealthCare have initiated Phase 3 programs of VEGF Trap-Eye in wet AMD, CRVO, and CNV of the retina as a result of pathologic myopia, and a Phase 2 clinical study in DME. We are also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

The \$75.0 million up-front payment and the \$20.0 million milestone payment received in August 2007 from Bayer HealthCare were recorded to deferred revenue. In 2010, 2009, and 2008, we recognized \$9.9 million, \$9.9 million, and \$12.4 million, respectively, of revenue related to these payments. The \$10.0 million substantive milestone payments received from Bayer HealthCare in each of December 2010 and January 2011 were recognized as collaboration revenue in 2010, and the \$20.0 million substantive performance milestone payment received from Bayer HealthCare in July 2009 was recognized as collaboration revenue in 2009.

Under the terms of the agreement, in 2009 and thereafter, all agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared equally. In 2010 and 2009, this resulted in net payments by us of \$2.6 million and \$0.3 million, respectively, to Bayer HealthCare. In 2008, the first \$70.0 million of VEGF Trap-Eye development expenses were shared equally and we were solely responsible for up to the next \$30.0 million, which resulted in a net payment by us of \$11.3 million to Bayer HealthCare. At December 31, 2010 and 2009, accrued expenses included \$2.3 million and \$1.2 million, respectively, due to Bayer HealthCare.

Bayer HealthCare has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to VEGF Trap-Eye.

License Agreement with AstraZeneca

Under this non-exclusive license agreement, AstraZeneca made a \$20.0 million annual, non-refundable payment to us in each of 2010, 2009, 2008, and 2007. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement, effective in February 2011. We remain entitled to receive mid-single digit royalties on any future sales of antibody products discovered by MedImmune using our *VelocImmune*® technology.

License Agreement with Astellas

Under this non-exclusive license agreement, Astellas made a \$20.0 million annual, non-refundable payment to us in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a \$165.0 million up-front payment to us in August 2010. In addition, Astellas will make a \$130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune*® technology.

National Institutes of Health Grant

Under our five-year grant from the NIH, as amended, we are entitled to receive a minimum of \$25.3 million over the five-year period beginning in September 2006, subject to compliance with the grant's terms and annual funding approvals, including \$1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium. In 2010, 2009, and 2008, we recognized \$4.6 million, \$5.5 million, and \$4.9 million, respectively, of revenue related to the NIH Grant, of which \$1.0 million and \$1.2 million, respectively, was received at the end of 2010 and 2009. Under the NIH grant, as amended, we have received \$21.6 million from the grant's inception through December 31, 2010. In 2011, we expect to receive funding of approximately \$3.7 million for reimbursement of our expenses related to the NIH Grant.

License Agreement with Cellectis

In July 2008, we and Cellectis S.A. entered into an Amended and Restated Non-Exclusive License Agreement. The amended license agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which we licensed certain patents and patent applications relating to a process for the specific replacement of a copy of a gene in the receiver genome by homologous recombination. Pursuant to the amended license agreement, in July 2008, we made a non-refundable \$12.5 million payment to Cellectis and agreed to pay Cellectis a low single-digit royalty based on revenue received by us from any future licenses or sales of our *VelociGene®* or *Velocimmune®* products and services. No royalties are payable to Cellectis with respect to our *Velocimmune®* license agreements with AstraZeneca and Astellas or our antibody collaboration with sanofi-aventis. In addition, no royalties are payable to Cellectis on any revenue from commercial sales of antibodies from our *Velocimmune®* technology.

We are amortizing our \$12.5 million payment to Cellectis in proportion to past and anticipated future revenues under our license agreements with AstraZeneca and Astellas and our antibody discovery agreement with sanofi-aventis (as amended in November 2009). In 2010, 2009, and 2008 we recognized \$0.9 million, \$2.3 million, and \$2.7 million, respectively, of expense related to the Cellectis agreement.

Lease - Tarrytown, New York Facilities:

We lease approximately 545,600 square feet of laboratory and office space at facilities in Tarrytown, New York, under a December 2006 lease agreement, as amended. These facilities include approximately 230,000 square feet of newly constructed space in two new buildings (Buildings A and B) that were completed during the third quarter of 2009 and, under a December 2009 amendment to the lease, approximately 131,000 square feet of additional new space in a third new building (Building C), which we expect to occupy in early 2011. The lease will expire in June 2024 and contains three renewal options to extend the term of the lease by five years each, as well as early termination options on approximately 316,000 square feet of space. The lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Certain premises under the lease are accounted for as operating leases. However, for Buildings A, B, and C that we are leasing, we are deemed, in substance, to be the owner of the landlord's buildings in accordance with the application of FASB authoritative guidance, and the landlord's costs of constructing these new facilities are required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet.

In connection with the lease, we issued a letter of credit to our landlord, currently in the amount of \$3.4 million, which is fully collateralized by cash and marketable securities.

In connection with Buildings A and B, we capitalized our landlord's costs of constructing these new facilities, which totaled \$58.4 million as of December 31, 2010, and recognized a corresponding facility lease obligation of \$58.4 million. We also recognized, as an additional facility lease obligation, reimbursements totaling \$56.9 million from our landlord during 2010 and 2009 for tenant improvement costs that we incurred since, under FASB authoritative guidance, these reimbursements from our landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. At December 31, 2010 and 2009, the facility lease obligation balance in connection with Buildings A and B was \$113.7 million and \$81.0 million, respectively.

In addition, as described above, we amended our lease in December 2009 to include additional new laboratory and office space in Building C. As of December 31, 2010, we capitalized \$27.8 million of our landlord's costs of constructing Building C and recognized a corresponding facility lease obligation of \$27.8 million. We also recognized, as an additional facility lease obligation, reimbursements totaling \$14.2 million from our landlord during 2010 for tenant improvement costs that we will incur since, under FASB authoritative guidance, these reimbursements from our landlord are deemed to be a financing obligation. Monthly lease payments on the Building C facilities commenced in January 2011 and additional charges for utilities, taxes, and operating expenses commenced in January 2010. Rent expense in connection with the land element of these additional facilities, which is accounted for as an operating lease, commenced in December 2010 and were recorded as a deferred liability until lease payments commence in January 2011. In addition, interest expense is imputed at a rate of approximately 9%, and is capitalized and deferred in connection with this facility lease obligation. At December 31, 2010 and 2009, the facility lease obligation balance in connection with Building C was \$46.4 million and \$28.0 million, respectively.

Capital Expenditures

Our cash expenditures for property, plant, and equipment totaled \$99.7 million in 2010, \$97.3 million in 2009, and \$34.9 million in 2008. In February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, as described above, sanofi-aventis has funded \$22.9 million of agreed-upon capital expenditures incurred by us during 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at December 31, 2010.

We expect to incur capital expenditures of approximately \$50 to \$75 million in 2011, primarily in connection with tenant improvements at our leased Tarrytown facilities, capital improvements at our Rensselaer, New York manufacturing facilities, and purchases of equipment. We expect to be reimbursed for a portion of these capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements

Our total expenses for research and development from inception through December 31, 2010 were approximately \$2.5 billion. We have entered into various agreements related to our activities to develop and commercialize product candidates and utilize our technology platforms, including collaboration agreements such as those with sanofi-aventis and Bayer HealthCare, and agreements to use our *Velocigene*® technology platform. We incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost sharing of collaborator's development expenses, where applicable, of \$431.4 million, \$333.7 million, and \$230.6 million in 2010, 2009, and 2008, respectively.

We expect to continue to incur substantial funding requirements for research and development activities (including preclinical and clinical testing). As described above, expenses that we incur in connection with our aflibercept and antibodies collaborations are, generally, fully funded by sanofi-aventis. In addition, as described above, we and Bayer HealthCare share agreed-upon development expenses that both companies incur in connection with our VEGF Trap-Eye collaboration. After taking into account anticipated reimbursements from our collaborators, we currently estimate that approximately 30-40% of our funding requirements for 2011 will be directed toward technology development, basic research and early preclinical activities, and the preclinical and clinical development of our product candidates (principally, for ARCALYST® and VEGF Trap-Eye). For 2011, we also currently estimate that approximately 20-30% of our funding requirements will be directed toward preparing for the potential commercialization of our late-stage product candidates; approximately 15-25% of our funding requirements will be applied to capital expenditures (as described above); and the remainder of our funding requirements will be used for general corporate purposes.

In connection with our funding requirements, the following table summarizes our contractual obligations as of December 31, 2010. These obligations and commitments assume non-termination of agreements and represent expected payments based on current operating forecasts, which are subject to change:

		Payments Due by Period			
		Less than			Greater than
	Total	one year	1 to 3 years	3 to 5 years	5 years
			(In millions		
Operating leases()	\$ 96.3	\$ 6.3	\$12.2	\$13.6	\$ 64.2
Capital leases	3.2	1.1	2.1		
Purchase obligations@	108.6	99.7	94		
Other long-term liabilities(3)	250.0	13.8	32.5	35.4	168.3
Total contractual obligations	\$458.1	\$120.4	<u>\$56.2</u>	<u>\$49.0</u>	<u> </u>

- (1) Excludes future contingent costs for utilities, real estate taxes, and operating expenses. In 2010, these costs were \$10.3 million. See Note 11(a) to our Financial Statements
- (2) Purchase obligations primarily relate to (i) research and development commitments, including those related to clinical trials, (ii) capital expenditures for equipment acquisitions, and (iii) license payments. Our obligation to pay certain of these amounts may increase or be reduced based on certain future events. Open purchase orders for the acquisition of goods and services in the ordinary course of business are excluded from the table above.
- (3) Represents payments with respect to facility lease obligations in connection with our lease of facilities in Tarrytown, New York, as described above. See Note 11 (a) to our Financial Statements.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare will share agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as described above. In addition, under our collaboration agreements with sanofi-aventis and Bayer HealthCare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer HealthCare for a defined percentage (generally 50%) of agreed-upon development expenses incurred by sanofi-aventis and Bayer HealthCare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for our aflibercept collaboration with sanofi-aventis, royalties on product sales in Japan) otherwise payable to us, unless, in some cases, we elect to reimburse these expenses at a faster rate. Given the

uncertainties related to drug development (including the development of aflibercept and co-developed antibody candidates in collaboration with sanofi-aventis and VEGF Trap-Eye in collaboration with Bayer HealthCare), such as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer HealthCare will become profitable.

The amount we need to fund operations will depend on various factors, including the potential regulatory approval and commercialization of our product candidates, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and pending or future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Our commercialization costs over approximately the next few years will depend on, among other things, the results of Phase 3 clinical trials of our late-stage product candidates and whether and when such product candidates receive regulatory approval, market potential for such product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on product sales of ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or share the profits from such sales pursuant to our license or collabora

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, in connection with preparing to commercialize and launch potential products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we anticipate that we would (i) seek sources of additional capital through collaborative arrangements and/or additional public or private financing, including debt and equity financing and/or (ii) prioritize available capital to fund selected preclinical and clinical development programs and/or preparations for the potential commercialization of our late-stage product candidates, or license selected products.

Other than letters of credits totaling \$3.8 million, including the \$3.4 million letter of credit issued in connection with our lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of December 31, 2010, we had \$0.7 million of financing available under a capital equipment lease line. Aside from this lease line, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate consideration to be received in a multiple-element revenue arrangement by requiring the use of estimated selling prices to allocate the consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We will adopt this amended guidance effective for the fiscal year beginning January 1, 2011. We do not anticipate that the adoption of this guidance will have a material impact on our financial statements.

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We will adopt this amended guidance for the fiscal year beginning January 1, 2011. We do not anticipate that the adoption of this guidance will have a material impact on our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a \$5.9 million and \$0.6 million decrease in the fair value of our investment portfolio at December 31, 2010 and 2009, respectively. The increase in interest rate risk year over year is due primarily to higher balances of marketable debt securities with maturities in excess of one year that we held at December 31, 2010 compared to 2009.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of \$0.1 million, \$0.1 million, and \$2.5 million in 2010, 2009, and 2008, respectively.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item are included on pages F-1 through F-34 of this report. The supplementary financial information required by this Item is included at page F-34 of this report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company's management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")) as of

the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to the Company's management, including the Company's chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the framework in *Internal Control – Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2010. The effectiveness of our internal control over financial reporting as of December 31, 2010 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which appears herein.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management, including our chief executive officer and chief financial officer, does not expect that our disclosure controls and procedures or internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any, within the company have been detected. Projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

ITEM 9B. OTHER INFORMATION		
None.		

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PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item (other than the information set forth in the next paragraph in this Item 10) will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our officers, directors, and employees. The full text of our code of business conduct and ethics can be found on the Company's website (http://www.regeneron.com) under the "Corporate Governance" heading on the "About Us" page. We may satisfy the disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or a waiver from, a provision of our code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions, by posting such information on our website where it is accessible through the same link noted above.

ITEM 11. EXECUTIVE COMPENSATION

The information called for by this item will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information called for by this item will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information called for by this item will be included in our definitive proxy statement with respect to our 2011 Annual Meeting of Shareholders to be filed with the SEC, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) 1. Financial Statements

The financials statements filed as part of this report are listed on the Index to Financial Statements on page F-1.

2. Financial Statement Schedules

All schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and, therefore, have been omitted.

3. Exhibits

Exhihit

Numher		Description
3.1	(H)	Restated Certificate of Incorporation
3.2	(a) -	By-Laws, as amended.
10.1 +	(0) -	Amended and Restated 2000 Long-Term Incentive Plan
10.1.1 +	(b) -	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's non-employee directors
998090900000		and named executive officers.
10.1.2 +	(b) -	Form of option agreement and related notice of grant for use in connection with the grant of options to the Registrant's executive officers other than the named executive officers.
10.1.3 +	(c) -	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the
		Registrant's executive officers.
1014+	(c) -	Form of option agreement and related notice of grant for use in connection with the grant of stock options to certain of the Registrant's
10.1.5 +	(s) -	executive officers in connection with a fantiary 2005 Option Exchange Program Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the
10.1.5 ⊤	(s) -	Registrant's non-employee directors and executive officers.
1016+	(8)	Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the
		Registrant's executive officers
10.1.7 +	-	Form of restricted stock award agreement and related notice of grant for use in connection with the grant of restricted stock awards to the
10.1.8 ±		Registrant's executive officers (revised). Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the
*****		Registrant's executive officers (revised)
10.2 +	(r) -	Amended and Restated Employment Agreement, dated as of November 14, 2008, between the Registrant and Leonard S. Schleifer, M.D., Ph.D.
10.3* +	(d)	Employment Agreement, dated as of December 31, 1998, between the Registrant and P. Roy Vagelos, M.D.
10.4 +	(r) -	Regeneron Pharmaceuticals, Inc. Change in Control Severance Plan, amended and restated effective as of November 14, 2008.
10.5*	(c) -	IL-1 License Agreement, dated June 26, 2007, by and among the Registrant, Immunex Corporation, and Amgen Inc.
10,6*	(t) -	IL-1 Antibody Termination Agreement by and between Novartis Pharma AG, Novartis Pharmaceuticals Corporation and the Registrant, dated as
		of June 8, 2009.
10.7*	(1) -	Trap-2 Termination Agreement by and between Novartis Pharma AG. Novartis Pharmaceuticals Corporation and the Registrant, dated as of June 2, 2009
10,8*	(f) -	Collaboration Agreement, dated as of September 5, 2003, by and between Aventis Pharmaceuticals Inc. and the Registrant.
10.8.1*	(d)	Amendment No. 1 to Collaboration Agreement, by and between Avenus Pharmacenticals inc. and the Registrant, effective as of December 31
*****		Titla
10.8.2	(g) -	Amendment No. 2 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of January 7, 2005.
1083*	(h) -	Amendment No. 3 to Collaboration Agreement, by and between Aventis Pharmaceuticals Inc. and the Registrant, effective as of December 21, mass
10,8,4*	(h) -	Amendment No. 4 to Collaboration Agreement, by and between sanofi-aventis U.S., LLC (successor in interest to Aventis Pharmaceuticals, Inc.)
	<u> </u>	and the Registrant, effective as of January 31, 2006.
10.9*	(1) -	License and Callaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and the Registrant.
10,10*	(j) -	Non Exclusive License and Material Transfer Agreement, dated as of February 5, 2007, by and between AstraZeneca UK Limited and the
		Registrant.

10.11	(k)	 Lease, dated as of December 21, 2006, by and between EMR-Landmark at Eastview LLC and the Registrant.
10,11,1*	(m)	- First Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of October 24, 2007.
10 11 2	(q)	- Second Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of September 30, 2008.
10.11.3	(s)	- Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of April 29, 2009.
10.11.4	(u)	- Fourth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, effective as of December 3, 2009
10.11.5	(v)	- Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010.
10 11 6	(x)	- Sixth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 4, 2010.
10.11.7		- Seventh Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of December 22, 2010.
10.12*	(1)	- Non-Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma inc. and the Registrant
10.12.1*	(y)	- Amendment to the Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007 by and between Astellas Pharma Inc.
		and the Registrant, dated as of July 28, 2010.
10 13*	(w)	- Amended and Restated Discovery and Prectimical Development Agreement dated as of November 10, 2009, by and between Aventis
		Pharmaceuticals Inc. and the Registrant
10.14*	(w)	- Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009, by and among Aventis Pharmaceuticals Inc.,
		sanofi-aventis Amerique Du Nord, and the Registrant.
10 15	(n)	- Stock Purchase Agreement, dated as of November 28, 2007, by and among sanoti-averus Amerique Du Nord, sanoti-avenus US LLC, and the
		Registrant
10.16	(n)	- Investor Agreement, dated as of December 20, 2007, by and among sanofi-aventis, sanofi-aventis US LLC, Aventis Pharmaceuticals Inc.,
		sanofi-aventis Amerique du Nord, and the Registrant.
10.16.1	(18)	First Amendment to the December 20, 2007 Investor Agreement, dated as of November 10, 2009, by and among sanofi-aventis US LEC.
		Avents Pharmaconticuls, Inc., sanofi-aventis Amerique du Nord, and the Registrant.
10.17*	(p)	- Amended and Restated Non-Exclusive License Agreement, dated as of July 1, 2008 by and between Cellectis, S.A. and the Registrant.
23.1		Consent of PricewaterhouseCoopers EEP. Independent Registered Public Accounting Firm
24.1		- Power of Attorney (included on the signature page of this Annual Report on Form 10-K).
31.1		 Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934
31.2		- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32		- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350
101		- Interactive Data File
101 INS		XBRL Instance Document
101.SCH		- XBRL Taxonomy Extension Schema
101.CAL		XBRL Textmenty Extension Calculation Embbase
101.LAB	50000000000000000000000000000000000000	- XBRL Taxonomy Extension Label Linkbase
101.PRE		- XBRL Taxonomy Extension Presentation Linkbase
101.DEF		- XBRL Taxonomy Extension Definition Document

- (a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed November 13, 2007.
- (b) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 16, 2005.
- (c) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 13, 2004.
- (d) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2004, filed March 11, 2005.
- (e) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2002, filed August 13, 2002.
- (f) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2003, filed November 12, 2003.
- (g) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed January 11, 2005.
- (h) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2005, filed February 28, 2006.
- (i) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2006, filed November 6, 2006.
- (j) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2006, filed March 12, 2007.
- (k) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 22, 2006.
- (l) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2007, filed May 4, 2007.
- (m) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2007, filed November 7, 2007.
- (n) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2007, filed February 27, 2008.
- (o) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed June 17, 2008.
- (p) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2008, filed August 1, 2008.
- (q) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2008, filed November 5, 2008.
- (r) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2008, filed February 26, 2009.
- (s) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended March 31, 2009, filed April 30, 2009.
- (t) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2009, filed August 4, 2009.
- (u) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed December 8, 2009.

- (v) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed February 16, 2010.
- (w) Incorporated by reference from the Form 10-K for Regeneron Pharmaceuticals, Inc., for the year ended December 31, 2009, filed February 18, 2010.
- (x) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended June 30, 2010, filed July 28, 2010.
- (y) Incorporated by reference from the Form 10-Q for Regeneron Pharmaceuticals, Inc., for the quarter ended September 30, 2010, filed October 28, 2010.
- * Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.
- + Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

By: /s/ LEONARD S. SCHLEIFER

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

Dated: Tarrytown, New York February 17, 2011

Arthur F. Ryan

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Leonard S. Schleifer, President and Chief Executive Officer, and Murray A. Goldberg, Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, and each of them, his true and lawful attorney-in-fact and agent, with the full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities therewith, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent, or either of them, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title
/s/ Leonard S. Schleifer,	President, Chief Executive Officer, and
Leonard S. Schleifer, M.D., Ph.D.	Director (Principal Executive Officer)
/s/ Murray A. Goldberg	Senior Vice President, Finance & Administration,
Murray A. Goldberg	Chief Financial Officer, Treasurer, and Assistant Secretary
	(Principal Financial Officer)
/s/ Douglas S. McCorkle	Vice President, Controller, and
Douglas S. McCorkle	Assistant Treasurer (Principal Accounting Officer)
/s/ GEORGE D. YANCOPOULOS	Executive Vice President, Chief Scientific Officer,
George D. Yancopoulos, M.D., Ph.D	President, Regeneron Research Laboratories, and Director
/s/ P. Roy Vagelos	Chairman of the Board
P. Roy Vagelos, M.D.	
/s/ Charles A. Baker	Director
Charles A. Baker	
/s/ MICHAEL S. BROWN	Director
Michael S. Brown, M.D.	
/s/ Alfred G. Gilman	Director
Alfred G. Gilman, M.D., Ph.D.	
/s/ Joseph L. Goldstein	Director
Joseph L. Goldstein, M.D.	•
/s/ Christine A. Poon	Director
Christine A. Poon	
/s/ Arthur F. Ryan	Director
	•

/s/ ERIC M. SHOOTER Director
Eric M. Shooter, Ph.D.

/s/ GEORGE L. SING Director
George L. Sing

REGENERON PHARMACEUTICALS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Regeneron Pharmaceuticals, Inc.:

In our opinion, the accompanying balance sheets and the related statements of operations, stockholders' equity and cash flows present fairly, in all material respects, the financial position of Regeneron Pharmaceuticals, Inc. at December 31, 2010 and December 31, 2009, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2010 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

New York, New York February 17, 2011

$\begin{array}{c} \textbf{REGENERON PHARMACEUTICALS, INC.} \\ \textbf{BALANCE SHEETS} \end{array}$

December 31, 2010 and 2009 (In thousands, except share data)

	2010	2009
ASSETS Current assets		
	112.572 136,796	\$ 207.073 134,255
Accounts receivable from the sanofi-aventis Group	79,603	62,703
Accounts receivable - other Prepaid expenses and other current assets	13,509 15.142	2,865 18.610
Total current assets	357,622	425,508
Restricted cash and marketable securities Marketable securities	7. 518 370,053	1.600 47,080
Property, plant, and equipment, at cost, not of accumulated depreciation and amortization	347,450	259,676
Other assets	6,789	7,338
Total #ssets	1.089.432	<u>\$ 741.202</u>
LIABILITIES and STOCKHOLDERS' EQUITY Current Habilities		
Accounts payable and accrued expenses \$ Deferred revenue from sanofi-aventis, current portion	53,658 19.5 06	\$ 49,031 17,523
Deferred revenue - other, current portion Facility lease obligations, current portion	35,217	27,021
Total current liabilities	109,056	93,575
Deferred revenue from sanofi-aventis	97,081	90,033
Deferred revenue - other Facility lease obligations	188,775 159,355	46,951 1 09,022
Other long term liabilities Total habilities	7,350 561.617	3,959 344,440
Commitments and contingencies		
Stockholders' equity Proferred stock \$.01 par value: 30,000,000 shares authorized, issued		
and outstanding none Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized;		
shares issued and outstanding - 2,182,036 in 2010 and 2,244,698 in 2009	2	2
Common Stock, \$ 001 par value: 160,000,000 shares authorized, shares issued and outstanding: 87,218,301 in 2010 and 78,360,362 in 2009	87	79
Additional paid-in capital	1,575,780	1,336,732
Accumulated deficit Accumulated other comprehensive (loss) income	(2,491)	(941.095) 1,044
Total stockholders equity	527.815 1.080.432	396.762 \$ 741.202
Total liabilities and stockholders' equity	1,089,432	\$ 741,202

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. STATEMENTS OF OPERATIONS

For the Years Ended December 31, 2010, 2009, and 2008 (In thousands except share data)

	2010	2009	2008
Revenues			
Sanofi-aventis collaboration revenue	\$ 311,332	\$247,140	\$153,972
Other collaboration revenue	75,393	67,317	31.166
Technology licensing	40,150	40,013	40,000
Net product sales	25 254	18,364	6,249
Contract research and other	6,945	6,434	7,070
	459 074	379,268	238,457
Expenses			
Research and development	489,252	398,762	274,903
Selling, general, and administrative	65,201	52,923	48,880
Cast of goods said	2,093	1,686	923
	556,546	453,371	324,706
Loss from operations	(97,472)	(74,103)	(86,249)
Other income (expense)			
Investment income	2,122	4,488	18,161
Interest expense	(9,118)	(2,337)	(7,752)
Loss on early extraguishment of debt			(938)
	(6,996)	2,151	9,471
Net loss before income tax expense	(104.468)	(71,052)	(76,778)
Income (ax (benefit) expense		(4.122)	1351
Net loss	<u>\$(104,468)</u>	\$(67,830)	\$ (79,129)
Net loss per share, basic and diluted	\$ (1.26)	5 (0.85)	\$ (1.00)
Weighted average shares outstanding, basic and diluted	82,926	79,782	78,827

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. STATEMENTS OF STOCKHOLDERS' EQUITY

For the Years Ended December 31, 2010, 2009, and 2008 (In thousands)

					Accumulated				
					Additional		Other	Total	
	Class	A Stock	Comm	on Stock	Paid-in	Accumulated	Comprehensive	Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2007	7,264	52	76,592	\$77	\$1,253,249	\$ (794,136)	§ 170	§ 459.348	
Issuance of Common Stock in connection with									
exercise of stock options, net of shares tendered			980	1	7,948	***************************************		7,949	
Issuence of Common Stock in connection with									
Company 401(k) Savines Plan contribution			49		1,997			1,107	
Conversion of Class A Stock to Common Stock	(11)		11			***************************************			
Strick-based compansation expense					2,423			32,523	
Net loss, 2008						(79,129)		(79,129)	\$ (79,129)
Change in net arrestored gain (loss) an marketable securities							(284)	(284)	(284)
Balance, December 31, 2008	2,249	2	77,642	78	1,294,813	(873,265)	(114)	421,514	\$ (79,413)
Issurace of Common Stock in connection with									
exercise of stock options, not of status tendened			1.134	1	9.269			9.270	
Issuance of Common Stock in connection with									
Company 401(k) Savings Plan contribution			81		1,391			1,391	
Conversion of Class A Stock to Commen Stock	(4)		4						
Stock-based compensation expense					31,259			31,259	
Net biss, 2009						(67. 8 30)		(67.830)	\$ (67.830)
Change in net unrealized gain (loss) on marketable securities,									
net of tax effect of \$0.7 million						···	1,158	1,158	1,158
Balance, December 31, 2009	2,345	2	78.861	70	1,336,732	(941,095)	1.044	396,762	3 (56.677)
Issuance of Common Stock in a public offering, net of issuance costs			6,325	6	174,822			174,828	
Issuance of Common Stock in connection with									
exercise of stock opnions, not of stores tendered			1,533	2	21,462			21,464	
Issuance of Common Stock in connection with									
Company 401(k) Savings Plan contribution			111		2,867			2,867	
Issuance of restricted Common Stock under									
Long-Term Incentive Plan			345						
Conversion of Class A Stock to Common Stock	(63)		63						
Stack-based compensation expense					39,897			39,897	
Net loss, 2010						(104,468)		(104,468)	\$(104,468)
Change in not carealized gain (loss) on marketable securities							(0.595)	(1.595)	0.595)
Balance, December 31, 2010	2,182	\$2	87,238	\$87	\$1,575,780	\$(1,045,563)	\$(2,491)	\$ 527,815	\$(108,003)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. STATEMENTS OF CASH FLOWS

For the Years Ended December 31, 2010, 2009, and 2008 (In thousands)

	2010	2009	2008
Cash flows from operating activities Net loss	\$(104,468)	\$ (67,830)	\$ (79,129)
Adjustments to reconcile net loss to net cash	3(104,408)	<u> </u>	3 (73,123)
provided by (used in) operating activities			
Depreciation and amortization	19,687	14,247	11,287
Non-cash compensation expense Loss on early outlingwishment of debt	39,897	31,259	32,523 938
Loss on early extinguishment of debt Net realized loss (gain) on markemble securities Changes in assets and liabilities	293	(56)	1310
Increase in accounts receivable	(27,544)	(30,356)	(16,892)
Decrease (increase) in prepaid expenses and other assets	2,723	(4,574)	(6,560)
Increase (decrease) in deferred revenue	158,151	(27,497)	(26.834)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	7,605	12,577	(5,729)
Total adjustments	200,812	(4,400)	(9.957)
Net cash provided by (used in) operating activities	96,344	(72,230)	(89,086)
Cash flows from investing activities Purchases of marketable securities	(605,124)	(199,997)	(581,139)
Sales or maturities of marketable securities	276,601	297,411	646,861
Purchases of restricted marketable securities	(7,063)		
Degrense (increase) in restricted cash	1.122 (99,689)	50 (07.219)	(34.957)
Capital expenditures Net cash (used in) provided by investing activities	(99,089) (434.153)	(97,318) 146	(34,857) 30, 81 5
			····
Eash flows from transeing activities			
Repurchases or repayment of notes payable Proceeds in connection with facility lease obligation	47.544	23,640	(200,807)
Payments in connection with facility lease obligation	(924)	(875)	
Net proceeds from the issuance of Common Stock	196,790	8,598	7.949
Payments in connection with capital lease obligation	(104)		
Net cash provided by (used in) financing activities	243,306	31,363	(192.858)
Net decrease in cash and cash equivalents	(94,503)	(40,721)	(25) [20]
Cash and cash equivalents at beginning of period	207.075	247.796	498,925
Cash and cash equivalents at end of period	<u>\$ 112.572</u>	<u>\$ 207.075</u>	<u>\$ 247.796</u>
Supplemental disclosure of cash flow information Cash paid for interest	\$ 12,737	\$ 2,525	\$ 9,348
Cash paid for income taxes		-,	\$ 3,079

 $\label{thm:companying} \textit{The accompanying notes are an integral part of the financial statements}.$

For the years ended December 31, 2010, 2009, and 2008 (Unless otherwise noted, dollars in thousands, except per share data)

1. Organization and Business

Regeneron Pharmaceuticals, Inc. (the "Company" or "Regeneron") was incorporated in January 1988 in the State of New York. The Company is engaged in the research, development, and commercialization of pharmaceutical products for the treatment of serious medical conditions. In 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for the Company's first commercial drug product, ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company's facilities are primarily located in New York. The Company's business is subject to certain risks including, but not limited to, uncertainties relating to conducting pharmaceutical research, obtaining regulatory approvals, commercializing products, and obtaining and enforcing patents.

2. Summary of Significant Accounting Policies

Cash and Cash Equivalents

For purposes of the statement of cash flows and the balance sheet, the Company considers all highly liquid debt instruments with a maturity of three months or less when purchased to be cash equivalents. The carrying amount reported in the balance sheet for cash and cash equivalents approximates its fair value.

Marketable Securities

The Company has an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. The Company has invested its excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. The Company considers its marketable securities to be "available-for-sale," as defined by authoritative guidance issued by the Financial Accounting Standards Board ("FASB"). These assets are carried at fair value and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a marketable security in the Company's investment portfolio is deemed to be other-than-temporary, the Company writes down the security to its current fair value and recognizes a loss that may be charged against income. As described under "Use of Estimates" below, on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary.

Inventory

Inventories are stated at the lower of cost or estimated realizable value. The Company determines the cost of inventory using the first-in, first-out, or FIFO, method. The Company capitalizes inventory costs associated with the Company's products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The Company periodically analyzes its inventory levels to identify inventory that may expire prior to expected sale or has a cost basis in excess of its estimated realizable value, and writes-down such inventories as appropriate.

Property, Plant, and Equipment

Property, plant, and equipment are stated at cost, net of accumulated depreciation. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations. The estimated useful lives of property, plant, and equipment are as follows:

Building and improvements	10-40 years
Laboratory and other equipment	3-10 years
Furniture and fixtures	5 years

(Unless otherwise noted, dollars in thousands, except per share data)

Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the lease term, without assuming renewal features, if any, are exercised. Costs of construction of certain long-lived assets include capitalized interest which is amortized over the estimated useful life of the related asset.

Accounting for the Impairment of Long-Lived Assets

The Company periodically assesses the recoverability of long-lived assets, such as property, plant, and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Asset impairment is determined to exist if estimated future undiscounted cash flows are less than the carrying amount. For all periods presented, no impairment losses were recorded.

Patents

As a result of the Company's research and development efforts, the Company obtains and applies for patents to protect proprietary technology and inventions. All costs associated with patents for product candidates under development are expensed as incurred. Patent costs related to commercial products are capitalized and amortized over the shorter of their estimated useful life or the remaining patent term. To date, the Company has no capitalized patent costs.

Operating Leases

On certain of its operating lease agreements, the Company may receive rent holidays and other incentives. The Company recognizes operating lease costs on a straight-line basis without regard to deferred payment terms, such as rent holidays that defer the commencement date of required payments. In addition, lease incentives that the Company receives are treated as a reduction of rent expense over the term of the related agreements.

Revenue Recognition

a. Collaboration Revenue

The Company earns collaboration revenue in connection with collaboration agreements to develop and commercialize product candidates and utilize the Company's technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of the Company, are deferred and recognized over the related performance period. The Company estimates its performance period based on the specific terms of each agreement, and adjusts the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development lifecycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

The Company enters into collaboration agreements that include varying arrangements regarding which parties perform and bear the costs of research and development activities. The Company may share the costs of research and development activities with a collaborator, such as in the Company's VEGF Trap-Eye collaboration with Bayer HealthCare LLC, or the Company may be reimbursed for all or a significant portion of the costs of the Company's research and development activities, such as in the Company's aflibercept and antibody collaborations with the

(Unless otherwise noted, dollars in thousands, except per share data)

sanofi-aventis Group. The Company records its internal and third-party development costs associated with these collaborations as research and development expenses. When the Company is entitled to reimbursement of all or a portion of the research and development expenses that it incurs under a collaboration, the Company records those reimbursable amounts as collaboration revenue proportionately as the Company recognizes its expenses. If the collaboration is a cost-sharing arrangement in which both the Company and its collaborator perform development work and share costs, in periods when the Company's collaborator incurs development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of the collaborator's development expenses that the Company is obligated to reimburse.

In connection with non-refundable licensing payments, the Company's performance period estimates are principally based on projections of the scope, progress, and results of its research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are likely to occur periodically, and could result in material changes to the amount of revenue recognized each year in the future. In addition, estimated performance periods may change if development programs encounter delays, or the Company and its collaborators decide to expand or contract the clinical plans for a drug candidate in various disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, the Company would recognize any unamortized remainder of an up-front or previously deferred payment at the time of the termination.

b. VelocImmune® Technology Licensing

The Company enters into non-exclusive license agreements with third parties that allow the third party to utilize the Company's *VelocImmune*® technology in its internal research programs. The terms of these agreements include up-front payments and entitle the Company to receive royalties on any future sales of products discovered by the third party using the Company's *VelocImmune*® technology. Up-front payments under these agreements, where continuing involvement is required of the Company, are deferred and recognized ratably over their respective license periods.

c. Product Revenue

Revenue from product sales is recognized when persuasive evidence of an arrangement exists, title to product and associated risk of loss has passed to the customer, the price is fixed or determinable, collection from the customer is reasonably assured, and the Company has no further performance obligations. Revenue and deferred revenue from product sales are recorded net of applicable provisions for prompt pay discounts, product returns, estimated rebates payable under governmental programs (including Medicaid), distribution fees, and other sales-related deductions. The Company reviews its estimates of rebates payable each period and records any necessary adjustments in the current period's net product sales.

Investment Income

Interest income, which is included in investment income, is recognized as earned.

Research and Development Expenses

Research and development expenses include costs directly attributable to the conduct of research and development programs, including the cost of salaries, payroll taxes, employee benefits, materials, supplies, depreciation on and maintenance of research equipment, costs related to research collaboration and licensing agreements, the cost of services provided by outside contractors, including services related to the Company's clinical trials, clinical trial expenses, the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, amounts that the Company is obligated to reimburse to collaborators for research and development expenses that they incur, and the allocable portions of facility costs, such as rent, utilities, insurance, repairs and maintenance, depreciation, and general support services. All costs associated with research and development are expensed as incurred.

(Unless otherwise noted, dollars in thousands, except per share data)

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as contract research organizations ("CROs"), independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and/or the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by CROs. CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 20% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of the Company's contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues expense on an estimated cost-per-patient basis, based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates. The Company's estimates and assumptions for clinical expense recognition could differ significantly from its actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

Stock-based Compensation

The Company recognizes stock-based compensation expense for grants of stock option awards and restricted stock under the Company's Long-Term Incentive Plans, to employees and non-employee members of the Company's board of directors, based on the grant-date fair value of those awards. The grant-date fair value of an award is generally recognized as compensation expense over the award's requisite service period. In addition, the Company has granted performance-based stock option awards which vest based upon the optionee satisfying certain performance and service conditions as defined in the agreements. Potential compensation cost, measured on the grant date, related to these performance options will be recognized only if, and when, the Company estimates that these options will vest, which is based on whether the Company consider the options' performance conditions to be probable of attainment. The Company's estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods.

The Company uses the Black-Scholes model to compute the estimated fair value of stock option awards. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of the board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Common Stock, and (iv) risk-free interest rates. Stock-based compensation expense also includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

(Unless otherwise noted, dollars in thousands, except per share data)

Income Taxes

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred tax liabilities and assets are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts ("temporary differences") at enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is established for deferred tax assets for which realization is uncertain.

Uncertain tax positions are accounted for in accordance with FASB authoritative guidance, which prescribes a comprehensive model for the manner in which a company should recognize, measure, present, and disclose in its financial statements all material uncertain tax positions that the company has taken or expects to take on a tax return. Those positions, for which management's assessment is that there is more than a 50% probability of sustaining the position upon challenge by a taxing authority based upon its technical merits, are subjected to certain measurement criteria.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense.

Comprehensive Income (Loss)

Comprehensive income (loss) of the Company includes net income (loss) adjusted for the change in net unrealized gain or loss on marketable securities, net of any tax effect. Comprehensive income (loss) for the years ended December 31, 2010, 2009, and 2008 have been included in the Statements of Stockholders' Equity.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of cash, cash equivalents, marketable securities (see Note 6), and receivables from sanofi-aventis.

Per Share Data

Net income (loss) per share, basic and diluted, is computed on the basis of the net income (loss) for the period divided by the weighted average number of shares of Common Stock and Class A Stock outstanding during the period. Basic net income (loss) per share excludes restricted stock awards until vested. Diluted net income per share is based upon the weighted average number of shares of Common Stock and Class A Stock outstanding, and of common stock equivalents outstanding when dilutive. Common stock equivalents include: (i) outstanding stock options and restricted stock awards under the Company's Long-Term Incentive Plans, which are included under the "treasury stock method" when dilutive, and (ii) Common Stock to be issued under the assumed conversion of the Company's formerly outstanding convertible senior subordinated notes, which are included under the "if-converted method" when dilutive. The computation of diluted net loss per share for the years ended December 31, 2010, 2009, and 2008 does not include common stock equivalents, since such inclusion would be antidilutive.

Risks and Uncertainties

Developing and commercializing new medicines entails significant risk and expense. Since its inception, the Company has not generated any significant sales or profits from the commercialization of ARCALYST® or any of the Company's other product candidates. Before revenues from the commercialization of the Company's current or future product candidates can be realized, the Company (or its collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render the Company's products and technologies uncompetitive or obsolete. The Company may be subject to legal claims by third parties seeking to enforce patents to limit or prohibit the Company from marketing or selling its products. The Company is also dependent upon the services

(Unless otherwise noted, dollars in thousands, except per share data)

of its employees, consultants, collaborators, and certain third-party suppliers, including single-source unaffiliated third-party suppliers of certain raw materials and equipment. Regeneron, as licensee, licenses certain technologies that are important to the Company's business which impose various obligations on the Company. If Regeneron fails to comply with these requirements, licensors may have the right to terminate the Company's licenses.

The Company has generally incurred net losses and negative cash flows from operations since its inception. Revenues to date have principally been limited to (i) up-front, license, milestone, and reimbursement payments from the Company's collaborators and other entities related to the Company's development activities and technology platforms, (ii) payments for past contract manufacturing activities, (iii) ARCALYST® product sales, and (iv) investment income. Collaboration revenue in 2010 was earned from sanofi-aventis and Bayer HealthCare under collaboration agreements (see Note 3 for the terms of these agreements). These collaboration agreements contain early termination provisions that are exercisable by sanofi-aventis or Bayer HealthCare, as applicable.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Estimates which could have a significant impact on the Company's financial statements include:

- Product rebates and returns in connection with the recognition of revenue from product sales.
- Periods over which payments, including non-refundable up-front, license, and milestone payments, are recognized as revenue in connection with collaboration
 and other agreements to develop and commercialize product candidates and utilize the Company's technology platforms.
- Periods over which certain clinical trial costs, including costs for clinical activities performed by contract research organizations, are recognized as research and development expenses.
- In connection with stock option awards, (i) the fair value of stock options on their date of grant using the Black-Scholes option-pricing model, based on assumptions with respect to (a) expected volatility of the Company's Common Stock price, (b) the periods of time for which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (c) expected dividend yield on the Company's Common Stock, and (d) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives; (ii) the number of stock option awards that are expected to be forfeited; and (iii) with respect to performance-based stock option awards, if and when the options' performance conditions are considered to be probable of attainment.
- The Company's determination of whether marketable securities are other than temporarily impaired. The Company conducts a quarterly review of its portfolio of marketable securities, using both quantitative and qualitative factors, to determine, for securities whose current fair value is less than their cost, whether the decline in fair value below cost is other-than-temporary. In making this determination, the Company considers factors such as the length of time and the extent to which fair value has been less than cost, financial condition and near-term prospects of the issuer, recommendations of investment advisors, and forecasts of economic, market, or industry trends. This review process also includes an evaluation of the Company's ability and intent to hold individual securities until they mature or their full value can be recovered. This review is subjective and requires a high degree of judgment.
- Useful lives of property, plant, and equipment.
- Capitalized inventory costs associated with the Company's products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized.
- The extent to which deferred tax assets and liabilities are offset by a valuation allowance.

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(Unless otherwise noted, dollars in thousands, except per share data)

In addition, the Company's share of VEGF Trap-Eye development expenses incurred by Bayer HealthCare, including the Company's share of Bayer HealthCare's estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter, are included in research and development expenses. The Bayer HealthCare estimate for the most recent fiscal quarter is adjusted in the subsequent quarter to reflect actual expenses for the quarter.

Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate consideration to be received in a multiple-element revenue arrangement by requiring the use of estimated selling prices to allocate the consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company will adopt this amended guidance effective for the fiscal year beginning January 1, 2011. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. The Company will adopt this amended guidance for the fiscal year beginning January 1, 2011. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

3. Collaboration and Contract Research Agreements

The Company has entered into various agreements related to its activities to develop and commercialize product candidates and utilize its technology platforms. Amounts earned by the Company in connection with these agreements totaled \$393.7 million, \$320.9 million, and \$192.2 million in 2010, 2009, and 2008, respectively. Total Company-incurred expenses associated with these agreements, which include reimbursable and non-reimbursable amounts, an allocable portion of general and administrative costs, and cost-sharing of a collaborator's development expenses, where applicable (see Bayer HealthCare below), were \$431.4 million, \$333.7 million, and \$230.6 million in 2010, 2009, and 2008, respectively. Significant agreements of this kind are described below.

a. The sanofi-aventis Group

Aflibercept

In September 2003, the Company entered into a collaboration agreement (the "Aflibercept Agreement") with Aventis Pharmaceuticals Inc. (predecessor to sanofiaventis U.S.), to jointly develop and commercialize aflibercept. In connection with this agreement, sanofiaventis made a non-refundable up-front payment of \$80.0 million and purchased 2,799,552 newly issued unregistered shares of the Company's Common Stock for \$45.0 million.

In January 2005, the Company and sanofi-aventis amended the Aflibercept Agreement to exclude intraocular delivery of aflibercept to the eye ("Intraocular Delivery") from joint development under the agreement, and product rights to aflibercept in Intraocular Delivery reverted to Regeneron. In connection with this amendment, sanofi-aventis made a \$25.0 million non-refundable payment to Regeneron (the "Intraocular Termination Payment").

In December 2005, the Company and sanofi-aventis amended the Aflibercept Agreement to expand the territory in which the companies are collaborating on the development of aflibercept to include Japan. In connection with this amendment, sanofi-aventis agreed to make a \$25.0 million non-refundable up-front payment to the Company, which was received in January 2006. Under the Aflibercept Agreement, as amended, the Company and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan, for disease indications included in the companies' collaboration. The Company is entitled to a royalty of approximately 35% on annual sales of aflibercept in Japan, subject to certain potential adjustments. The Company may also receive up to \$400 million

(Unless otherwise noted, dollars in thousands, except per share data)

in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight affibercept oncology and other indications in the United States or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five affibercept oncology indications in Japan.

Under the Aflibercept Agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of these development expenses, or half of \$707.3 million as of December 31, 2010, in accordance with a formula based on the amount of development expenses and Regeneron's share of the collaboration profits and Japan royalties, or at a faster rate at Regeneron's option. Regeneron has the option to conduct additional pre-Phase III studies at its own expense. In connection with the January 2005 amendment to the Aflibercept Agreement, the Intraocular Termination Payment of \$25.0 million will be considered an aflibercept development expense and will be subject to 50% reimbursement by Regeneron to sanofi-aventis, as described above, if the collaboration becomes profitable. In addition, if the first commercial sale of an aflibercept product under the collaboration by two years, Regeneron will begin reimbursing sanofi-aventis for up to \$7.5 million of aflibercept development expenses in accordance with a formula until the first commercial aflibercept sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, Regeneron's obligation to reimburse sanofi-aventis, for 50% of aflibercept development expenses will terminate, and the Company will retain all rights to aflibercept.

In accordance with the Company's revenue recognition policy described in Note 2, the up-front payments received in September 2003 and January 2006, of \$80.0 million and \$25.0 million, respectively, and reimbursement of Regeneron-incurred development expenses, are being recognized as collaboration revenue over the related performance period. During the fourth quarter of 2008, the Company shortened its estimated performance period in connection with the \$80.0 million and \$25.0 million up-front payments from sanofi-aventis. The net effect of this change in the Company's estimate resulted in the recognition of an additional \$1.2 million in collaboration revenue in 2010 and 2009, compared to amounts recognized in connection with these deferred payments in 2008.

The Company recognized \$26.4 million, \$36.5 million, and \$44.4 million of collaboration development revenue in 2010, 2009, and 2008, respectively, in connection with the Aflibercept Agreement, as amended. At December 31, 2010 and 2009, amounts receivable from sanofi-aventis totaled \$3.9 million and \$3.6 million, respectively, and deferred revenue was \$32.6 million and \$42.5 million, respectively, in connection with the Aflibercept Agreement.

Antibodies

In November 2007, the Company entered into a global, strategic collaboration (the "Antibody Collaboration") with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies. In connection with the collaboration, in December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for \$312.0 million (see Note 12).

The Antibody Collaboration is governed by a Discovery and Preclinical Development Agreement (the "Discovery Agreement") and a License and Collaboration Agreement (the "License Agreement"). The Company received a non-refundable up-front payment of \$85.0 million from sanofi-aventis under the Discovery Agreement. In addition, under the Discovery Agreement, sanofi-aventis is funding the Company's research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded \$174.5 million of such research from the collaboration's inception through December 31, 2009. In November 2009, the Company and sanofi-aventis amended these collaboration agreements to expand and extend the Antibody Collaboration. Pursuant to the Discovery Agreement, as amended, sanofi-aventis agreed to fund up to \$160 million per year of the Company's research activities in 2010 through 2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria were not satisfied. In 2010, as the Company scaled up its capacity to conduct

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antibody discovery activities, sanofi-aventis funded \$137.7 million of the Company's preclinical research under the amended Discovery Agreement. The balance between that amount and \$160 million, or \$22.3 million, has been added to the funding otherwise available to the Company in 2011-2012 under the amended Discovery Agreement. The amended Discovery Agreement will expire on December 31, 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

For each drug candidate identified under the Discovery Agreement, sanofi-aventis has the option to license rights to the candidate under the License Agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with the Company through product approval. If sanofi-aventis does not exercise its option to license rights to a particular drug candidate under the License Agreement, the Company retains the exclusive right to develop and commercialize such drug candidate, and sanofi-aventis will receive a royalty on sales, if any. The Company and sanofi-aventis are currently co-developing eight therapeutic antibodies under the License Agreement.

Under the License Agreement, agreed upon worldwide development expenses incurred by both companies during the term of the agreement are funded by sanofiaventis, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate ("Shared Phase 3 Trial Costs") are shared 80% by sanofi-aventis and 20% by Regeneron. If the Antibody Collaboration becomes profitable, Regeneron will be obligated to reimburse sanofi-aventis for 50% of development expenses that were fully funded by sanofi-aventis (or half of \$341.0 million as of December 31, 2010) and 30% of Shared Phase 3 Trial Costs, in accordance with a defined formula based on the amounts of these expenses and the Company's share of collaboration profits from commercialization of collaboration products. However, the Company is not required to apply more than 10% of its share of the profits from the antibody collaboration in any calendar quarter to reimburse sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the License Agreement, subject to the Company's right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (Regeneron) and ending at 55% (sanofi-aventis)/45% (Regeneron), and losses outside the United States at 55% (sanofi-aventis)/45% (Regeneron). In addition to profit sharing, the Company is entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing only if and after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

Regeneron is obligated to use commercially reasonable efforts to supply clinical requirements of each drug candidate under the Antibody Collaboration until commercial supplies of that drug candidate are being manufactured. In connection with the November 2009 amendment of the collaboration's Discovery Agreement, sanofi-aventis is funding up to \$30 million of agreed-upon costs incurred by the Company to expand its manufacturing capacity at the Company's Rensselaer, New York facilities, of which \$23.4 million has been received or is receivable at December 31, 2010.

With respect to each antibody product which enters development under the License Agreement, sanofi-aventis or the Company may, by giving twelve months notice, opt-out of further development and/or commercialization of the product, in which event the other party retains exclusive rights to continue the development and/or commercialization of the product. The Company may also opt-out of the further development of an antibody product if it gives notice to sanofi-aventis within thirty days of the date that sanofi-aventis enters joint development of such antibody product under the License Agreement. Each of the Discovery Agreement and the License Agreement contains other termination provisions, including for material breach by the other party. Prior to December 31, 2017, sanofi-aventis has the right to terminate the amended Discovery Agreement without cause with at least three months advance written notice; however, except under defined circumstances, sanofi-aventis would be obligated to immediately pay to the Company the full amount of unpaid research funding during the remaining term of the research agreement through December 31, 2017. Upon termination of the collaboration in its entirety, the Company's obligation to reimburse sanofi-aventis for development costs out of any future profits from collaboration products will terminate. Upon expiration of the amended Discovery Agreement, sanofi-aventis has an option to license the Company's VelocImmune® technology for agreed upon consideration.

(Unless otherwise noted, dollars in thousands, except per share data)

In connection with the Antibody Collaboration, in August 2008, the Company entered into a separate agreement with sanofi-aventis to use Regeneron's proprietary VelociGene® technology platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease (the "VelociGene® Agreement"). The VelociGene® Agreement provides for minimum annual order quantities for the term of the agreement, which extends through December 2012, for which the Company expects to receive payments totaling a minimum of \$21.5 million.

In accordance with the Company's revenue recognition policy described in Note 2, the (i) \$85.0 million up-front payment received in December 2007, (ii) reimbursement of Regeneron-incurred expenses under the Discovery and License Agreements, (iii) \$21.5 million of aggregate minimum payments under the VelociGene® Agreement, and (iv) reimbursement of agreed-upon costs to expand the Company's manufacturing capacity are being recognized as collaboration revenue over the related performance period. In connection with the amendments to expand and extend the Company's antibody collaboration with sanofi-aventis, during the fourth quarter of 2009, the Company extended its estimated performance period related to the \$85.0 million up-front payment received from sanofi-aventis under the Discovery Agreement and the \$21.5 million of aggregate minimum payments under the VelociGene® Agreement The effect of this change in estimate resulted in the recognition of \$5.3 million less in collaboration revenue in 2010, compared to 2009.

In connection with the Antibody Collaboration, the Company recognized \$284.9 million, \$210.7 million, and \$109.6 million of collaboration revenue in 2010, 2009, and 2008, respectively. In addition, at December 31, 2010 and 2009, amounts receivable from sanofi-aventis totaled \$75.7 million and \$59.1 million and deferred revenue was \$84.0 million and \$66.0 million, respectively.

b. Bayer HealthCare LLC

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to the Company of \$75.0 million. In August 2007, the Company received a \$20.0 million milestone payment from Bayer HealthCare (which, for the purpose of revenue recognition, was not considered substantive) following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in the neovascular form of age-related macular degeneration ("wet AMD"). In July 2009, the Company received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in Central Retinal Vein Occlusion ("CRVO"). In the fourth quarter of 2010, the Company earned two \$10.0 million substantive milestone payments (for a total of \$20.0 million) from Bayer HealthCare for achieving positive 52-week results in the Phase 3 study of VEGF Trap-Eye in wet AMD and positive 6-month results in the Phase 3 study of VEGF Trap-Eye in CRVO. One of these \$10.0 million payments was received in December 2010 and the other \$10.0 million payment was received in January 2011. The Company is eligible to receive up to \$50 million in future milestone payments related to marketing approvals of VEGF Trap-Eye in major market countries outside the United States. The Company is also eligible to receive up to \$135 million in sales milestone payments when and if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

The Company will share equally with Bayer HealthCare in any future profits arising from the commercialization of VEGF Trap-Eye outside the United States. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer HealthCare out of its share of the collaboration profits for 50% of the agreed upon development expenses that Bayer HealthCare has incurred (or half of \$241.2 million as of December 31, 2010) in accordance with a formula based on the amount of development expenses that Bayer HealthCare has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option. Within the United States, the Company is responsible for any future commercialization of VEGF Trap-Eye and retains exclusive rights to any future profits from such commercialization in the United States.

In 2008, the first \$70.0 million of agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, were shared equally and the Company was solely responsible for up to the next \$30.0 million of development expenses. In 2009 and thereafter, all development expenses are being shared equally. The Company is also obligated to use commercially reasonable efforts to supply clinical and commercial product requirements.

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Bayer HealthCare has the right to terminate the Bayer Agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to VEGF Trap-Eye.

The \$75.0 million up-front licensing payment and the \$20.0 million milestone payment received in August 2007 from Bayer HealthCare are being recognized as collaboration revenue over the related estimated performance period in accordance with the Company's revenue recognition policy as described in Note 2. During the fourth quarter of 2008, the Company extended the estimated performance period in connection with these up-front and non-substantive milestone payments, which resulted in the recognition of \$2.5 million less in collaboration revenue in 2009 and 2010, compared to amounts recognized in connection with these deferred payments in 2008. In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration, the Company also recognizes, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable from Bayer HealthCare. In periods when Bayer HealthCare incurs agreed upon VEGF Trap-Eye development expenses that benefit the collaboration and Regeneron, the Company also recognizes, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse.

The Company recognized \$75.4 million, \$67.3 million, and \$31.2 million of collaboration revenue from Bayer HealthCare in 2010, 2009, and 2008, respectively. In both 2010 and 2009, collaboration revenue from Bayer HealthCare included \$20.0 million in milestone payments, as described above, which, for the purpose of revenue recognition, were considered substantive. In addition, in 2010, 2009, and 2008, the Company recognized as additional research and development expense \$48.9 million, \$37.7 million, and \$30.0 million, respectively, of VEGF Trap-Eye development expenses that the Company was obligated to reimburse to Bayer HealthCare.

At December 31, 2010, one \$10.0 million milestone payment was receivable from Bayer HealthCare, as described above. In connection with cost-sharing of VEGF Trap-Eye expenses under the collaboration, \$2.3 million and \$1.2 million was payable to Bayer HealthCare at December 31, 2010 and 2009, respectively. In addition, at December 31, 2010 and 2009, deferred revenue from the Company's collaboration with Bayer HealthCare was \$47.0 million and \$56.8 million, respectively.

c. National Institute of Health

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. As amended, the NIH grant provides a minimum of \$25.3 million in funding over a five-year period, including \$1.5 million in funding to optimize certain existing technology, subject to compliance with its terms and annual funding approvals, for the Company's use of its *VelociGene*® technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells which can be used to produce knockout mice. The Company records revenue in connection with the NIH grant using a proportional performance model as it incurs expenses related to the grant, subject to the grant's terms and annual funding approvals. In 2010, 2009, and 2008, the Company recognized contract research revenue of \$4.6 million, \$5.5 million, and \$4.9 million, respectively, from the NIH Grant.

4. Technology Licensing Agreements

In February 2007, the Company entered into a six-year, non-exclusive license agreement with AstraZeneca UK Limited to allow AstraZeneca to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million annual, non-refundable payment to the Company in each of 2010, 2009, 2008, and 2007. Each annual payment was deferred and recognized as revenue ratably over approximately the ensuing twelve-month period. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement, effective in February 2011, thereby canceling its obligation to make either of the final two annual payments. Regeneron remains entitled to receive mid-single digit royalties on any future sales of antibody products discovered by MedImmune/AstraZeneca using the *VelocImmune*® technology.

(Unless otherwise noted, dollars in thousands, except per share data)

In connection with the AstraZeneca license agreement, for each of the years ended December 31, 2010, 2009, and 2008, the Company recognized \$20.0 million of technology licensing revenue. In addition, deferred revenue at December 31, 2010, 2009, and 2008 was \$2.9 million.

In March 2007, the Company entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million annual, non-refundable payment to the Company in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a \$165.0 million up-front payment to the Company in August 2010, which was deferred upon receipt and will be recognized as revenue ratably over the seven-year period beginning in mid-2011. In addition, Astellas will make a \$130.0 million second payment to the Company in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as a material breach of the agreement by the Company, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to the Company under the July 2010 amendment to the agreement. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune*® technology. In connection with the Astellas license agreement, for each of the years ended December 31, 2010, 2009, and 2008, the Company recognized \$20.0 million of technology licensing revenue. In addition, deferred revenue at December 31, 2010, 2009, and 2008 was \$173.7 million, \$8.7 million, and \$8.7 million, respectively.

5. ARCALYST® Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST® Injection for Subcutaneous Use for the treatment of CAPS. The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, \$4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by \$0.06 in 2010.

ARCALYST® net product sales totaled \$25.3 million, \$18.4 million, and \$6.3 million for the years ended December 31, 2010, 2009, and 2008, respectively. ARCALYST® net product sales during 2010 included \$20.5 million of net product sales made during this period and \$4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at December 31, 2010. At December 31, 2009, deferred ARCALYST® net product sales revenue was \$4.8 million.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled \$2.1 million, \$1.7 million, and \$0.9 million for the years ended December 31, 2010, 2009, and 2008, respectively. To date, ARCALYST® shipments to the Company's customers have primarily consisted of supplies of inventory manufactured and expensed as research and development costs prior to 2008; therefore, the costs of these supplies were not included in costs of goods sold. Inventories related to ARCALYST®, which were included in prepaid expenses and other current assets, consisted of \$0.7 million of work-in-process and \$0.1 million of finished goods at December 31, 2010, and \$0.4 million of work-in-process at December 31, 2009.

6. Marketable Securities

Marketable securities at December 31, 2010 and 2009 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was \$3.6 million and \$5.5 million at December 31, 2010 and 2009, respectively, and the aggregate cost basis of which was \$4.0 million at both December 31, 2010 and 2009. The Company also held restricted marketable securities at December 31, 2010, which consisted of debt securities, as detailed below, that collateralize (i) a letter of credit in connection with the Company's lease of facilities in Tarrytown, New York and (ii) capital lease obligations. See Note 11a. The Company held no restricted marketable securities at December 31, 2009.

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The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at December 31, 2010 and 2009. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair		Unrealized	
At December 31, 2010	Cost Basis	Value	Gains	(Losses)	Net
Unrestricted Maturities within one year					
U.S. government obligations	\$ 83,635	\$ 83,684	\$ 54	\$ (5)	\$ 49
U.S. government guaranteed corporate bonds U.S. government guaranteed collateralized	48,173	48,531	358		358
montgage obligations	2,027	2,131	104		104
Municipal bonds	1,597	1,603	6		6
Mortgage-backed securities	875	847		(28)	(28)
	136,307	136,796	522	(33)	489
Maturities between one and five years	352,345	250 692	6.4	(1.726)	(1.662)
U.S. government obligations U.S. government guaranteed corporate bonds	332,343 13.522	350,683 15.4 77	64	(1,726) (45)	(1,662) (45)
Mortgage-backed securities	110	38		(72)	(72)
The light of the least of the light of the l	367,977	366,198	64	(1.843)	(1779)
Maturities between five and seven years	····	···		···	·············
Mortgage-backed securities	284	243		(41)	(41)
	504,568	503,237	586	(1,917)	(1,331)
Restricted					
Maturities within one year	n name	2.024			
U.S. government obligations Maturities between one and three years	2,922	2.921		(1)	113
U.S. payerment obligations	4.135	4,118		(17)	(17)
	7,057	7,039		(18)	(18)
	\$511,625	\$510,276	\$ 586	\$(1,935)	\$(1,349)
		··· <u></u> ···			
At December 31, 2009					000000000000000000000000000000000000000
Carestricted					
Maturities within one year U.S. government obligations	\$100.491	\$100,573	\$ 82		6 6 9 9
U.S. government guaranteed corporate bonds	17,176	17,340	164		164
Corporate bonds	10.142	10 342	200		200
U.S. government guaranteed collateralized					
mortgage obligations	3,612	3,662	50		50
Mortgage-tracked securities	2.471	2.338		\$ (133)	(133)
	133,892	134,255	496	(133)	363
Maturities between one and two years U.S. government obligations	0.412	0.247		(46)	(16)
U.S. government conganous U.S. government guaranteed corporate bonds	9,413 31,064	9,367 31,344	280	(46)	(46) 28 0
Mortgage-backed securities	1,168	900		(268)	(268)
3.	41,645	41,611	280	(314)	(34)
	\$175,537	\$175,866	\$ 776	\$ (447)	\$ 329

(Unless otherwise noted, dollars in thousands, except per share data)

At December 31, 2010 and 2009, marketable securities included an additional unrealized loss of \$0.4 million and an additional unrealized gain of \$1.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at December 31, 2010 and 2009. The debt securities listed at December 31, 2010, excluding mortgage-backed securities, mature at various dates through November 2013. The mortgage-backed securities listed at December 31, 2010 mature at various dates through January 2017.

	Less than 12 Months		12 Months or Greater		То	tal
		Unrealized		Unrealized		Unrealized
At December 31, 2010	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss
Unrestricted						
U.S. government obligations	\$ 340,444	\$ (1,731)			\$ 340,444	\$ (1,731)
U.S. government guaranteed						
corporate bonds	19,005	(45)			19,005	(45)
Equity security	3,612	(433)			3,612	(433)
Mongage-backed securities			\$ 1,128	\$ (141)	1.128	(141)
	363,061	(2,209)	1,128	(141)	364,189	(2,350)
Restricted						
U.S. government obligations	6,154	(18)			6,154	(18)
	6,154	(18)			6.154	(18)
	\$ 369,215	\$ (2,227)	\$ 1,128	\$ (141)	\$ 370,343	\$ (2,368)
At December 31, 2009						
U.S. government obligations	\$ 9,367	\$ (46)			\$ 9367	\$ (46)
Mortgage-backed securities			\$ 3,238	\$ (401)	3,238	(401)
	5 9,367	\$ (46)	\$ 338	5 (401)	S 12.605	\$ (447)

Realized gains and losses are included as a component of investment income. For the year ended December 31, 2010, realized losses on sales of marketable securities totaled \$0.2 million and realized gains on sales of marketable securities were not significant. For the years ended December 31, 2009 and 2008, realized gains on sales of marketable securities totaled \$0.2 million and \$1.2 million, respectively, and realized losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

(Unless otherwise noted, dollars in thousands, except per share data)

The Company's assets that are measured at fair value on a recurring basis, at December 31, 2010 and 2009, were as follows:

		Fair Value Measurements at Reporting Date Using				
		Quoted Prices in				
		Active Markets for	Significant Other	Significant		
		Identical Assets	Observable Inputs	Unobservable Inputs		
	Fair Value	(Level 1)	(Level 2)	(Level 3)		
At December 31, 2010						
Liprestricted						
Available-for-sale marketable securities						
U.S. government obligations	\$ 434 367		\$ 434,367			
U.S. government guaranteed corporate bonds	64,008		64,008			
U.S. government guaranteed collateralized						
morigage obligations	2.131		2.131			
Municipal bonds	1,603		1,603			
Montgage-backed securities	1.128		1,128			
Equity security	3,612	\$ 3,612				
	506.849	3,612	503,237			
Restricted						
Available-for-sale marketable securities						
U.S. government obligations	7,039		7,039			
	S 513 888	\$ 3,612	\$ 510,276			
At December 31, 2009						
Available-for-sale marketable securities						
U.S. government obligations	\$ 109,940		\$ 109,940			
U.S. government guaranteed corporate bonds	48.684		48.684			
Corporate bonds	10,342		10,342			
U.S. government guaranteed collateralized						
mongage obligations	3,662		3,662			
Mortgage-backed securities	3,238		3,238			
Едину сесинну	5.469	\$ 5,469				
	\$ 181,335	\$ 5,469	\$ 175,866	••••••		

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During each of the years ended December 31, 2010 and 2008, deterioration in the credit quality of a marketable security subjected the Company to the risk of not being able to recover the carrying value of these securities. As a result, the Company recognized a \$0.1 million and \$1.8 million impairment charge related to its Level 2 marketable securities for the years ended December 31, 2010 and 2008, respectively, which the Company considered to be other-than-temporarily impaired. During the year ended December 31, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

(Unless otherwise noted, dollars in thousands, except per share data)

The Company held one Level 3 marketable security, which had no fair value at December 31, 2010 and 2009, and whose fair value was \$0.1 million at December 31, 2008. This Level 3 security was valued using information provided by the Company's investment advisors and other sources, including quoted bid prices which took into consideration the securities' lack of liquidity. During the years ended December 31, 2009 and 2008, the Company recorded charges of \$0.1 million and \$0.7 million, respectively, for other-than-temporary impairment of this Level 3 marketable security; therefore, as of December 31, 2009, the fair value of this security had been written down to zero. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the years ended December 31, 2010 and 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the years ended December 31, 2010 and 2009.

As described in Note 2 above under "Use of Estimates", on a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

7. Property, Plant, and Equipment

Property, plant, and equipment as of December 31, 2010 and 2009 consist of the following:

	2010	2009
Land	2.117	\$ 2.117
Building and improvements	242,035	177,710
Leasehold improvements	4,063	4,023
Construction-in-progress	70,356	58,541
Laboratory and other equipment	137.951	114,099
Furniture, computer and office equipment, and other	22,235	15,964
	478,757	372.454
Less, accumulated depreciation and amortization	(131,307)	(112,778)
	347,450	\$ 259 676

Depreciation and amortization expense on property, plant, and equipment amounted to \$19.7 million, \$14.2 million, and \$10.6 million for the years ended December 31, 2010, 2009, and 2008, respectively. Effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, were extended. The effect of this change in estimate was to lower depreciation expense by \$4.0 million and to lower the Company's net loss per share by \$0.05 for the year ended December 31, 2010.

Included in property, plant, and equipment at December 31, 2010 was \$2.8 million of leased equipment under capital leases (see Note 11a); related accumulated amortization was \$0.1 million at December 31, 2010. The Company held no leased equipment under capital leases at December 31, 2009.

Building and improvements at December 31, 2010 and 2009 includes \$58.4 million and \$58.2 million, respectively, of costs incurred by the Company's landlord to construct new laboratory and office facilities in Tarrytown, New York in connection with the Company's December 2006 lease, as amended, of these new facilities. In addition, construction-in-progress at both December 31, 2010 and 2009 includes \$27.8 million of costs incurred by the Company's landlord in connection with these new facilities. See Note 11a.

The Company capitalized interest costs of \$6.4 million and \$0.5 million in 2010 and 2009, respectively. The Company did not capitalize any interest costs in 2008.

(Unless otherwise noted, dollars in thousands, except per share data)

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of December 31, 2010 and 2009 consist of the following:

	2010	2009
Accounts payable	\$15,589	\$18,638
Accrued payroll and related costs	12,025	9,444
Accrued climical trial expense	9 727	11,673
Accrued property, plant, and equipment costs	7,622	1,883
Other accrued expenses and habilities	6.441	6,207
Payable to Bayer HealthCare	2,254	1,186
	\$53,658	\$49,031

9. Deferred Revenue

Deferred revenue as of December 31, 2010 and 2009 consists of the following:

	2010	2009
Ситен ротнов:		
Received from sanofi-aventis (see Note 3a)	\$ 19,506	\$ 17,523
Received from Bayer HealthCare (see Note 3b)	9.884	9,884
Received for technology license agreements (see Note 4)	25,008	11,579
Other	325	5.558
	\$ 54,723	\$ 44,544
Long-term portion		
Received from sanofi-aventis (see Note 3a)	\$ 97,081	\$ 90,933
Received from Bayer HealthCare (see Note 3b)	37,067	46,951
Received for technology license agreements (see Note 4)	151,708	
	\$285,856	\$137,884

10. Convertible Debt

In October 2001, the Company issued \$200.0 million aggregate principal amount of convertible senior subordinated notes ("Notes") in a private placement for proceeds to the Company of \$192.7 million, after deducting the initial purchasers' discount and out-of-pocket expenses (collectively, "Deferred Financing Costs"). The Notes bore interest at 5.5% per annum, payable semi-annually, and matured on October 17, 2008. Deferred Financing Costs, which were included in other assets, were amortized as interest expense over the period from the Notes' issuance to stated maturity. During the second and third quarters of 2008, the Company repurchased \$82.5 million in principal amount of the Notes for \$83.3 million and recognized a \$0.9 million loss on early extinguishment of debt, representing the premium paid on the Notes plus related unamortized Deferred Financing Costs. The remaining \$117.5 million of outstanding Notes were repaid in full upon their maturity in October 2008.

11. Commitments and Contingencies

a. Leases

 $Descriptions\ of\ Lease\ Agreements$

The Company leases laboratory and office facilities in Tarrytown, New York, under a December 2006 lease agreement, as amended (the "Tarrytown Lease"). The facilities leased by the Company under the Tarrytown Lease include (i) space in previously existing buildings, (ii) newly constructed space in two new buildings ("Buildings A and B") that was completed during the third quarter of 2009 and, (iii) under a December 2009 amendment to

(Unless otherwise noted, dollars in thousands, except per share data)

the Tarrytown Lease, additional new space that is under construction in a third new building ("Building C") and expected to be completed in the first quarter of 2011. The Tarrytown Lease will expire in June 2024 and contains three renewal options to extend the term of the lease by five years each, escalations at 2.5% per annum, and early termination options for various portions of the space exclusive of the newly constructed space in Buildings A and B. The Tarrytown Lease provides for monthly payments over its term and additional charges for utilities, taxes, and operating expenses. Certain premises under the Tarrytown Lease are accounted for as operating leases. However, for Buildings A, B, and C that the Company is leasing, the Company is deemed, in substance, to be the owner of the landlord's buildings in accordance with the application of FASB authoritative guidance, and the landlord's costs of constructing these new facilities are required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet.

In connection with the Tarrytown Lease, at lease inception, the Company issued a letter of credit in the amount of \$1.6 million to its landlord, which was collateralized by a \$1.6 million bank certificate of deposit at December 31, 2009. During 2010, the Company increased this letter of credit to \$3.4 million, in accordance with the provisions of the Tarrytown Lease, and collateralized the letter of credit with cash and marketable debt securities totaling \$3.6 million. Such collateral at December 31, 2010 and 2009 has been classified as restricted cash and marketable securities.

In October 2008, the Company entered into a sublease with sanofi-aventis U.S. Inc. for office space in Bridgewater, New Jersey. The lease commenced in January 2009 and expires in July 2011. The Company also formerly leased additional office space in Tarrytown, New York under operating subleases that ended at various times through September 2009.

The Company also leases certain laboratory and office equipment under operating and capital leases which expire at various times through 2013.

Commitments under Operating Leases

The estimated future minimum noncancelable lease commitments under operating leases were as follows:

December 31,	Facilities	Equipment	Total
2011	\$ 6.098	\$225	\$ 6,323
2012	5,468	118	5,586
2013	6,617	24	6.641
2014	6,733		6,733
2015	6.866		6.866
Thereafter	64,196		64,196
	\$95,978	<u>8367</u>	\$96,345

Rent expense under operating leases was:

Year Ending December 31,	Facilities	Equipment	Total
Hio	\$7301	\$335	\$7.636
2009	7,722	395	8,117
2008	6.530	416	6 946

In addition to its rent expense for various facilities, the Company paid rental charges for utilities, real estate taxes, and operating expenses of \$10.3 million, \$8.4 million, and \$8.4 million for the years ended December 31, 2010, 2009, and 2008, respectively.

(Unless otherwise noted, dollars in thousands, except per share data)

Commitments under Capital Leases

In 2010, the Company entered into capital leases in connection with acquisitions of new equipment. The lease obligations are collateralized with marketable debt securities totaling \$3.5 million; such collateral has been classified as restricted cash and marketable securities at December 31, 2010.

The estimated future minimum noncancelable lease commitments under capital leases were as follows:

ipment
137
.,135
995
,267
(438)
,829

At the end of the lease term, the Company is required to purchase the leased equipment for a nominal amount defined in the lease agreement. At December 31, 2010, capital lease obligations totaling \$2.8 million were included in other liabilities. There were no capital lease obligations at December 31, 2009. As of December 31, 2010, the Company had \$0.7 million of financing available under a capital equipment lease line.

Facility Lease Obligations

As described above, in connection with the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Buildings A and B, the Company capitalized the landlord's costs of constructing the new facilities, which totaled \$58.4 million as of December 31, 2010, and recognized a corresponding facility lease obligation of \$58.4 million. The Company also recognized, as additional facility lease obligation, reimbursements totaling \$56.9 million from the Company's landlord during 2010 and 2009 for tenant improvement costs that the Company incurred since, under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. The new facilities were placed in service by the Company in September 2009. For the years ended December 31, 2010 and 2009, the Company recognized in its statement of operations \$9.1 million and \$2.3 million, respectively, of interest expense in connection with the facility lease obligation. At December 31, 2010 and 2009, the facility lease obligation balance in connection with Buildings A and B was \$113.7 million and \$81.0 million, respectively.

In addition, as described above, in December 2009, the Company amended its December 2006 agreement to lease additional new laboratory and office facilities in Building C that is under construction. In connection with the application of FASB authoritative guidance to the Company's lease of these additional new facilities, the Company is deemed, in substance, to be the owner of the landlord's building, and the landlord's costs of constructing Building C is required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet. As of December 31, 2010, the Company capitalized \$27.8 million of the landlord's costs of constructing Building C, and recognized a corresponding facility lease obligation of \$27.8 million. The Company also recognized, as additional facility lease obligation, reimbursements totaling \$14.2 million from the Company's landlord during 2010 for tenant improvement costs that the Company incurred since, under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation. Monthly lease payments on these facilities will commence in January 2011. Rent expense in connection with the land element of these additional facilities, which is accounted for as an operating lease, commenced in December 2009 and is recorded as a deferred liability until lease payments commence in January 2011. In addition, interest expense is imputed at a rate of approximately 9%, and is capitalized and deferred in connection with this facility lease obligation. At December 31, 2010 and 2009, the facility lease obligation balance in connection with Building C was \$46.4 million and \$28.0 million, respectively.

(Unless otherwise noted, dollars in thousands, except per share data)

The estimated future minimum noncancelable commitments under these facility lease obligations, as of December 31, 2010, were as follows:

December 31,	Buildings A and B	Building C	Total
2011	\$ 11.347	\$ 2,468	\$ 13,815
2012	12,603	2,767	15,370
2013	12,843	4 285	17.128
2014	13,090	4,403	17,493
2015	13.343	4,524	17.867
Thereafter	124,515	43,783	168,298
		\$62,230	\$249,971

b. Research Collaboration and Licensing Agreements

As part of the Company's research and development efforts, the Company enters into research collaboration and licensing agreements with related and unrelated companies, scientific collaborators, universities, and consultants. These agreements contain varying terms and provisions which include fees and milestones to be paid by the Company, services to be provided, and ownership rights to certain proprietary technology developed under the agreements. Some of the agreements contain provisions which require the Company to pay royalties, as defined, at rates that range from 0.25% to 16.5%, in the event the Company sells or licenses any proprietary products developed under the respective agreements.

Certain agreements under which the Company is required to pay fees permit the Company, upon 30 to 90-day written notice, to terminate such agreements. With respect to payments associated with these agreements, the Company incurred expenses of \$1.6 million, \$2.8 million, and \$3.5 million for the years ended December 31, 2010, 2009, and 2008, respectively.

In connection with the Company's receipt of marketing approval from the FDA for ARCALYST® for the treatment of CAPS, in 2008, the Company commenced paying royalties under various licensing agreements based on ARCALYST® net product sales. For the years ended December 31, 2010, 2009, and 2008, ARCALYST® royalties totaled \$1.7 million, \$1.5 million, and \$0.6 million, respectively, and are included in cost of goods sold.

In July 2008, the Company and Cellectis S.A. ("Cellectis") entered into an Amended and Restated Non-Exclusive License Agreement (the "Cellectis Agreement"). The Cellectis Agreement resolved a dispute between the parties related to the interpretation of a license agreement entered into by the parties in December 2003 pursuant to which the Company licensed certain patents and patent applications from Cellectis. Pursuant to the Cellectis Agreement, in July 2008, the Company made a non-refundable \$12.5 million payment to Cellectis (the "Cellectis Payment") and agreed to pay Cellectis a low single-digit royalty based on revenue received by the Company from any future licenses or sales of the Company's VelociGene® or Velocimmune® products and services. No royalties are payable to Cellectis with respect to the Company's Velocimmune® license agreements with AstraZeneca and Astellas or the Company's antibody collaboration with sanofi-aventis. Moreover, no royalties are payable to Cellectis on any revenue from commercial sales of antibodies from the Company's Velocimmune® technology.

The Company began amortizing the Cellectis Payment in the second quarter of 2008 in proportion to past and future anticipated revenues under the Company's license agreements with AstraZeneca and Astellas and the Discovery and Preclinical Development Agreement under the Company's antibody collaboration with sanofi-aventis (as amended in November 2009). In 2010, 2009, and 2008, the Company recognized \$0.9 million, \$2.3 million, and \$2.7 million, respectively, of expense in connection with the Cellectis Payment. At December 31, 2010 and 2009, the unamortized balance of the Cellectis Payment, which was included in other assets, was \$6.6 million and \$7.6 million, respectively. The Company estimates that it will recognize expense of \$1.0 million in each of 2011, 2012, and 2013, and \$0.9 million in each of 2014 and 2015, in connection with the Cellectis Payment.

(Unless otherwise noted, dollars in thousands, except per share data)

12. Stockholders Equity

The Company's Restated Certificate of Incorporation provides for the issuance of up to 40 million shares of Class A Stock, par value \$0.001 per share, and 160 million shares of Common Stock, par value \$0.001 per share. Shares of Class A Stock are convertible, at any time, at the option of the holder into shares of Common Stock on a share-for-share basis. Holders of Class A Stock have rights and privileges identical to Common Stockholders except that each share of Class A is entitled to ten votes per share, while each share of Common Stock is entitled to one vote per share. Class A Stock may only be transferred to specified Permitted Transferees, as defined. Under the Company's Restated Certificate of Incorporation, the Company's board of directors is authorized to issue up to 30 million shares of preferred stock, in series, with rights, privileges, and qualifications of each series determined by the board of directors.

In September 2003, sanofi-aventis purchased 2,799,552 newly issued, unregistered shares of the Company's Common Stock for \$45.0 million. See Note 3.

In December 2007, sanofi-aventis purchased 12 million newly issued, unregistered shares of the Company's Common Stock for an aggregate cash price of \$312.0 million. As a condition to the closing of this transaction, sanofi-aventis entered into an investor agreement with the Company, which was amended in November 2009. Under the amended investor agreement, sanofi-aventis has three demand rights to require the Company to use all reasonable efforts to conduct a registered underwritten public offering with respect to shares of the Company's Common Stock beneficially owned by sanofi-aventis immediately after the closing of the transaction. Until the later of the fifth anniversaries of the expiration or earlier termination of the License and Collaboration Agreement, as amended in 2009, under the Company's antibody collaboration with sanofi-aventis (see Note 3) and the Company's collaboration agreement with sanofi-aventis for the development and commercialization of aflibercept (see Note 3), sanofi-aventis will be bound by certain "standstill" provisions. These provisions include an agreement not to acquire more than a specified percentage of the outstanding shares of the Company's Class A Stock and Common Stock. The percentage is currently 25% and will increase to 30% after December 20, 2011. Under the amended investor agreement, sanofi-aventis has also agreed not to dispose of any shares of the Company's Common Stock that were beneficially owned by sanofi-aventis immediately after the closing of the transaction until December 20, 2017, subject to certain limited exceptions. Following December 20, 2017, sanofi-aventis will be permitted to sell shares of the Company's Common Stock (i) in a registered underwritten public offering undertaken pursuant to the demand registration rights granted to sanofi-aventis and described above, subject to the underwriter's broad distribution of securities sold, (ii) pursuant to Rule 144 under the Securities Act and transactions exempt from registration under the Securities Act, subject to a volume limitation of one million shares of the Company's Common Stock every three months and a prohibition on selling to beneficial owners, or persons that would become beneficial owners as a result of such sale, of 5% or more of the outstanding shares of the Company's Common Stock, and (iii) into an issuer tender offer, or a tender offer by a third party that is recommended or not opposed by the Company's board of directors. Sanofi-aventis has agreed to vote, and cause its affiliates to vote, all shares of the Company's voting securities they are entitled to vote, at sanofi-aventis' election, either as recommended by the Company's board of directors or proportionally with the votes cast by the Company's other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of the Company's Class A Stock and Common Stock, and new equity compensation plans or amendments if not materially consistent with the Company's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events.

In October 2010, the Company completed an underwritten public offering of 6,325,000 shares of Common Stock and received net proceeds of \$174.8 million. Sanofiaventis purchased 1,017,401 shares of Common Stock in this offering.

(Unless otherwise noted, dollars in thousands, except per share data)

13. Long-Term Incentive Plans

During 2000, the Company established the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan which, as amended and restated (the "2000 Incentive Plan"), provides for the issuance of up to 29,307,016 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, (collectively, "Participants") may receive awards as determined by a committee of independent directors ("Committee"). The awards that may be made under the 2000 Incentive Plan include: (a) Incentive Stock Options ("ISOs") and Nonqualified Stock Options, (b) shares of Restricted Stock, (c) shares of Phantom Stock, (d) Stock Bonuses, and (e) Other Awards.

Stock Option awards grant Participants the right to purchase shares of Common Stock at prices determined by the Committee; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the Option is granted. Options vest over a period of time determined by the Committee, generally on a pro rata basis over a three to five year period. The Committee also determines the expiration date of each Option; however, no ISO is exercisable more than ten years after the date of grant. The maximum term of options that have been awarded under the 2000 Incentive Plan is ten years.

Restricted Stock awards grant Participants shares of restricted Common Stock or allow Participants to purchase such shares at a price determined by the Committee. Such shares are nontransferable for a period determined by the Committee ("vesting period"). Should employment terminate, as defined by the 2000 Incentive Plan, the ownership of the Restricted Stock, which has not vested, will be transferred to the Company, except under defined circumstances with Committee approval, in consideration of amounts, if any, paid by the Participant to acquire such shares. In addition, if the Company requires a return of the Restricted Shares, it also has the right to require a return of all dividends paid on such shares.

Phantom Stock awards provide the Participant the right to receive, within 30 days of the date on which the share vests, an amount, in cash and/or shares of the Company's Common Stock as determined by the Committee, equal to the sum of the fair market value of a share of Common Stock on the date such share of Phantom Stock vests and the aggregate amount of cash dividends paid with respect to a share of Common Stock during the period from the grant date of the share of Phantom Stock to the date on which the share vests. Stock Bonus awards are bonuses payable in shares of Common Stock which are granted at the discretion of the Committee.

Other Awards are other forms of awards which are valued based on the Company's Common Stock. Subject to the provisions of the 2000 Incentive Plan, the terms and provisions of such Other Awards are determined solely on the authority of the Committee.

The 2000 Incentive Plan contains provisions that allow for the Committee to provide for the immediate vesting of awards upon a change in control of the Company, as defined in the plan.

As of December 31, 2010, there were 434,564 shares available for future grants under the 2000 Incentive Plan.

During 1990, the Company established the 1990 Incentive Plan which, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Employees of the Company, including officers, and nonemployees, including consultants and nonemployee members of the Company's board of directors, received awards as determined by a committee of independent directors. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. Awards under the 1990 Incentive Plan consisted of Incentive Stock Options and Nonqualified Stock Options which generally vested on a pro rata basis over a three or five year period and had a term of ten years.

(Unless otherwise noted, dollars in thousands, except per share data)

a. Stock Options

Transactions involving stock option awards during 2010 under the 1990 and 2000 Incentive Plans are summarized in the table below.

			Weighted-	
			Average	
			Remaining	
			Contractual	Intrinsic
	Number of	Weighted-Average	Term	Value
Stock Options:	Shares	Exercise Price	(in years)	(in thousands)
Outstanding at December 31, 2009	21,788,755	\$18.45		
2010: Granted	4,319,856	\$29.43		
Forfeited	(183,252)	\$20.22		
Expired	(887,281)	\$38.63		
Exercised	(1.675.830)	\$15.24		
Outstanding at December 31, 2010	23,362,248	\$19.93	6.47	\$308,766
Vested and expected to vest at December 31, 2010	22,803,097	\$19.81	6.38	\$304.116
Exercisable at December 31, 2010	12,910,390	\$17.54	4.91	\$201,662

The Company satisfies stock option exercises with newly issued shares of the Company's Common Stock. The total intrinsic value of stock options exercised during 2010, 2009, and 2008 was \$21.4 million, \$13.2 million, and \$11.9 million, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

The Company grants stock options with exercise prices that are equal to or greater than the average market price of the Company's Common Stock on the date of grant ("Market Price"). The table below summarizes the weighted-average exercise prices and weighted-average grant-date fair values of options issued during the years ended December 31, 2010, 2009, and 2008. The fair value of each option granted under the 2000 Incentive Plan during 2010, 2009, and 2008 was estimated on the date of grant using the Black-Scholes option-pricing model.

		Weighted-	Weighted-
	Number of	Average Exercise	Average Fair
	Options Granted	Price	Value
2010:			
Exercise price equal to Market Price	4,319,856	\$29.43	\$13.36
2009:			
Exercise price equal to Market Price	3,490,560	\$20.69	\$10.89
2008:			
Exercise price equal to Market Price	4,126,600	\$17.38	\$ 8.45

For the years ended December 31, 2010, 2009, and 2008, \$29.4 million, \$27.4 million, and \$30.3 million, respectively, of non-cash stock-based compensation expense related to non-performance based stock option awards was recognized in operating expenses. As of December 31, 2010, there was \$57.5 million of stock-based compensation cost related to outstanding non-performance based stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years.

In addition, there were 2,486,510 performance-based options which were unvested as of December 31, 2010 of which, subject to the optionee satisfying certain service conditions, 664,760 options that were issued in 2005 would vest upon achieving certain defined sales targets for the Company's products and 1,821,750 options that were issued in 2008, 2009, and 2010 would vest upon achieving certain development milestones for the Company's product candidates. In light of the status of the Company's development programs at December 31, 2010, the Company estimates that all of the performance-based options issued in 2008, 2009, and 2010 will vest since the Company

(Unless otherwise noted, dollars in thousands, except per share data)

considers these options' performance conditions to be probable of attainment. Principally as a result, in 2010, the Company recognized \$8.1 million of non-cash stock-based compensation expense related to these performance options. In light of the status of the Company's development programs at December 31, 2009, the Company estimated that approximately two-thirds of the performance-based options issued in 2008 and 2009 would vest; therefore, in 2009, the Company recognized \$1.7 million of non-cash stock-based compensation expense, related to these performance-based options. As of December 31, 2010, there was \$17.6 million of stock-based compensation cost which had not yet been recognized in operating expenses related to the performance-based options that the Company currently estimates will vest. The Company expects to recognize this compensation cost over a weighted-average period of 2 years. In addition, potential compensation cost of \$2.5 million related to the performance options issued in 2005, whose performance conditions (based on current facts and circumstances) are not currently considered by the Company to be probable of attainment, will begin to be recognized only if, and when, the Company estimates that it is probable that these options will vest. The Company's estimates of the number of performance-based options that will vest will be revised, if necessary, in subsequent periods. Changes in these estimates may materially affect the amount of stock-based compensation recognized in future periods related to performance-based options.

Fair value Assumptions:

The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants during 2010, 2009, and 2008.

	2010	2009	2008
Expected volatility	47%	54%	53%
Expected lives from grant date	5.6 years	5.9 years	5.5 years
Expected dividend yield	0^{6}	69%	9%
Risk-free interest rate	2.11%	2.87%	1.73%

Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's historical exercise experience with previously issued employee and board of directors option grants. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The risk-free interest rates are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives.

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the year ended December 31, 2010 is summarized below:

		Weighted-
		Average
	Number of	Grant Date
Restricted Stock:	Shares	Fair Value
Outstanding at December 31, 2009	500,000	\$21.92
2010: Granted	345,000	\$30.37
Outstanding at December 31, 2010	845,000	\$25.37

The Company recognized non-cash stock-based employee compensation expense from Restricted Stock awards of \$2.4 million, \$2.2 million, and \$2.2 million in 2010, 2009, and 2008, respectively. As of December 31, 2010, there were 845,000 unvested shares of Restricted Stock outstanding and \$14.6 million of stock-based compensation cost related to these unvested shares which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 2.4 years.

(Unless otherwise noted, dollars in thousands, except per share data)

14. Executive Stock Purchase Plan

In 1989, the Company adopted an Executive Stock Purchase Plan (the "Plan") under which 1,027,500 shares of Class A Stock were reserved for restricted stock awards. The Plan provides for the compensation committee of the board of directors to award employees, directors, consultants, and other individuals ("Plan participants") who render service to the Company the right to purchase Class A Stock at a price set by the compensation committee. The Plan provides for the vesting of shares as determined by the compensation committee and, should the Company's relationship with a Plan participant terminate before all shares are vested, unvested shares will be repurchased by the Company at a price per share equal to the original amount paid by the Plan participant. During 1989 and 1990, a total of 983,254 shares were issued, all of which vested as of December 31, 1999. As of December 31, 2010, there were 44,246 shares available for future grants under the Plan.

15. Employee Savings Plan

In 1993, the Company adopted the provisions of the Regeneron Pharmaceuticals, Inc. 401(k) Savings Plan (the "Savings Plan"). The terms of the Savings Plan provide for employees who have met defined service requirements to participate in the Savings Plan by electing to contribute to the Savings Plan a percentage of their compensation to be set aside to pay their future retirement benefits, as defined. The Savings Plan, as amended and restated, provides for the Company to make discretionary contributions ("Contribution"), as defined. The Company recognized \$3.2 million, \$2.6 million, and \$1.5 million of Contribution expense in 2010, 2009, and 2008, respectively. At December 31, 2010 and 2009, accrued Contribution expense totaled \$2.9 million and \$2.6 million, respectively. During the first quarter of 2011 and 2010, the Company contributed 91,761 and 111,419 shares, respectively, of Common Stock to the Savings Plan in satisfaction of these obligations.

16. Income Taxes

For the year ended December 31, 2010, the Company incurred a net loss for tax purposes and recognized a full valuation allowance against deferred taxes. Accordingly, no provision or benefit for income taxes was recorded in 2010.

For the year ended December 31, 2009, the Company incurred a net loss for tax purposes and recognized a full valuation allowance against deferred taxes. In 2009, the Company recognized a \$4.1 million income tax benefit, consisting of (i) \$2.7 million resulting from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allows the Company to claim a refund of U.S. federal alternative minimum tax ("AMT") that the Company paid in connection with its 2007 U.S. federal income tax return, as described below, (ii) \$0.7 million income tax benefit resulting from a provision in the American Recovery and Reinvestment Act of 2009 that allows the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2009 U.S. federal income tax return, and (iii) \$0.7 million income tax benefit in connection with the net tax effect of the Company's unrealized gain on "available-for-sale" marketable securities, which is included in other comprehensive income in 2009.

For the year ended December 31, 2008, the Company incurred a net loss for tax purposes and recognized a full valuation allowance against deferred taxes. During 2008, the Company implemented a tax planning strategy to utilize net operating loss carry-forwards (which were otherwise due to expire in 2008 through 2012) on its 2007 U.S. federal and New York State income tax returns that were filed in September 2008. The tax planning strategy included electing, for tax purposes only, to capitalize \$142.1 million of 2007 research and development ("R&D") costs and amortize these costs over ten years for tax purposes. By capitalizing these R&D costs, the Company was able to generate taxable income for tax year 2007 and utilize the net operating loss carry-forwards to offset this taxable income. As a result, the Company incurred and paid income tax expense of \$3.1 million in 2008, which related to U.S. federal and New York State AMT and included \$0.2 million of interest and penalties. This expense was partly offset by the Company's recognition of a \$0.7 million income tax benefit in 2008, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed the Company to claim a refund for a portion of its unused pre-2006 research tax credits on its 2008 U.S federal income tax return.

(Unless otherwise noted, dollars in thousands, except per share data)

The tax effect of temporary differences, net operating loss carry-forwards, and research and experimental and other tax credit carry-forwards as of December 31, 2010 and 2009 is as follows:

	2010	2009
Deferred tax assets:		
Net operating loss carry-forward	\$ 243,893	\$ 200,266
Freed assets	13,600	13,833
Deferred revenue	70,443	73,865
Deferred compensation	39.120	29.736
Research and experimental and other tax credit carry-forwards	45,588	22,377
Capitalized research and development costs	38.865	49 107
Other	10,863	10,142
Valuation allowance	(462,372)	(399,326)

The Company's valuation allowance increased by \$63.0 million in 2010, due primarily to increases in the net operating loss carry-forward and tax credit carry-forwards. In 2009, the Company's valuation allowance increased by \$19.0 million, due primarily to the increase in the net operating loss carry-forward.

The Company is primarily subject to U.S. federal and New York State income tax. The difference between the Company's effective income tax rate and the U.S federal statutory rate of 35% is primarily attributable to an increase in the deferred tax valuation allowance. Due to the Company's history of losses, all tax years remain open to examination by U.S. federal and state tax authorities. In January 2011, U.S. federal tax authorities commenced an examination of the Company's 2007 and 2008 U.S. federal income tax returns.

As of December 31, 2010 and 2009, the Company had no accruals for interest or penalties related to income tax matters.

As of December 31, 2010, the Company had available for tax purposes unused net operating loss carry-forwards of \$614.9 million which will expire in various years from 2018 to 2030 and included \$7.1 million of net operating loss carry-forwards related to exercises of Nonqualified Stock Options and disqualifying dispositions of Incentive Stock Options, the tax benefit from which, if realized, will be credited to additional paid-in capital. The Company's research and experimental and other tax credit carry-forwards expire in various years from 2011 to 2030. Under the Internal Revenue Code and similar state provisions, substantial changes in the Company's ownership have resulted in an annual limitation on the amount of net operating loss and tax credit carry-forwards that can be utilized in future years to offset future taxable income. This annual limitation may result in the expiration of net operating losses and tax credit carry-forwards before utilization.

The following table summarizes the gross amounts of unrecognized tax benefits at the beginning and end of 2010:

	2010
Data a confirm on 1	
Balance as of January I	*********
Gross increases related to current year tax positions	3,550
Gross increases related to prior year tax positions	9 269
	200225
Balance as of December 31 \$1:	2,819

In 2010, the gross increases in unrecognized tax benefits related to prior year tax positions was primarily due to the Company's calculations of certain pre-2010 tax credits. Due to the amounts of the Company's net operating loss carry-forward and tax credit carry-forwards, the Company has not accrued interest or penalties related to these unrecognized tax benefits. In addition, unrecognized tax benefits at December 31, 2010, if recognized, would not affect the Company's effective tax rate since the adjustments to deferred tax assets would be fully offset by

(Unless otherwise noted, dollars in thousands, except per share data)

adjustments to the Company's valuation allowance. For the years ended December 31, 2009 and 2008, income tax positions that were deemed uncertain under the recognition thresholds and measurement attributes prescribed in FASB authoritative guidance were not significant.

17. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition. Legal costs associated with the Company's resolution of legal proceedings are expensed as incurred.

On November 19, 2010, the Company filed a complaint against Genentech, Inc. in the United States District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint. The motion is currently pending. The Company may initiate similar actions in countries outside the United States.

18. Net Loss Per Share Data

The Company's basic net loss per share amounts have been computed by dividing net loss by the weighted average number of Common and Class A shares outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. In 2010, 2009, and 2008, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	December 31,		
	2010	2009	2008
Net loss (Numerator)	\$(104.468)	\$(67.830)	\$(79,129)
Weighted-average shares, in thousands (Denominator)	82,926	79,782	78,827
Basic and diluted not loss per share			

Shares issuable upon the exercise of options and vesting of restricted stock awards, which have been excluded from the diluted per share amounts because their effect would have been antidilutive, include the following:

	December 31,		
	2010	2009	2008
Options:			
Weighted average number, in thousands	21,428	20,040	17,598
Weighted average exercise price	S 18.80	\$ 1766	\$ 17.31
Restricted Stock:			
Weighted average number; in thousands	526	500	500

19. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at December 31, 2010, 2009, and 2008 were \$10.7 million, \$9.8 million, and \$7.0 million of accrued capital expenditures, respectively.

REGENERON PHARMACEUTICALS, INC. NOTES TO FINANCIAL STATEMENTS (Continued)

(Unless otherwise noted, dollars in thousands, except per share data)

Included in accounts payable and accrued expenses at December 31, 2009, 2008, and 2007 were \$2.6 million, \$1.5 million, and \$1.1 million, respectively, of accrued 401(k) Savings Plan contribution expense. During the first quarter of 2010, 2009, and 2008, the Company contributed 111,419, 81,086, and 58,575 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Pursuant to the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Tarrytown, New York (see Note 11a), the Company recognized a facility lease obligation of \$0.2 million and \$31.7 million during 2010 and 2009, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in facility lease obligations and property, plant, and equipment at December 31, 2010 was \$3.7 million of capitalized and deferred interest for the year ended December 31, 2010, as the related facilities being leased by the Company are currently under construction and lease payments on these facilities do not commence until January 2011.

The Company incurred capital lease obligations of \$2.9 million during 2010 in connection with acquisitions of new equipment.

Included in other assets at December 31, 2010 and 2009 was \$0.2 million and \$0.7 million, respectively, due to the Company in connection with employee exercises of stock options in December 2010.

Included in marketable securities at December 31, 2010, 2009, and 2008 were \$1.4 million, \$0.6 million, and \$1.7 million of accrued interest income, respectively.

20. Unaudited Quarterly Results

Summarized quarterly financial data for the years ended December 31, 2010 and 2009 are set forth in the following tables.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	Ended	Ended	Ended	Ended
	March 31, 2010	June 30, 2010	September 30, 2010	December 31, 2010
		(Un	audited)	
Revenues	\$103,534	\$115.886	\$105,979	\$133,675
Net loss	(30,522)	(25,474)	(33,875)	(14,597)
Net loss per share, basic and diluted.	5 (0.38)	\$ (0.31)	\$ (0.41)	\$ (0.17)
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	Ended	Ended	Ended	Ended
	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009
		(Un	audited)	
Revenues	\$ 74,981	\$ 90,032	\$117,455	\$ 96,800
Net loss	(15,388)	(14,938)	(1,015)	(36,489)
Net loss per share, busic and diluted	\$ 10.191	\$ (0.19)	\$ (0.01)	

Notice of Grant of Award And Award Agreement	777 Old Saw Mill River Road Tarrytown, New York 10591
[NAME] [ADDRESS]	Award Number: [] Plan: 04
Effective < date> (the "Grant Date") you have been granted an award of [] shares of Regeneron Pharmaceuticals, Inc. (the Company) common

Regeneron Pharmaceuticals, Inc.

The current total value of the award is [\$].

stock. These shares are restricted until the vest date(s) shown below.

The award will vest on the date(s) shown.

 Shares
 Full Vest

 []*
 []*

 []*
 []*

 []*
 []*

You and the Company agree that this award is granted under and governed by the terms and conditions of the Company's 2000 Long-Term Incentive Plan as amended and the Award Agreement, both of which are attached and made a part of this document.

1

REGENERON PHARMACEUTICALS, INC.

RESTRICTED STOCK AGREEMENT PURSUANT TO THE 2000 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT, made as of the date on the *Notice of Grant of Restricted Stock*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Restricted Stock* (the "Recipient");

WHEREAS, the Recipient is an employee of the Company and the Company desires to afford the Recipient the opportunity to acquire or enlarge the Recipient's stock ownership in the Company so that the Recipient may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the 2000 Long-Term Incentive Plan (the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Restricted Stock*) to the Recipient the shares of Restricted Stock as set forth in the *Notice of Grant of Restricted Stock*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

- 1. <u>Grant of Award</u>. Pursuant to Section 8 of the Plan, the Company grants to the Recipient, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth herein, the number of shares of Restricted Stock as shown on the *Notice of Grant of Restricted Stock*. The Participant's grant and record of Restricted Stock share ownership shall be kept on the books of the Company until the restrictions on transfer have lapsed. At the Recipient's request, vested shares may be evidenced by stock certificates.
- 2. <u>Vesting</u>. (a) The shares of Restricted Stock granted to the Recipient shall vest in installments as provided in the *Notice of Grant of Restricted Stock*. The vesting schedule in the *Notice of Grant of Restricted Stock* indicates each date upon which the restrictions on transfer on the specified number of shares of Restricted Stock shall lapse, entitling the Recipient to freely transfer such shares, provided that the Recipient has not incurred a termination of employment with the Company and all Subsidiaries (collectively, the Company and its Subsidiaries shall be referred to herein as the "Employer"). There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Restricted Stock* and all vesting shall occur only on the Full Vest Dates. Except as set forth in the Plan or in any employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the grant date specified in the *Notice of Grant of Restricted Stock*, no vesting shall occur after the termination of a Recipient's employment with the Employer for any reason.
- (b) Notwithstanding anything herein (except the following sentence) or in the Notice of Grant of Restricted Stock to the contrary, the Restricted Stock granted to Recipient shall be fully vested on the date the Recipient's employment with the Employer is terminated if the Recipient's employment with the Employer is terminated (i) by the Company (other than for Cause) or (ii) by the Recipient for Good Reason (provided that such termination for Good Reason occurs on or within two years after the occurrence of a Change in Control). Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date of grant specified in the Notice of Grant of Restricted Stock, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment (collectively, the "Company Payments") would result in the Recipient being subject to excise tax payable under Internal Revenue Code Section 4999 (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Recipient to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Recipient (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Recipient minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Recipient or, in the event the parties cannot agree, in the following order (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur, (2) any lump sum severance based on a multiple of base salary or bonus. (3) any other cash amounts payable to the Recipient. (4) any benefits valued as parachute payments, and (5) acceleration of vesting of any equity not covered by (1) above.

- (c) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date of grant specified in the *Notice of Grant of Restricted Stock* (or where there is such an agreement but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Recipient substantially to perform his or her duties and obligations to the Employer, including without limitation, repeated refusal to follow the reasonable directions of the Employer, knowing violation of law in the course of performance of the duties of the Recipient's employment with the Employer, repeated absences from work without a reasonable excuse, and intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours (other than any such failure resulting from his or her incapacity due to physical or mental illness); (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date of grant specified on the *Notice of Grant of Restricted Stock* that defines "cause" (or words of like import), as defined under such agreement. For purposes of this Section 3(c), no act, or failure to act, on a Recipient's part shall be considered "willful" unless done, or omitted to be done, by the Recipient in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.
- (d) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date of grant specified in the Notice of Grant of Restricted Stock (or where there is such an agreement but it does not define "good reason" (or words of like import)) a termination of employment by the Recipient within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Recipient to the Employer that Recipient intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Recipient's duties and responsibilities from that which exists immediately prior to a Change in Control (except in each case in connection with the termination of the Recipient's employment for Cause or as a result of the Recipient's death, or temporarily as a result of the Recipient's illness or other absence), or (2) the assignment to the Recipient of duties and responsibilities materially inconsistent with the position held by the Recipient; (B) any material breach by the Employer of any material provision of any written agreement with the Recipient or failure to timely pay any compensation obligation to the Recipient; (C) a reduction in the Recipient's annual base salary or target bonus opportunity (if any) from that which exists immediately prior to a Change in Control; or (D) if the Recipient is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Recipient's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement in effect between the Employer and the Recipient on the date on the Notice of Grant of Restricted Stock that defines "good reason" (or words of like import), as defined under such agreement.
- 3. <u>Termination of Service</u>. Subject to the terms of the Plan and Section 2(b), if the Recipient's employment with the Company is terminated for any reason (other than as set forth in Section 2(b) and as a result of Recipient's death or Disability), the Recipient shall forfeit any or all of the shares of Restricted Stock that have not vested in accordance with Section 2 hereof (the "Unvested Shares"). Shares of Restricted Stock granted to the Recipient in the Notice of Grant of Restricted Stock shall become fully vested as of the date of death of the Recipient, provided that the Recipient is employed by the Employer on the date of his/her death, or upon the termination of the Recipient's employment due to Disability. For purposes of the forgoing sentence "Disability" shall have the meaning set forth in Treasury Regulation 1.409A-3(i)(4)(i)(B) and shall be determined in accordance with such regulation.

- 4. <u>Restrictions on Transfer</u>. Unvested Shares may not be transferred or otherwise disposed of by the Recipient including by way of sale, assignment, transfer, pledge, hypothecation or otherwise, except as permitted by the Committee in its sole discretion.
- 5. <u>Securities Laws Requirements</u>. The Company shall not be obligated to transfer any Unvested Shares or other shares of Company Stock to the Recipient, if such transfer, in the opinion of counsel for the Company, would violate the Securities Act (or any other federal or state statutes having similar requirements as may be in effect at that time).
- 6. <u>Invalid Transfers</u>. No purported sale, assignment, mortgage, hypothecation, transfer, pledge, encumbrance, gift, transfer in trust (voting or other) or other disposition of, or creation of a security interest in or lien on, any of the shares of Restricted Stock by any holder thereof in violation of the provisions of this Restricted Stock Agreement or the Certificate of Incorporation or the by-laws of the Company, shall be valid, and the Company will not transfer any of said shares of Restricted Stock on its books nor will any of said shares of Restricted Stock be entitled to vote, nor will any dividends be paid thereon, unless and until there has been full compliance with said provisions to the satisfaction of the Company. The foregoing restrictions are in addition to and not in lieu of any other remedies, legal or equitable, available to enforce said provisions.
- 7. <u>Taxes</u>. The Recipient shall promptly notify the Company of any election made pursuant to Section 83(b) of the Code. The Recipient shall pay to the Company promptly upon request, and in any event at the time the Recipient recognizes taxable income in respect to the shares of Restricted Stock (including if the Recipient makes an election under Section 83(b) of the Code in connection with such grant), an amount equal to the federal, state and/or local taxes the Company determines it is required to withhold under applicable tax laws with respect to the shares of Restricted Stock. The Recipient may satisfy the foregoing requirement by making a payment to the Company in cash or, with the consent of the Company, by authorizing the Company to withhold cash otherwise due to the Recipient. In addition, except where the Recipient makes an election under Section 83(b) of the Code, Recipient may elect to have any withholding obligation satisfied by surrendering to the Company a portion of the shares of Restricted Stock the vesting of which gives rise to the withholding obligation (but only to the extent of the minimum withholding required by law). Shares so surrendered by the Recipient shall be credited against any such withholding obligation at the Fair Market Value of such Shares on the date of such vesting (and the amount equal to the Fair Market Value of such Shares shall be remitted by the Company to the appropriate tax authorities). The Recipient understands that s/he (and not the Company) shall be responsible for any tax liability that may arise as a result of the transactions contemplated by this Restricted Stock Agreement.

THE RECIPIENT ACKNOWLEDGES THAT IT IS THE RECIPIENT'S SOLE RESPONSIBILITY AND NOT THE COMPANY'S TO FILE TIMELY THE ELECTION UNDER SECTION 83(b) OF THE CODE, IN THE EVENT THAT THE RECIPIENT DESIRES TO MAKE THE ELECTION.

- 8. <u>Rights as a Stockholder</u>. Pursuant to Section 8(e) of the Plan, the Company shall hold in escrow all dividends, if any, that are paid with respect to the Unvested Shares until all restrictions on such shares have lapsed. Pursuant to Section 8(f) of the Plan, the Recipient agrees (i) that the right to vote any Unvested Shares will be held by the Company and (ii) to execute an irrevocable proxy in favor of the Company in such form supplied by the Company.
- 9. Compliance with Law and Regulations. The award and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company may require, as a condition of the issuance and delivery of certificates evidencing Restricted Stock pursuant to the terms hereof, that the certificates bear such legends as set forth in the Plan, in addition to any other legends required under federal and state securities laws or as otherwise determined by the Committee. Except to the extent preempted by any federal law, this Restricted Stock Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

- 10. Recipient Bound by Plan. The Recipient acknowledges receipt of a copy of the Plan and this Restricted Stock Agreement and agrees to be bound by all the terms and provisions thereof. The Plan is incorporated by reference, and any capitalized terms used but not defined herein shall have the same meanings as in the Plan. To the extent that this Restricted Stock Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Restricted Stock Agreement shall be deemed to be modified accordingly.
- 11. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Company, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Recipient, to: the Recipient at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Recipient has terminated service with the Company, to the last address for the Recipient indicated in the records of the Company, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 11.

Regeneron Pharmaceuticals, Inc.

ID: [

777 Old Saw Mill River Road Tarrytown, New York 10591

Notice of Grant of Stock Options and Option Agreement for Performance Vesting Option Awards

[OPTIONEE NAME] Option Number: []
[OPTIONEE ADDRESS Plan: 04
ID []

Effective <data> (the Grant Date) you have been granted a Non-Qualified Stock Option to buy [] shares of Regeneron Pharmaceuticals, Inc. (the Company) stock at [\$] per share.

The total option price of the shares granted is [\$].

Stock options granted pursuant to this award will be eligible to vest on []*. The number of stock options that will vest on that date will be determined based on the total number of points that are earned according to the table below during the period commencing on [] and ending on []* (the Performance Measurement Period):

Total Points	Stock Options to Vest on []*
orless	0
[]	[]
	1 1
[]	[]
1 1	I 1
	[]
or more	1 1

Total points in the table set forth above will be calculated based on the following criteria as achieved during the Performance Measurement Period:

[Description of performance criteria and allocation of points for achieving specific milestones]

For the avoidance of doubt, points may be earned upon achievement of the specified criteria by or on behalf of the Company or any subsidiary of the Company, including by any other entity pursuant to or in connection with any license or collaboration agreement under which such entity has rights to develop the Drug Candidate. For the further avoidance of doubt, the development of a Drug Candidate may earn points for [insert certain criteria].

Notwithstanding the foregoing, if [insert certain criteria] have not been achieved during the Performance Measurement Period, then the number of stock options from this award that will vest on []* may not exceed [] unless otherwise determined by the Compensation Committee or there is an acceleration of this stock option award following a Change in Control pursuant to any employment agreement, change in control agreement or similar agreement in effect between the Grantee and the Company.

Notwithstanding anything to the contrary set forth herein, the Compensation Committee of the Board of Directors of the Company shall have the discretion to cause or accelerate the vesting of any or all of the stock options granted pursuant to this award.

The Compensation Committee of the Board of Directors of the Company shall have the authority in its sole discretion to determine whether the criteria required for earning the points in the table set forth above were achieved.

Notwithstanding anything to the contrary in the enclosed Option Agreement, if your employment with the Company ends before []* as a result of your retirement, then stock options granted pursuant to this award will be eligible to vest on []*, subject to the terms of this award, except that the number of stock options that will vest on that date will be equal to the product of (i) the total number of stock options that would have vested on that date absent your retirement based on the total number of points that are earned during the Performance Measurement Period in accordance with the table set forth above, and (ii) a fraction, where (A) the numerator equals the total number of full calendar months during which you were employed by the Company from [] through the effective date of your retirement, and (B) the denominator equals thirty-six (36).

The Non-Qualified Stock Option expires on [10 years from the Grant Date].

You and the Company agree that these options are granted under and governed by the terms and conditions of the Company's Amended and Restated 2000 Long-Term Incentive Plan and the enclosed Option Agreement, both of which are attached and made a part of this document.

* This date will be the last day of the Performance Measurement Period.

REGENERON PHARMACEUTICALS, INC. OPTION AGREEMENT PURSUANT TO THE 2000 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT, made as of the date on the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee named on the *Notice of Grant of Stock Options* (the "Grantee");

WHEREAS, the Grantee is an employee of the Company and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the 2000 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's Common Stock (\$.001 par value) (the "Common Stock") as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

- 1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth here, the option to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share (the "Option") as shown on the *Notice of Grant of Stock Options*. [No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").]* [Notwithstanding the foregoing, the Option will not qualify as an Incentive Stock Option, among other events, (i) if the Grantee disposes of the Common Stock acquired pursuant to the Option at any time during the two year period following the date of this Agreement or the one year period following the date on which the Option is exercised, or (ii) if the Grantee is not employed by the Company or a subsidiary of the Company within the meaning of Section 424 of the Code (a "Subsidiary") at all times during the period beginning on the date of this Agreement and ending on the day three months before the date of exercise of the Option, or (iii) to the extent the aggregate fair market value (determined as of the time the Option is granted) of the stock subject to Incentive Stock Options which become exercisable for the first time in any calendar year exceeds \$100,000. To the extent that the Option does not qualify as an Incentive Stock Option, it shall constitute a separate Non-Qualified Stock Option.]**
- 2. Vesting; Exercise. (a) The Option is exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Section 7(c)(1) & (2), the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. [In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having a Fair Market Value (as measured on the date of exercise) equal to the Option exercise price.]* The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.

- (b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall be entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (collectively, the Company and all Subsidiaries shall be referred to herein as the "Employer" and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on the Full Vest Dates. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by the Employer and all unvested Options shall be forfeited at such time.
- (c) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of termination of the Grantee's employment with the Employer if the Grantee's employment with the Employer is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Grantee for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the Notice of Grant of Stock Options, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Internal Revenue Code Section 4999 (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the Employer and the Grantee or, in the event the parties cannot agree, in the following order (1) acceleration of vesting of any option where the exercise price exceeds the fair market value of the underlying shares at the time the acceleration would otherwise occur, (2) any lump sum severance based on a multiple of base salary or bonus, (3) any other cash amounts payable to the Grantee, (4) any benefits valued as parachute payments, and (5) acceleration of vesting of any equity not covered by (1) above.
- **3. Option Term.** (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as set forth in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement, or long-term disability, (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement, (C) one year after the termination if such termination is due to the Grantee's death or long-term disability, (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered) or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is by the Employer without Cause or by the Grantee for Good Reason.

- (b) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Company and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer, including without limitation, repeated refusal to follow the reasonable directions of the Employer, knowing violation of law in the course of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, and intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours (other than any such failure resulting from his or her incapacity due to physical or mental illness); (B) fraud or material dishonesty against the Employer, or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.
- (c) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the Notice of Grant of Stock Options (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by the Grantee within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Grantee to the Employer that Grantee intends to terminate his employment hereunder for one of the reasons set forth below; (A) (1) any material diminution in the Grantee's duties and responsibilities from that which exists immediately prior to a Change in Control (except in each case in connection with the termination of the Grantee's employment for Cause or as a result of the Grantee's death, or temporarily as a result of the Grantee's illness or other absence), or (2) the assignment to the Grantee of duties and responsibilities materially inconsistent with the position held by the Grantee; (B) any material breach by the Employer of any material provision of any written agreement with the Grantee or failure to timely pay any compensation obligation to the Grantee; (C) a reduction in the Grantee's annual base salary or target bonus opportunity (if any) from that which exists immediately prior to a Change in Control; or (D) if the Grantee is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Grantee's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the Notice of Grant of Stock Options that defines "good reason" (or words of like import), as defined under such agreement or plan.

- 4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.
- **5. Rights of a Stockholder.** The Grantee shall have no rights as a stockholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates for such shares. No adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor.
- 6. Compliance with Law and Regulations. This award and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates bear such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.
- 7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof. The Plan is incorporated herein by reference, and any capitalized term used but not defined herein shall have the same meaning as in the Plan. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.
- **8. Notices.** Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment or service, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.

9. No Obligation to Continue Employment. This	s Agreement does not guarantee that the Employer will employ the Grantee for any specifi	ied
time period, nor does it modify in any respect the Gr	rantee's employment or compensation.	

- * For Non-Qualified Stock Option Awards.
- ** For Incentive Stock Option Awards.

SEVENTH AMENDMENT TO LEASE

THIS SEVENTH AMENDMENT TO LEASE (this "Seventh Amendment") is entered into as of this 22nd day of December, 2010 ("Execution Date"), by and between BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("Landlord"), and REGENERON PHARMACEUTICALS, INC., a New York corporation ("Tenant").

RECITALS

- A. WHEREAS, Landlord and Tenant entered into that certain Lease dated as of December 21, 2006 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of October 24, 2007 (the "First Amendment"), that certain Second Amendment to Lease dated as of September 30, 2008 (the "Second Amendment"), that certain Third Amendment to Lease dated as of April 29, 2009 (the "Third Amendment"), that certain Fourth Amendment to Lease dated as of December 3, 2009 (the "Fourth Amendment"), that certain Fifth Amendment to Lease dated as of February 11, 2010 (the "Fifth Amendment"), and that certain Sixth Amendment to Lease dated as of June 4, 2010 (the "Sixth Amendment" and, collectively with the Original Lease and the First Amendment, Second Amendment, Third Amendment, Fourth Amendment, Fifth Amendment, and as the same may have been further amended, supplemented or otherwise modified from time to time, the "Lease"), whereby Tenant leases certain premises (the "Premises") from Landlord at 735, 745, 755, 765 and 777 Old Saw Mill River Road in Tarrytown, New York (collectively, the "Buildings");
- B. WHEREAS, pursuant to the Sixth Amendment, Tenant leased from Landlord and Landlord leased to Tenant certain space identified as the "765 Expansion Premises," consisting of two different phases; "Phase 1" and "Phase 2" (as such terms are defined in the Sixth Amendment), and as of the Execution Date hereof, Phase 2 has not yet been delivered to Tenant;
- C. WHEREAS, pursuant to the Fifteenth Amendment of the Old Lease, Tenant leased from Landlord and Landlord leased to Tenant certain space, containing approximately five thousand two hundred thirty-three (5,233) square feet of Rentable Area and located on the C-Level of the 777 Building as shown on Exhibit D attached hereto (the "Old C-Level Storage Space");
- D. WHEREAS, Tenant desires to lease from Landlord and Landlord desires to lease to Tenant the following space at the Project; (i) approximately five thousand one hundred twenty-one (5,121) square feet of Rentable Area on the mezzanine level of the 765 Building, as shown on Exhibit A attached hereto (the "765 Expansion Premises II"); (ii) approximately two thousand nine hundred two (2,902) square feet of Rentable Area (that is currently Common Area) located on the ground level of the 765 Building, as shown on Exhibit B attached hereto (the "Corridor Space"); and approximately five thousand ninety-five (5,095) square feet of Rentable Area on the C level of the 777 Building, as shown on Exhibit C attached hereto (the "New C-Level Storage Space");

Form dated 5/3/07

- E. WHEREAS, Tenant desires to terminate the Lease with respect to the Swing Premises (as defined in the Fourth Amendment and consisting of approximately sixteen thousand seven hundred twenty-five (16,725) square feet of Rentable Area that is located on the Lobby level of the 777 Building); and
 - F. WHEREAS, Landlord and Tenant desire to modify and amend the Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

- 1. <u>Definitions</u>. For purposes of this Seventh Amendment, capitalized terms shall have the meanings ascribed to them in the Lease unless otherwise defined herein. The Lease, as amended by this Seventh Amendment, is referred to herein as the "<u>Amended Lease</u>."
- 2. Additions to Premises. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord the following space on the following terms:
- a. the 765 Expansion Premises II, effective as of Landlord's delivery to Tenant of the same in the condition required under this Seventh Amendment including, without limitation, with the HVAC system located in the southeast corner of the 765 Expansion Premises being in good working condition and order. Landlord shall use commercially reasonable efforts to deliver the 765 Expansion Premises II on or before January 24, 2011. Landlord shall be responsible for demising the 765 Expansion Premises II at Landlord's sole cost and expense and shall deliver the 765 Expansion Premises II properly demised. The Term for the 765 Expansion Premises II shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, and (b) Tenant's termination option set forth in Section 7 below. Commencing as of the delivery of the 765 Expansion Premises II to Tenant and continuing through the Term, and subject to the provisions of Section 7 hereof, Tenant shall pay Landlord Basic Annual Rent for the 765 Expansion Premises II at an initial rate equal to Eighteen Dollars (\$18.00) per square foot of Rentable Area, per year, in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the 765 Expansion Premises II shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011. In addition to Basic Annual Rent, commencing as of the delivery date of the 765 Expansion Premises II, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the 765 Expansion Premises II. For the avoidance of doubt (i) HVAC for the 765 Expansion Premises II shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the 765 Expansion Premises II shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (as of the commencement date for the 765 Expansion Premises II);

b. the Corridor Space, effective as of Landlord's delivery to Tenant of the same in the condition required under this Seventh Amendment, and which shall be on the same date as the delivery of Phase 2 of the 765 Expansion Premises. Landlord shall use commercially reasonable efforts to deliver the Corridor Space on or before February 28, 2011. The Term for the Corridor Space shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, and (b) Tenant's termination option set forth in Section 7 below. Commencing as of the delivery of the Corridor Space to Tenant and continuing through the Term, and subject to the provisions of Section 7 hereof, Tenant shall pay Landlord Basic Annual Rent for the Corridor Space at an initial rate equal to Twenty-Four Dollars (\$24) per square foot of Rentable Area, per year, in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the Corridor Space shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011. In addition to Basic Annual Rent, commencing as of the delivery date of the Corridor Space, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the Corridor Space. For the avoidance of doubt (i) HVAC for the Corridor Space shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the Corridor Space shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (as of the commencement date for the Corridor Space); and

c. the New C-Level Storage Space, effective as of Landlord's delivery to Tenant of the same in the condition required under this Seventh Amendment. Landlord shall use commercially reasonable efforts to deliver the New C-Level Storage Space on or before January 24, 2011. Landlord shall be responsible for demising the New C-Level Storage Space at Landlord's sole cost and expense and shall deliver the New C-Level Storage Space properly demised. The Term for the New C-Level Storage Space shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, and (b) Tenant's termination option set forth in Section 7 below. Commencing as of the delivery of the New C-Level Storage Space to Tenant and continuing through the Term, and subject to the provisions of Section 7 hereof, Tenant shall pay Landlord Basic Annual Rent for the New C-Level Storage Space at an initial rate equal to Five Dollars (\$5) per square foot of Rentable Area, per year, in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the New C-Level Storage Space shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011. In addition to Basic Annual Rent, commencing as of the delivery date of the New C-Level Storage Space, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Por Rata Share of Operating Expenses with respect to the New C-Level Storage Space shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the New C-Level Storage Space shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (as of the commencement

- 3. Extension of Old C-Level Storage Space. The parties acknowledge that the term of the Old Lease expired on the Rent Commencement Date for the New Premises and that Tenant has been occupying the Old C-Level Storage Space on a month-to-month basis. Effective as of the date hereof, the Old C-Level Storage Space shall be included in the Amended Lease as a part of the Premises and the Old C-Level Storage Space shall be governed in all respects by the Amended Lease. The Term with respect to the Old C-Level Storage Space shall continue until the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in Article 44 of the Amended Lease, and (b) Tenant's termination option set forth in Section 7 below. Subject to the provisions of Section 7 hereof, Tenant shall pay Landlord Basic Annual Rent for the Old C-Level Storage Space at an initial rate equal to Five Dollars (\$5.00) per square foot of Rentable Area, per year, in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the Old C-Level Storage Space shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011. In addition to Basic Annual Rent, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the Old C-Level Storage Space shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the Old C-Level Storage Space shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with Exhibit O of the Amended Lease (in each case, as of the applicable commencement date for each such portion of the Premises).
- 4. <u>Tenant's Pro Rata Shares</u>. From and after the delivery to Tenant of the 765 Expansion Premises II, the Corridor Space and the New C-Level Storage Space in the condition required hereunder, the Premises shall thereafter be deemed to include the premises so delivered and Tenant's Pro Rata Shares of the Building, Existing Project, New Project and Entire Project shall be incrementally adjusted as set forth in <u>Exhibit E</u> attached hereto. As of each such delivery date, the defined terms in <u>Section 2.2</u> of the Lease shall be automatically amended to reflect the adjustments set forth in this Section 4. Rentable Area and Tenant's Pro Rata Shares are all subject to adjustment under the Amended Lease, including pursuant to <u>Section 9.2</u>.
- 5. <u>Tenant Improvements</u>. Landlord shall make available to Tenant a tenant improvement allowance equal to One Hundred Forty Nine Thousand Three Hundred Sixty Five Dollars (\$149,365) (based on Fifteen Dollars (\$15) per square foot of Rentable Area of the 765 Expansion Premises II and Twenty Five Dollars (\$25) per square foot of Rentable Area of the Corridor Space)) (the "765 Allowance"). The 765 Allowance shall be disbursed in the same manner as the Base TI Allowance under the applicable provisions of <u>Article 5</u> of the Lease, including, without limitation, the Disbursement Conditions, in order to finance improvements to the Premises in the 765 Building, consistent with the provisions of the Lease and the Permitted Use (such improvements, the "765 Improvements"). Tenant shall be responsible for performing and completing the 765 Improvements. Tenant shall pay Landlord a construction oversight fee of two and one-half percent (2.5%) of the total cost of the 765 Improvements, including, without limitation, the 765 Allowance to the extent disbursed to Tenant, which construction oversight fee may be paid out of the 765 Allowance.

- 6. <u>Parking</u>. The parties acknowledge that, in accordance with the Lease, Tenant shall be entitled to its pro rata share of unreserved parking spaces with respect to each portion of the Premises leased to Tenant hereunder.
- 7. Termination Options. Tenant shall be entitled to terminate the Lease with respect to (a) the entire 765 Expansion Premises II, effective as of January 1, 2017, (b) the Corridor Space, effective as of January 1, 2017 and (c) the New C-Level Storage Space and the Old C-Level Storage Space (the "C-Level Spaces"), on June 30, 2014, December 31, 2015 or December 31, 2016; provided that (x) Tenant provides Landlord with no less than nine (9) months' prior written notice and (y) concurrently with such notice, Tenant pays to Landlord an amount equal to (A) with respect to a termination of the 765 Expansion Premises II, Seventy-Three Thousand Nine Hundred Forty Seven and Fourteen and 24/100s Dollars (\$73,947.24) (based on Fourteen and 44/100s Dollars (\$14.44) per square foot of Rentable Area of the applicable portion of the Premises), (B) with respect to a termination the Corridor Space Fifty-Eight Thousand Forty and No/100s Dollars (\$58,040.00) (based on Twenty and No/100 Dollars (\$20.00) per square foot of Rentable Area of the applicable portion of the Premises) and (C) with respect to a termination of the C-Level Spaces, if terminated on June 30, 2014, Twenty Thousand Three Hundred Seventy-Eight Dollars (\$20,378), if terminated on December 31, 2015, Seventeen Thousand Two Hundred Fourteen and 63/100s Dollars (\$17,214.63) and if terminated on December 31, 2016, Fifteen Thousand One Hundred Eighty-Nine and 38/100s Dollars (\$15,189.38).

If Tenant timely exercises its option to terminate the Lease with respect to one or more of the portions of the Premises set forth in this Section, then Tenant shall surrender the applicable Premises to Landlord on the applicable surrender date in the condition required by the Amended Lease for surrendering Premises upon the expiration. Notwithstanding anything to the Amended Lease to the contrary, if Tenant terminates the 765 Expansion Premises II in accordance with this Section 7, Tenant shall demise the 765 Expansion Premises II at its expense, such demising to be performed in accordance with Applicable Laws; <u>provided</u>, that the foregoing requirements shall in no event be deemed to require Tenant to perform any work to conform the 765 Expansion Premises II with Applicable Laws (other than the demising thereof), except as may be expressly required by the Amended Lease. Time is of the essence with respect to the exercise of the termination options granted in this Section.

8. <u>Termination of Swing Premises</u>. Effective upon the surrender of the Swing Premises in the condition required by the Amended Lease, the Lease shall terminate and shall be of no further force and effect with respect to the Swing Premises, except for those terms that expressly survive the expiration or earlier termination of the Amended Lease. Notwithstanding the foregoing, Tenant shall not be responsible for payment of Base Rent or Tenant's Pro Rata Share of Operating Expenses with respect to the Swing Premises effective as of the mutual execution and delivery of this Seventh Amendment; provided, however, Tenant shall surrender the Swing Premises in the required condition on or before the date that is sixty (60) days after the delivery of the New C-Level Space. If Tenant shall fail to timely surrender the Swing Premises in the requisite condition, Tenant shall become a tenant at sufferance of only the entire Swing Premises subject to the terms and conditions of the Amended Lease, except that the monthly rent beginning the first day after the expiration of such sixty (60) day period shall be recalculated to equal one hundred fifty percent (150%) of the Rent rates in effect immediately prior to the Execution Date hereof with respect of the Swing Premises.

- 9. <u>Lease Extension Options</u>. From and after the Execution Date, the first paragraph of <u>Article 44</u> of the Lease is hereby deleted and replaced with the following:
 - 44. Option to Extend Term. Tenant shall have three (3) options (each, an "Option") to extend the Term of this Lease (and, in each case, the Term Expiration Date) by five (5) years, in each case on the same terms and conditions as this Lease, except as provided below. If Tenant desires to exercise any Option, Tenant must do so by giving Landlord written notice of such exercise at least one (1) year before the Term would otherwise expire. Tenant may exercise its Option to extend the Term only as to any one or more of the following: (a) the entire Retained Premises plus the Corridor Space, (b) the entire New Whole Building Premises, (c) the entire New Multiple Tenant Building Premises, (d) the Modified Additional Premises, (e) the Swap Premises, (f) each full floor of the 755 Premises, (h) the 765 Expansion Premises, (i) the 765 Expansion Premises II, (j) C-Level Storage Spaces. If Tenant fails to exercise an Option with respect to less than all of the Premises and the time to do so has lapsed (or if a Retained Premises Early Termination or a termination pursuant to a Swap Premises Termination Option has occurred), then Tenant shall no longer have an Option with respect to those portions of the Premises for which it failed to exercise an Option. Tenant's Options for the remaining Premises shall remain in full force and effect.

- 10. Condition of Premises. Except as otherwise provided herein (including without limitation Section 2 hereof), Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the 765 Expansion Premises II, the Corridor Space, the Old C-Level Storage Space, or the New C-Level Storage Space with respect to the suitability of the same for the conduct of Tenant's business. Tenant acknowledges that (a) it is generally familiar with the condition of the 765 Expansion Premises II, the Corridor Space, the Old C-Level Storage Space, and the New C-Level Storage Space, notwithstanding anything contained in the Amended Lease to the contrary, agrees to take the same in its condition "as is" as of the applicable delivery date, and with respect to the Old C-Level Storage Space, as of the Execution Date hereof. Tenant's taking of possession of the 765 Expansion Premises II, the Corridor Space and the new C-Level Storage Space shall, except as otherwise agreed to in writing by Landlord and Tenant, conclusively establish that the same were at such time in good, sanitary and satisfactory condition and repair. Notwithstanding the foregoing, Landlord represents and warrants that, with the exception of the HVAC system located in the southeast corner of the 765 Expansion Premises II (which Landlord acknowledges is currently not in good working condition), the Building Systems in the 765 Expansion Premises II, the Corridor Space, the Old C-Level Storage Space, and the New C-Level Storage Space are, and will be (including the HVAC system located in the southeast corner of the 765 Expansion Premises II), in good working condition and that the same are adequately serviced by Utilities and other base building services.
- 11. <u>Hazardous Materials</u>. From and after the Execution Date, the second to last sentence of <u>Section 40.1</u> of the Lease shall be deleted and replaced in its entirety with the following:

Landlord acknowledges that Tenant shall not be responsible for environmental conditions or contamination now or hereafter existing on, under or in the Entire Project, in the New Whole Building, in the New Multiple Tenant Building, or in the Premises (as the Premises may be modified from time to time) caused by Landlord or tenants other than Tenant or by third parties in the Entire Project prior to the Execution Date or after such date, or for environmental conditions or contamination coming from off-site so long as Tenant, Tenant's Affiliates, its permitted sublessees or its agents did not cause or contribute to such environmental conditions or contamination.

12. <u>Broker</u>. Each of Landlord and Tenant represents and warrants to the other that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Seventh Amendment, other than Studley ("<u>Broker</u>") on behalf of Tenant, and each agrees to indemnify, defend and hold the other harmless from any and all cost or liability for compensation claimed by any such broker or agent, other than Broker, employed or engaged by it or claiming to have been employed or engaged by it. Broker is entitled to a leasing commission in connection with this Seventh Amendment, and Landlord shall pay such commission to Broker pursuant to a separate agreement between Landlord and Broker.

- 13. No Default; Authority; Non-Contravention. Each of Landlord and Tenant represents, warrants and covenants that, to the best of its respective knowledge, neither Landlord nor Tenant is in default of any of its respective obligations under the Lease and no event has occurred that, with the passage of time or the giving of notice (or both), would constitute a default by either Landlord or Tenant thereunder. Each of Landlord and Tenant further represents, warrants and covenants that it has the full power and authority to execute, deliver and comply with the terms of this Seventh Amendment, and doing so will not conflict with or result in the violation of or default under any provision of any agreement or other instrument to which it is a party.
- 14. Effect of Amendment. Except as modified by this Seventh Amendment, the Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. The covenants, agreements, terms, provisions and conditions contained in this Seventh Amendment shall bind and inure to the benefit of the parties hereto and their respective successors and, except as otherwise provided in the Lease, their respective assigns. In the event of any conflict between the terms contained in this Seventh Amendment and the Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties. From and after the date hereof, the term "Lease" as used in the Lease shall mean the Lease, as modified by this Seventh Amendment.
- 15. <u>Miscellaneous</u>. This Seventh Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Seventh Amendment are included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference.
- 16. <u>Counterparts</u>. This Seventh Amendment may be executed in one or more counterparts that, when taken together, shall constitute one original.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Landlord and Tenant have hereunto set their hands as of the date and year first above written, and acknowledge that they possess the requisite authority to enter into this transaction and to execute this Seventh Amendment to Lease.

LANDLORD:

BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company

By: /s/ Kevin M. Simonsen Name: Kevin M. Simonsen Title: VP, Real Estate Counsel

TENANT:

REGENERON PHARMACEUTICALS, INC., a New York corporation

By: /s/ Murray A; Goldberg Name: Murray A. Goldberg

Title: Senior Vice President, Finance & Administration and Chief Financial Officer

EXHIBIT A

765 EXPANSION PREMISES II

[IMAGE]

EXHIBIT B

CORRIDOR SPACE

[IMAGE]

EXHIBIT C

NEW C-LEVEL STORAGE SPACE

<u>[IN</u>	<u>(AGE)</u>

EXHIBIT D

OLD C-LEVEL STORAGE SPACE

[IMAGE]

EXHIBIT E

Definition or	Means the	Square	Tenant's	Tenant's	Tenant's
Provision	Following:	Feet of	Pro Rata	Pro Rata	Pro Rata
		Rentable	Share of	Share of	Share of the
		Area	Applicable	Existing	Entire
			Building	Project	Project
				(827,790)	(1,188,310)
Portion of added	765 Expansion	5,121	2.46 %	.62 %	.43%
"Premises" and	Premises II				
corresponding	Corridor Space	2,902	1.40 %	.35 %	.24%
Rentable Area	Old C-Level Storage	5,233	1.43 %	.63 %	.44%
	Space				
	New C-Level	5,095	1.39 %	.62 %	.43%
	Storage Space				

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-61132, 333-97375, 333-119257, 333-151941, and 333-169569) and on Form S-3 (No. 333-169786) of Regeneron Pharmaceuticals, Inc., of our report dated February 17, 2011 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

New York, New York February 17, 2011

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

- 1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make
 the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered
 by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting: and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 17, 2011 By: /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Murray A. Goldberg, certify that:
- 1. I have reviewed this annual report on Form 10-K of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting: and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 17, 2011 By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-K for the year ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
February 17, 2011

/s/ Murray A. Goldberg
Murray A. Goldberg
Chief Financial Officer
February 17, 2011

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 5/8/2006

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)		
Ø	QUARTERLY REPORT PURSU	ANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the quarterly period ended March 31,	2006
		OR
	TRANSITION REPORT PURSU	ANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the transition period from	to
		Commission File Number 0-19034
		PHARMACEUTICALS, INC. t name of registrant as specified in its charter)
	New York	13-3444607
	(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
	777 Old Saw Mill River Road Tarrytown, New York	10591-6707
	(Address of principal executive offices)	(Zip Code)
	_	(914) 347-7000
	(Regist	trant's telephone number, including area code)
		reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the rant was required to file such reports), and (2) has been subject to such filing requirements for the
		Yes ☑ No □
	in Rule 12b-2 of the Exchange Act.	ated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large Non-accelerated filer □
0		ny (as defined in Rule 12b-2 of the Exchange Act). □
Indicate the nun	ber of shares outstanding of each of the issue	er's classes of common stock as of April 30, 2006:
	Class of Common Stock	Number of Shares
	Class A Stock, \$0.001 par value Common Stock, \$0.001 par value	2,307,561 54,643,326

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PART I. FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS AT MARCH 31, 2006 AND DECEMBER 31, 2005 (Unaudited)

(In thousands, except share data)

	March 31, 2006	December 31, 2005
ASSETS		
Current assets	0 100 000	ም ትርዝ ድረር
Cash and cash equivalents Marketable securities	\$ 182,332 120,061	\$ 184,508 114,037
Accounts receivable	11,010	36,521
Prepaid expenses and other current assets	2,990	3,422
Inventory	3,254	2,904
Total current assets	319,647	341,392
Marketable securities	21,836	18,109
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization Other assets	57,421	60,535
Total assets	3,185	3,465
Total assets	<u>\$ 402,089</u>	<u>\$ 423,501</u>
LIABILITIES and STOCKHOLDERS' EQUITY Current liabilities		
Accounts payable and accrued expenses	\$ 18,383	\$ 23,337
Deferred revenue, current portion	15,284	17,020
Total current liabilities	33,667	40,357
Deferred revenue	66,099	69,142
Notes payable	200,000	200,000
Total liabilities	299,766	309,499
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized;	٥	4
shares issued and outstanding - 2.307,561 in 2006 and 2.347,073 in 2005 Common Stock, \$.001 par value; 160,000,000 shares authorized;	2	2
shares issued and outstanding - 54.614,557 in 2006 and 54.092,268 in 2005	55	54
Additional paid-in capital	708,297	700,011
Unearned compensation	// T	(315)
Accumulated deficit Accumulated other comprehensive loss	(605,660) (371)	(585,280) (470)
Total stockholders' equity	102,323	114,002
Total liabilities and stockholders' equity	\$ 402,089	\$ 423,501
Configuration and a config		······································

The accompanying notes are an integral part of the financial statements.

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REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share data)

	Three months o	ended March 31,
Revenues Contract research and development Contract manufacturing	\$ 14,587 3,632 18,219	\$ 13,502 2,707 16,209
Expenses Research and development Contract manufacturing General and administrative	32,084 1,852 5,946 39,882	35,912 2,491 6,146 44,549
Loss from operations	(21,663)	(28,340)
Other income (expense) Other contract income Investment income Interest expense	3,481 (3,011) 470	25,000 2,230 (3,013) 24,217
Net loss before cumulative effect of a change in accounting principle Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R") Net loss	(21,193) 813 (\$ 20,380)	(4,123) <u>(\$ 4,123</u>)
Net loss per share amounts, basic and diluted: Net loss before cumulative effect of a change in accounting principle Cumulative effect of adopting SFAS 123R Net loss	(\$ 0.37)	(\$ 0.07) (\$ 0.07)
Weighted average shares outstanding, basic and diluted	56,727	55,815
The accompanying notes are an integral part of the financial statements.		

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) For the three months ended March 31, 2006

(In thousands)

								Accumulated		
	Class A	Stock	Common	Stock	Additional Paid-in	Unearned	Accumulated	Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital Capital	Compensation	Deficit	Loss	Equity	Loss
Balance, December										
2005	2,347	\$ 2	54,092	\$54	\$700,011	\$(315)	\$(585,280)	\$(470)	\$114,002	
Issuance of										
Common Stock in										
connection										
with exercise of										
stock										
options,										
net of shares										
tendered			364	1	3,415				3,416	
Issuance of Common										
Common Stock in										
connection										
with Company										
401(k)										
Savings										
Plan contributio			121		1,884				1,884	
Conversion										
of Class A Stock to										
Common										
Stock	(40)		40							***************************************
Forfeitures of restricted Common Stock under Long-Term Incentive Plan			(2.)							
Stock-based										
compensati expense	on				4,115				4,115	
Adjustment									,	
to reduce unearned										
compensati										
upon adoption										
of SFAS										
123R					(315)	315				
Cumulative effect of										
adopting										
SFAS 123R				****************	(813)		22.282		(813)	B/20 200
Net loss Change in net							(20,380)		(20,380)	\$(20,380)
unrealized										
loss on marketable										
securities								99	99	99
Balance,										
March 31, 2006	2,307	\$2	54,615	\$55	\$708,297		\$(605,660)	\$(371)	\$102,323	\$(20,281)



REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Three months	ended March 31, 2005
Cash flows from operating activities Net loss	\$ (20,380)	<u>\$ (4,123)</u>
Adjustments to reconcile net loss to net cash provided by operating activities Depreciation and amortization	3,798	3,858
Non-cash compensation expense Cumulative effect of a change in accounting principle	4,079 (813)	5,881
Changes in assets and liabilities Decrease in accounts receivable	25,511	32,731
Decrease (increase) in prepaid expenses and other assets (Increase) decrease in inventory	1,023 (92)	(40) 527
Decrease in deferred revenue Decrease in accounts payable, accrued expenses, and other liabilities	(4,779) (3,069)	(4,653) (1,049)
Total adjustments Net cash provided by operating activities	<u>25,658</u> <u>5,278</u>	37,255 33,132
Cash flows from investing activities Purchases of marketable securities	(74,541)	(35,601)
Sales or maturities of marketable securities Capital expenditures	(74,341) 64,317 (646)	55,385 (1,359)
Net cash (used in) provided by investing activities	(10,870)	18,425
Cash flows from financing activities Net proceeds from the issuance of stock	3.416	1.030
Net cash provided by financing activities	3,416	1,030
Net (decrease) increase in cash and cash equivalents	(2,176)	52,587
Cash and cash equivalents at beginning of period	184,508	95,229
Cash and cash equivalents at end of period	<u>§ 182,332</u>	<u>\$ 147,816</u>

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2005 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. For the three months ended March 31, 2006 and 2005, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended March	
	2006	2005
Net loss (Numerator)	(\$ 20,380)	(\$ 4,123)
Weighted-average shares, in thousands (Denominator)	56,727	55,815
Basic and diluted net loss per share	(\$ 0.36)	(\$ 0.07)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the March 31, 2006 and 2005 diluted per share amounts because their effect would have been antidilutive, include the following:

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

_	Three months ended March 31,	
	2006	2005
Stock Options:		
	14,401	13,476
Weighted average number, in thousands Weighted average exercise price	\$ 14.27	\$ 14.73
Restricted Stock: Weighted average number, in thousands	54	213
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25

3. Stock-based Employee Compensation

Adoption of Statement of Financial Accounting Standards Nos. 123 and 123R

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, Accounting for Stock-Based Compensation, using the modified prospective method as described in SFAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, Share-Based Payment, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by \$813 and is

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

included in the Company's operating results for the first quarter of 2006 as a cumulative-effect adjustment of a change in accounting principle.

Long-Term Incentive Plans

The Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan"), as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, certain shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals, Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. The 1990 Incentive Plan, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. Under the provisions of the 1990 Incentive Plan, there will be no future awards from the plan. The Company has issued Incentive Stock Options ("ISOs") and Nonqualified Stock Options, and shares of Restricted Stock from the 1990 and 2000 Incentive Plans. The terms of the awards are determined by the Compensation Committee of the board of directors; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the ISO is granted and no ISO is exercisable more than ten years after the date of grant. As of March 31, 2006, there were 6,490,581 shares available for future grants under the 2000 Incentive Plan.

a. Stock Options

At March 31, 2006, there were 14,199,554 stock options outstanding with exercise prices ranging from \$4.83 to \$51.56. Options granted to employees generally vest annually on a pro rata basis over a four to five year period beginning one year from the date of grant. Certain performance-based options granted to the Company's executive vice president and senior vice presidents vest if both (i) the Company's products have achieved defined sales targets and (ii) the option recipient has remained employed by the Company for at least three years from the date of grant. Options granted to members of the Company's board of directors vest annually on a pro rata basis over three years beginning one year from the date of grant. A summary of the Company's stock option activity for the three months ended March 31, 2006 is presented in the following table:

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

		Weighted		
		Average	Weighted	
		Remaining	Average	Intrinsic
	Number	Contractual Contractual	Exercise	Value (in
	Outstanding	Life	Price	thousands)
Stock options outstanding at January 1, 2006	14,719,492		\$ 14.23	
Stock options granted	138,700		\$ 15.99	
Stock options exercised	(393,526)		\$ 9.93	
Stock options forfeited	(152,016)		\$ 10.60	
Stock options expired	(113,096)		\$ 26.52	
Stock options outstanding at March 31, 2006	14,199,554	6.8	\$ 14.31	\$ 67,940
Stock options vested and exercisable	7,226,662	5,3	\$ 17.68	\$ 27,579

The total intrinsic value of stock options exercised during the first quarter of 2006 and 2005 was \$2,592 and \$200, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

For the three months ended March 31, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") totaled \$3,931 and \$5,541, respectively. Stock Option Expense recognized in operating expenses for the three months ended March 31, 2006 and 2005 was \$3,895 and \$5,379, respectively, and \$36 and \$162, respectively, was capitalized into inventory. As of March 31, 2006, there was \$27,331 of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.8 years. In addition, there are 723,092 options which are unvested as of March 31, 2006 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2,688 and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Fair Value Assumptions:

The fair value of each option granted during the three months ended March 31, 2006 and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and board directors are expected to hold their options prior to exercise

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

(expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The weighted-average fair value of the options granted during the three months ended March 31, 2006 and 2005 was \$11.28 and \$5.86 per option, respectively. The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants.

	Three months	ended March 31,
	2006	2005
Expected volatility	69 %	75 %
Expected lives from grant date	7.7 years	6.2 years
Expected dividend yield	0 %	0 %
Did for interest of	4 (7 0/	2.06.07

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the three months ended March 31, 2006 is presented in the following table:

		weign	nea
	Number	Average	Grant
	in Shares	Date Fair	Value
Restricted stock outstanding as of January 1, 2006	95,188	5	11.16
Restricted stock released	(45,040)	\$	13.00
Restricted stock forfeited	(1,703)	5	9.74
Restricted stock outstanding as of March 31, 2006	48,445	\$	9.49

In accordance with generally accepted accounting principles, the Company recorded unearned compensation in Stockholders' Equity related to these Restricted Stock awards. The amount was based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restrictions lapse, which is approximately two years for grants issued in 2003 and 18 months for grants issued in 2004. No Restricted Stock awards were granted in 2005 or during the three months ended March 31, 2006. For the three months ended March 31, 2006 and 2005, the Company recognized compensation expense related to Restricted Stock awards of \$184 and \$502, respectively. Unrecognized compensation cost at March

Waighted

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

31, 2006 related to outstanding Restricted Stock awards totaled \$115, which the Company expects to recognize over a weighted-average period of approximately 2.5 months.

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2006 and December 31, 2005 are \$233 and \$234, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2005 and December 31, 2004 are \$827 and \$550, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2005 and 2004 are \$1,884 and \$632, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2006 and 2005, the Company contributed 120,960 and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at March 31, 2006 and December 31, 2005 are \$656 and \$1,228, respectively, of accrued interest income. Included in marketable securities at March 31, 2005 and December 31, 2004 are \$1,760 and \$2,601, respectively, of accrued interest income.

5. Severance Costs

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the expected completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005, with the remainder planned for 2006 following the completion of the Company's contract manufacturing activities for Merck

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and are being expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. The Company estimates that total costs associated with the 2005 and planned 2006 workforce reductions will approximate \$2.6 million, including \$0.2 million of non-cash expenses in 2005.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

Severance costs associated with the workforce reduction plan that were charged to expense in the first quarter of 2006 consist of the following:

	Three months ended			
	Accrued	March 3	31, 2006	Accrued
	liability at	Costs	Costs paid	liability at
	December 31,	charged to	or settled in	March 31,
	2005	expense	2006	2006
Employee severance, payroll taxes, and benefits	\$ 907	\$ 159	\$ 641	\$ 425
Other severance costs	176	14	190	
Total	<u>\$ 1,083</u>	<u>\$ 173</u>	<u>\$ 831</u>	<u>\$ 425</u>

These severance costs are included in the Company's Statement of Operations for the three months ended March 31, 2006 as follows:

	Research &	General &
	development	administrative
Employee severance, payroll taxes, and benefits	\$ 161	(\$ 2)
Other severance costs	14	
Total	9 110	(\$ 2)

For segment reporting purposes (see Note 10), all severance-related expenses are included in the Research & Development segment.

6. Accounts Receivable

Accounts receivable as of March 31, 2006 and December 31, 2005 consist of the following:

	March 31,	December 31,
	2006	2005
Receivable from the sanofi-aventis Group	\$ 10,972	\$ 36,412
Receivable from Merck & Co., Inc.	38	27
Other		<u>82</u>
	\$ 11,010	\$ 36,521

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

7. Inventories

Inventories consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which will expire in October 2006.

Inventories as of March 31, 2006 and December 31, 2005 consist of the following:

	March 31,	December 31,
	2006	2005
Raw materials	\$ 279	\$ 278
Work-in-process	785	1,423
Finished products	2,190	1,203
	\$ 3.254	\$ 2.904

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2006 and December 31, 2005 consist of the following:

	March 31,	December 31,
	2006	2005
Accounts payable	\$ 3,758	\$ 4,203
Accrued payroll and related costs	3,638	10,713
Accrued clinical trial expense	3,723	3,081
Accrued expenses, other	2,222	3,048
Interest payable on convertible notes	5,042	2,292
	\$ 18,383	\$ 23,337

9. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three months ended March 31, 2006 and 2005, the components of comprehensive loss are:

	Three months ended March 31,		
	2006	2005	
Net loss	(\$ 20,380)	(\$ 4,123)	
Change in net unrealized gain (loss) on marketable securities	99	(341)	
Total comprehensive loss	(\$ 20,281)	<u>(\$ 4,464</u>)	

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

10. Segment Information

The Company's operations are managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and (ii) the supply of research materials based on Regeneron-developed proprietary technology.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. The Company produces an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which will expire in October 2006.

The table below presents information about reported segments for the three months ended March 31, 2006 and 2005.

	Three months ended March 31, 2006			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 14,587	\$ 3,632		\$ 18,219
Depreciation and amortization	3,537	(1)	\$ 261	3,798
Non-cash compensation expense	5.984	95	(813)(2)	3,266
Interest expense	_	_	3,011	3,011
Net (loss) income	(23,443)	1,780	1,283 (3)	(20,380)
Capital expenditures	645	_	_	645
Total assets	67,159	4,526	330,404 (4)	402,089

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended March 31, 2005			
	Research &	Research & Contract I		
	Development	Manufacturing	Items	Total
Revenues	\$ 13,502	\$ 2,707		\$ 16,209
Depreciation and amortization	3,597	(1)	\$ 261	3,858
Non-cash compensation expense	5,881		<u>—</u>	5,881
Other contract income	25,000	_	_	25,000
Interest expense	 -		3,013	3,013
Net (loss) income	(3,556)	216	(783)(3)	(4,123)
Capital expenditures	1,637			1,637
Total assets	77,527	4,986	387,779 (4)	470,292

⁽¹⁾ Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

⁽²⁾ Represents the cumulative effect of adopting SFAS 123R (see Note 3).

⁽³⁾ Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the three months ended March 31, 2006, also includes the cumulative effect of adopting SFAS 123R.

⁽⁴⁾ Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: VEGF Trap in oncology, VEGF Trap eye formulation (VEGF Trap-Eye) in eye diseases using intraocular delivery, and IL-1 Trap in various inflammatory indications. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing Traps and Human Monoclonal Antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse pipeline of product candidates that we believe has the potential to address a variety of serious medical conditions. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our Traps, Human Monoclonal Antibody (VelocImmuneTM), and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Clinical Programs:

Below is a summary of the clinical status of our clinical candidates as of March 31, 2006:

1. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PIGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage. The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis, as described below. In September 2005, we and sanofi-aventis announced plans to expand our joint development program.

In the first quarter of 2006, we and sanofi-aventis initiated our phase 2 single-agent program for the VEGF Trap in cancer. Patient enrollment is underway in non-small cell adenocarcinoma and two additional safety/efficacy studies in advanced ovarian cancer and symptomatic malignant ascites are planned to begin shortly. In 2004, the United States Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for the treatment of symptomatic malignant ascites.

The companies also plan to conduct three efficacy/safety trials using the VEGF Trap in combination with standard chemotherapy regimens, the first of which is planned to begin in the second half of 2006, assuming successful completion of initial safety and tolerability studies. Currently there are five safety and tolerability studies underway for the VEGF Trap in combination with standard chemotherapy regimens in a variety of cancer types. The companies are also finalizing plans with the National Cancer Institute (NCI) Cancer Therapeutics Evaluation Program to commence at least ten additional cancer trials in 2006.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to support the tumor. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has been shown to provide therapeutic benefits. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (now a member of the sanofi-aventis Group) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the

exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to \$400.0 million in milestone payments upon receipt of specified marketing approvals, including up to \$360.0 million in milestone payments related to up to eight VEGF Trap oncology and other indications in the United States or the European Union.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obliged to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. (See "The sanofi-aventis Group Agreement" below.)

2. VEGF Trap — Eye Diseases

We are developing the VEGF Trap-Eye for the treatment of certain eye diseases. This product candidate has been purified and formulated in concentrations suitable for direct injection into the eye. We retain the exclusive right to develop and commercialize the VEGF Trap-Eye for the treatment of eye diseases utilizing local (intravitreal) delivery to the eye. We recently announced that we have initiated a phase 2 trial of the VEGF Trap-Eye delivered intravitreally in patients with the neovascular form of age-related macular degeneration (wet AMD).

At the May 2006 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO), we reported positive preliminary results from a phase 1 trial of the VEGF Trap-Eye in patients with the neovascular form of wet AMD. A total of 21 patients received a single dose of VEGF Trap-Eye at doses ranging of 0.05, 0.15, 0.5, 1, 2, and 4 milligrams (mg) intravitreally (direct injection into the eye) and were evaluated for six weeks to measure the durability of effects and provide guidance for dosing regimens to be used in future trials. All dose levels were generally well tolerated, and a maximum tolerated dose was not reached in the study. Patients receiving the VEGF Trap-Eye demonstrated large, rapid, and sustained (at least six weeks) reductions in retinal thickness, a clinical measure of disease activity in wet AMD as measured by ocular coherence tomography (OCT). As measured by the OCT reading center (posterior pole OCT scans), the median excess retinal thickness was 194 microns at baseline and 60 microns at 6 weeks. As measured by the computerized Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline and 27 microns at 6 weeks.

Of the 20 patients evaluable for efficacy, 95 percent had stabilization or improvement in visual acuity, defined as \leq 15 letter loss on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. Patients were also evaluated for best-corrected visual acuity (BCVA), the

best acuity a person can achieve with glasses. BCVA for all patients in the study increased by a mean of 4.8 letters at 6 weeks. In the two highest dose groups (2 mg and 4 mg), the mean improvement in BCVA was 13.5 letters, with three of six patients showing an improvement in BCVA of 15 or more letters.

Based on the preliminary phase 1 results in wet AMD, we initiated a 150 patient, 12 week, phase 2 trial of the VEGF Trap in wet AMD. The trial is designed to evaluate treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens, as well as safety and efficacy. We plan to conduct an initial evaluation of phase 2 study results after all patients have completed 12 weeks of treatment, which is expected to be prior to the end of 2006. Subject to a review of the initial phase 2 study results, we plan to initiate a phase 3 trial of the VEGF Trap in wet AMD in early 2007.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and Diabetic Retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) has been approved to treat patients with this condition.

Wet AMD and Diabetic Retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. It is estimated that in the U.S. 6% of individuals aged 65-74 and 20% of those older than 75 are affected with wet AMD. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as Diabetic Macular Edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

3. IL-1 Trap — Inflammatory Diseases

The IL-1 Trap is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors.

We are evaluating the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called CIAS1-Associated Periodic Syndrome (CAPS) and diseases associated with inflammation. These include Systemic Juvenile Idiopathic Arthritis (SJIA) and certain inflammatory vascular diseases.

In April 2006, we completed enrollment of the pivotal study of the IL-1 Trap in patients with CAPS. The six-month, placebo-controlled efficacy phase is expected to be completed by the end of 2006. This phase will be followed by a six-month open-label extension phase. In December 2004, the FDA granted orphan drug status to the IL-1 Trap for the treatment of CAPS. In April 2005, the FDA also granted orphan drug status to the IL-1 Trap for the treatment of SJIA.

An IL-1 receptor antagonist, Kineret® (Amgen Inc.), has been approved by the FDA for the treatment of rheumatoid arthritis. It has been publicly reported that in small trials Kineret

appears to reduce the symptoms in CAPS patients and SJIA patients, which supports the role of IL-1 in these diseases. CAPS includes rare genetic disorders, such as Familial Cold Auto-Inflammatory Syndrome (FCAS), Muckle Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disorder (NOMID), which affect a small group of people. Patients with these disorders develop fever, joint aches, headaches, and rashes. In certain indications, these symptoms can be extremely serious. There are no currently approved therapies for CAPS. SJIA is a severe inflammatory disorder which may be debilitating or fatal. It is estimated that there are between 5,000 and 10,000 children with SJIA in the United States.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our IL-1 Trap currently in clinical development.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2006, we had a cumulative loss of \$605.7 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and IL-1 Trap; advance new product candidates into clinical development from our existing research programs; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be

substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events and plans in 2006 are as follows:

Product candidate	2006 Events	2006 Plans
VEGF Trap — Oncology	Initiated phase 2 study of the VEGF Trap as a single agent in non-small cell lung adenocarcinoma	 Initiate two efficacy/safety studies of the VEGF Trap as a single agent in advanced ovarian cancer and symptomatic malignant ascites
	 Initiated two safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens 	Initiate an efficacy/safety study of the VEGF Trap in combination with a standard chemotherapy regimen in cancer patients
		 Design two additional efficacy/safety trials of the VEGF Trap in combination with standard chemotherapy regimens in different cancer indications
		 Finalize plans with the NCI to sponsor at least ten exploratory efficacy/safety studies evaluating the VEGF Trap in a variety of cancer types
VEGF Trap-Eye	 Reported positive preliminary results from phase 1 trial in wet AMD utilizing intravitreal injections in 21 patients up to a top dose of 4 mg Initiated a phase 2 trial in wet AMD utilizing intravitreal injections 	Report preliminary results of a phase 2 trial in wet AMD utilizing intravitreal injections
IL-1 Trap	Completed enrollment of pivotal trial of IL-1 Trap in CAPS	 Complete efficacy portion of pivotal study in CAPS Evaluate the IL-1 Trap for SJIA

Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, Accounting for Stock-Based Compensation, using the modified prospective method as described in SFAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated

expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, Share-Based Payment, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by \$0.8 million and is included in our operating results for the first quarter of 2006 as a cumulative-effect adjustment of a change in accounting principle.

For the three months ended March 31, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") totaled \$3.9 million and \$5.6 million, respectively, of which \$3.9 million and \$5.4 million was recognized in operating expenses. Stock Option Expense of \$0.2 million was capitalized into inventory in the first quarter of 2005. As of March 31, 2006, there was \$27.3 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.8 years. In addition, there are 723,092 options which are unvested as of March 31, 2006 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2.7 million and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average

values of the assumptions we used in computing the fair value of option grants during the three months ended March 31, 2006 and 2005:

	Three months ended March 31,		
	2006	2005	
Expected volatility	69 %	75 %	
Expected lives from grant date	7.7 years	6.2 years	
Expected dividend yield	0 %	0 %	
Risk-free interest rate	4.67 %	3,96 %	

Changes in any of these estimates may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

Results of Operations

Three Months Ended March 31, 2006 and 2005

Net Income (Loss):

Regeneron reported a net loss of \$20.4 million, or \$0.36 per share (basic and diluted), for the first quarter of 2006 compared to a net loss of \$4.1 million, or \$0.07 per share (basic and diluted), for the first quarter of 2005. Results for the first quarter of 2005 included a \$25.0 million one-time, non-recurring payment from sanofiaventis, which was recognized as other contract income, in connection with the January 2005 amendment to our collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye.

Revenues:

Revenues for the three months ended March 31, 2006 and 2005 consist of the following:

			Increase
(In millions)	2006	2005	(Decrease)
Contract research & development revenue			
The sanofi-aventis Group	\$ 13.9	\$ 9.8	\$ 4.1
The Procter & Gamble Company		3,1	(3.1)
Other	0.7	0.6	0.1
Total contract research & development revenue	14.6	13.5	1.1
Contract manufacturing revenue	3.6	2.7	0.9
Total revenue	\$ 18.2	<u>\$ 16.2</u>	\$ 2.0

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to \$105.0 million of non-refundable, upfront payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the

period over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104).

Sanofi-aventis Contract Research & Development Revenue

	Three mont	ths ended March 31,
(In millions)	2006	2005
Regeneron expense reimbursement	\$ 10.8	\$ 7.4
Recognition of deferred revenue related to up-front payments	3.1	2.4
Total	<u>\$ 13.9</u>	<u>\$ 9.8</u>

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses increased in the first quarter of 2006 from the same period in 2005, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in the first quarter of 2006 from the same period in 2005, due to our January 2006 receipt of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan. As of March 31, 2006, \$78.3 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract research and development revenue earned from Procter & Gamble decreased in the first quarter of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

Contract manufacturing revenue relates to our long-term agreement with Merck, which expires in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Contract manufacturing revenue increased in the first quarter of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Revenue and the related manufacturing expense are recognized as product is shipped, after acceptance by Merck. Included in contract manufacturing revenue in both the first three months of 2006 and 2005 were \$0.4 million and \$0.3 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. As of March 31, 2006, the remaining deferred balance of Merck's capital improvement reimbursements totaled \$0.9 million, which will be recognized as revenue as product is shipped based upon Merck's order quantities through October 2006.

Expenses:

Total operating expenses decreased to \$39.9 million in the first quarter of 2006 from \$44.5 million in the same period of 2005, due, in part, to our lower headcount. Our average headcount declined to 587 in the first quarter of 2006 from 734 in the same period of 2005 primarily as a result of workforce reductions made in the fourth quarter of 2005. (See "Severance Costs" below.)

Operating expenses in the first quarter of 2006 and 2005 include a total of \$3.9 million and \$5.4 million of Stock Option Expense, respectively, as detailed below:

(In millions)	For the three months ended March 31, 2006			
Expenses	Expenses before inclusion of Stock Option Expense	Stock Option <u>Expense</u>	Expenses as Reported	
Research and development Contract manufacturing	\$ 30.1 1.8	\$ 2.0 0.1	\$ 32.1 1.9	
General and administrative	4.1	1.8	5.9	
Total operating expenses	\$ 36.0	\$ 3.9	\$ 39.9	
(In millions)	For the three months ended March 31, 2005			
	Expenses before inclusion of Stock	Stock Option	Expenses as	
Expenses Research and development	Option Expense \$ 32.5	<u>Expense</u> \$ 3.4	Reported_ \$ 35,9	
Contract manufacturing General and administrative	2.5 4.1		2.5 6.1	
Total operating expenses	\$ 39.1	\$ 5.4	\$ 44.5	

Research and Development Expenses:

Research and development expenses decreased to \$32.1 million in the first quarter of 2006 from \$35.9 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2006 and 2005:

(In millions)	Three months ended March 31,					
					Incre	ease
Research and development expenses	2006		2005		(Decre	ease)
Payroll and benefits (1)	S 1	0.0	\$ I	4,4	S	(4.4)
Clinical trial expenses		3.4		2.1		1.3
Clinical manufacturing costs (2)		9.3		9.0		0.3
Research and preclinical development costs		3.5		4.9		(1.4)
Occupancy and other operating costs		<u>5.9</u>		<u>5,5</u>	<u> </u>	0.4
Total research and development	\$ 3	2.1	\$ 3	5.9	\$	(3.8)

⁽¹⁾ Includes \$1.6 million and \$3.0 million of Stock Option Expense for the three months ended March 31, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in the first quarter of 2006, as described above. Clinical trial expenses increased due to higher 2006 costs associated with (i) preparation for initiating a VEGF Trap-Eye phase 2 clinical trial in wet AMD utilizing intravitreal injections in the first half of 2006 and (ii) several IL-1 Trap clinical studies that were initiated in the fourth quarter of 2005. Clinical manufacturing costs increased as higher costs in 2006 related to manufacturing VEGF Trap clinical supplies were partially offset by lower costs

⁽²⁾ Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.3 million and \$0.4 million of Stock Option Expense for the three months ended March 31, 2006 and 2005, respectively.

related to manufacturing IL-1 Trap clinical supplies. Research and preclinical development costs decreased primarily as a function of our lower 2006 headcount. Occupancy and other operating costs increased primarily due to higher costs for utilities in 2006.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased to \$1.9 million in the first quarter of 2006 from \$2.5 million in the comparable quarter of 2005. Although we shipped more product to Merck in the first quarter of 2006 than the comparable quarter of 2005, we incurred higher expenses in 2005 resulting from unfavorable manufacturing costs which were expensed in the period incurred.

General and Administrative Expenses:

General and administrative expenses decreased to \$5.9 million in the first quarter of 2006 from \$6.1 million in the same period of 2005. In 2006, lower administrative personnel costs and legal expenses related to general corporate matters were partly offset by higher patent- related expenses.

Other Income and Expense:

As described above, in January 2005 we received a one-time \$25.0 million payment from sanofi-aventis, which was recognized as other contract income in the first quarter of 2005.

Investment income increased to \$3.5 million in the first quarter of 2006 from \$2.2 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was \$3.0 million in the first quarter of 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Procter & Gamble, and Merck, and investment income.

Three Months Ended March 31, 2006 and 2005

Cash Provided by Operations:

At March 31, 2006, we had \$324.2 million in cash, cash equivalents, and marketable securities compared with \$316.7 million at December 31, 2005. In January 2006, we received a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

In the first quarter of 2006, our net loss was \$20.4 million, however cash provided by our operations was \$5.3 million, principally because the above-described \$25.0 million payment from sanofi-aventis was receivable at December 31, 2005 and paid in January 2006. In the first quarter of 2005, our net loss was \$4.1 million, however cash provided by operations was \$33.1 million, principally due to our receipt from sanofi-aventis in the first quarter of 2005 of outstanding year-end 2004 receivables for (i) reimbursement of VEGF Trap development expenses incurred by us and (ii) a \$25.0 million clinical milestone payment earned in December 2004.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was \$10.9 million in the first quarter of 2006 compared to net cash provided by investing activities of \$18.4 million in the same period in 2005, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first quarter of 2006, purchases of marketable securities exceeded sales or maturities by \$10.2 million, whereas in the first quarter of 2005, sales or maturities of marketable securities exceeded purchases by \$19.8 million.

Cash Provided by Financing Activities:

Cash provided by financing activities increased to \$3.4 million in the first quarter of 2006 from \$1.0 million in the same period in 2005 due to an increase in issuances of Common Stock in connection with exercises of stock options.

The sanofi-aventis Group Agreement:

Under our collaboration agreement with sanofi-aventis, agreed upon worldwide VEGF Trap development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of a VEGF Trap product for intraocular delivery to the eye predates the first commercial sale of a VEGF Trap product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of VEGF Trap development expenses in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs. We and sanofi-aventis plan to initiate in 2006 multiple additional clinical studies to evaluate the VEGF Trap as both a single agent and in combination with other therapies in various cancer indications.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of VEGF Trap development expenses will terminate and we will retain all rights to the VEGF Trap.

Severance Costs:

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of our collaboration with Procter & Gamble, and the expected completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005, with the remainder planned for 2006 following the completion of our contract manufacturing activities for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included \$0.2 million of non-cash expenses. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and are being expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. We estimate that total costs associated with the 2005 and planned 2006 workforce reductions will approximate \$2.6 million, of which \$2.2 million was charged to expense in the fourth quarter of 2005 and \$0.2 million was charged to expense in the first quarter of 2006. We anticipate cost savings of approximately \$8 million in 2006 resulting from the implementation of our workforce reduction.

Capital Expenditures:

Our additions to property, plant, and equipment totaled \$0.6 million and \$1.6 million for the first three months of 2006 and 2005, respectively. During the remainder of 2006, we expect to incur approximately \$4 million to \$6 million in capital expenditures which will primarily consist of equipment for our manufacturing, research, and development activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). We currently anticipate that approximately 55%-65% of our expenditures for 2006 will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap. VEGF Trap-Eye, and IL-1 Trap; approximately 20%-25% of our expenditures for 2006 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2006 will be used for capital expenditures and general corporate purposes.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaboration with sanofiaventis. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for

manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least mid-2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of March 31, 2006, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In January 2005, we filed a shelf registration statement on Form S-3 to sell, in one or more offerings, up to \$200.0 million of equity or debt securities, together or separately, which registration statement was declared effective in February 2005. However, there is no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

During the three months ended March 31, 2006, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2005.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in

an approximately \$0.9 million and \$1.2 million change in the fair market value of our investment portfolio at March 31, 2006 and 2005, respectively. The decrease in the impact of an interest rate change at March 31, 2006, compared to March 31, 2005, is due to decreases in our investment portfolio's balance and duration to maturity at the end of March 2006 versus the end of March 2005.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2005 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2006, we had a cumulative loss of \$605.7 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We currently receive contract manufacturing revenue from our agreement with Merck and, until June 30, 2005, we received contract research and development revenue from our agreement with The Procter & Gamble Company. Our agreement with Procter & Gamble expired in June 2005 and our agreement with Merck will expire before the end of 2006. The expiration of these agreements results in a significant loss of revenue to the Company.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least mid-2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay

principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap in a variety of systemic inflammatory disorders. Most of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to

determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of the IL-1 Trap in different diseases after a phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate (s), and our business, financial condition, and results of operations may be materially harmed.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

Although the IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events in the phase 2 rheumatoid arthritis study completed in 2003, safety or tolerability concerns may arise as we test higher doses of the IL-1 Trap in patients with other

inflammatory diseases and disorders. Like TNF-antagonists such as Enbrel® (Amgen) and Remicade® (Centocor), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, there may be an increased risk for infections to develop in patients treated with the IL-1 Trap. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the IL-1 Trap.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date — in some cases even after pivotal clinical trials have been completed. Subjects who received the IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap develop antibodies to the product candidate.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap, VEGF Trap-Eye, IL-1 Trap, and IL-4/13 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to

the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap-Eye or in a damage award.

We are aware of certain United States and foreign patents relating to particular IL-4 and IL-13 receptors. Our IL-4/13 Trap includes portions of the IL-4 and IL-13 receptors. In addition, we are aware of a broad patent held by Genentech relating to proteins fused to certain immunoglobulin domains. Our Trap product candidates include proteins fused to immunoglobulin domains. Although we do not believe that we are infringing valid and enforceable third party patents, the holders of these patents may sue us for infringement and a court may find that we are infringing one or more validly issued patents, which may materially harm our business.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our

drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an

accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2005, which report was included in our Annual Report on Form 10-K for the year ended December 31, 2005. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval,

particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms,

or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. Under a long-term manufacturing agreement with Merck, which expires in October 2006, we produce an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. We also use our facilities to produce API for our own clinical and preclinical candidates. When we no longer use our facilities to manufacture the Merck intermediate or if clinical candidates are discontinued, we will have to absorb overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with

European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Onyx Pharmaceuticals and Bayer have received approval from the FDA to market and sell the first oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF

antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the Onyx/Bayer kinase inhibitor, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye diseases is also very competitive. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor for age-related macular degeneration (wet AMD). Novartis and Genentech are collaborating on the development of a VEGF antibody fragment for the treatment of wet AMD that is in phase 3 development. In December 2005, Genentech announced that it filed an application with the FDA to market and sell this VEGF inhibitor in patients with wet AMD. In addition, it has been reported that ophthalmologists are using a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The marketing approval of the OSI/Pfizer VEGF inhibitor and the potential off-label use of Avastin and approval of the Novartis/Genentech VEGF antibody fragment make it more difficult for us to successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it will be difficult for our drug to compete against the OSI/Pfizer drug and, if approved by the FDA, the Novartis/Genentech VEGF inhibitor, because doctors and patients will have significant experience using these medicines. Moreover, the relatively low cost of therapy with Avastin in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Amgen), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Novartis is developing an antibody to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the CIAS1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers.

Sales of biopharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payers, the market for any biopharmaceutical product will be limited. These third-party payers increasingly challenge the price and examine the cost-effectiveness of products and services. Significant uncertainty exists as to the reimbursement status of any new therapeutic, particularly if there exist lower-cost standards of care. Third-party payers may not reimburse sales of our products, which would harm our business.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, Murray A. Goldberg, our Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, Neil Stahl, Ph.D., our Senior Vice President, Preclinical Development and Biomolecular Science, and Randall G. Rupp, Ph.D., our Senior Vice President, Manufacturing Operations. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;

- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- · arrivals and departures of key personnel; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of April 13, 2006, our seven largest shareholders, including sanofi-aventis, beneficially owned 47.9% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 13, 2006. As of April 13, 2006, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 5.1% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, through September 5, 2006, sanofi-aventis may sell no more than 250,000 of these shares in any calendar quarter. After September 5, 2006, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofiaventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 13, 2006, holders of Class A Stock held 4.1% of all shares of Common Stock and Class A Stock then outstanding, and had 29.7% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 13, 2006:

- our current officers and directors beneficially owned 14.6% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2006, and 33.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2006; and
- our seven largest shareholders beneficially owned 47.9% of our outstanding shares of Common Stock assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 13, 2006. In addition, these seven shareholders held 54.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of April 13, 2006.

The anti-takeover effects of provisions of our charter, by-laws, and rights agreement, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws, our rights agreement and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and

• under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

We have a shareholder rights plan which could make it more difficult for a third party to acquire us without the support of our board of directors and principal shareholders. In addition, many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of the Company, as defined in the plan.

Item 6. Exhibits

(a) Exhibits

Exhibit	
Number	Description
12.1	 Statement re: computation of ratio of earnings to combined fixed charges.
31.1	 Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	 Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	— Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: May 8, 2006

By: /s/ Murray A. Goldberg

Murray A. Goldberg

 $Senior\ Vice\ President, Finance\ \&\ Administration,\ Chief\ Financial\ Officer,$

Treasurer, and Assistant Secretary

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Regeneron Pharmaceuticals, Inc. Computation of Ratio of Earnings to Combined Fixed Charges

(Dollars in thousands)

		Years	ended December 3	1,		Three months ended March 31,
	2001	2002	2003	2004	2005	2006
Earnings: Income (loss) from continuing operations before income (loss) from equity						
investee	(\$75,178)	(\$124,350)	(\$107,395)	\$41,565	(\$95,456)	(21,193)
Fixed charges	3,888	13,685	14,108	14,060	13,687	3,412
Amortization of capitalized interest			33	78	78	19
Interest capitalized		(222)	(276)		 -	
Adjusted earnings	(\$71,290)	(\$110,887)	(\$ 93,530)	\$55,703	(\$81,691)	(\$ 17,762)
Fixed charges: Interest expense Interest capitalized	\$ 2,657	\$ 11,859 222	\$ 11,932 276	\$12,175 —	\$ 12,046	\$ 3,011
Assumed interest component of rental charges	1,231	1,604	1,900	1,885	1,641	401
Total fixed charges	\$ 3,888	\$ 13,685	\$ 14,108	\$14,060	\$ 13,687	\$ 3,412
Ratio of earnings to fixed charges	(A)	(A)	(A)	3.96	(A)	(A)

⁽A) Due to the registrant's losses for the years ended December 31, 2001, 2002, 2003, and 2005, and for the three months ended March 31, 2006, the ratio coverage was less than 1:1. To achieve a coverage ration of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

						ee months ended
		Years ended	December 31,		M	arch 31,
	2001	2002	2003	2005		2006
Coverage deficiency	\$ 75,178	\$124,572	\$107,638	\$ 95,378	\$	21,174

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Leonard S. Schleifer, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions
 about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such
 evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2006 /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Murray A. Goldberg, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2006 /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance &
Administration, Chief Financial Officer,
Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer May 8, 2006

/s/ Murray A. Goldberg

Murray A. Goldberg Chief Financial Officer May 8, 2006

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 8/8/2006

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)		
Ø	QUARTERLY REPORT PURSUA	NT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the quarterly period ended June 30, 2006	
		OR
	TRANSITION REPORT PURSUAN	NT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the transition period fromto	
	C	Commission File Number <u>0-19034</u>
		PHARMACEUTICALS, INC.
	(Exact na	ame of registrant as specified in its charter)
	New York	13-3444607
	(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
	777 Old Saw Mill River Road Tarrytown, New York	10591-6707
	(Address of principal executive offices)	(Zip Code)
		(914) 347-7000
	(Registrar	t's telephone number, including area code)
		orts required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the t was required to file such reports), and (2) has been subject to such filing requirements for the
Indicate by cl	neck mark whether the registrant is a large accelerate	d filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large
	er" in Rule 12b-2 of the Exchange Act.	
	Large accelerated file	
Indicate by cl	neck mark whether the registrant is a shell company	as defined in Rule 12b-2 of the Exchange Act). □
Indicate the r	number of shares outstanding of each of the issuer's	classes of common stock as of July 31, 2006:
	Class of Common Stock	Number of Shares
	Class A Stock, \$0.001 par value	2,296,928
	Common Stock, \$0.001 par value	54,674,613

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PART I. FINANCIAL INFORMATION ITEM 1, FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS AT JUNE 30, 2006 AND DECEMBER 31, 2005 (Unaudited)

(In thousands, except share data)

	June 30, 2006	December 31, 2005
ASSETS		
Current assets	m ttaloro	201700
Cash and cash equivalents Marketable securities	\$ 114,960 158.616	\$ 184,508 114.037
Accounts receivable	12.141	36.521
Prepaid expenses and other current assets	3,211	3,422
Inventory	2,128	2,904
Total current assets	291,056	341,392
Marketable securities	30,507	18,109
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	53,854	60,535
Other assets	2,915	3,465
Total assets	\$ 378,332	<u>\$ 423,501</u>
LIABILITIES and STOCKHOLDERS' EQUITY Current liabilities		
Accounts payable and accrued expenses	\$ 16,466	\$ 23,337
Deferred revenue, current portion	15,042	17,020
Total current liabilities	31,508	40,357
Deferred revenue	63,057	69,142
Notes payable	200,000	200,000
Total liabilities	294,565	309,499
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,296,928 in 2006 and 2,347,073 in 2005	2	2
Common Stock, \$ 001 par value; 160,000,000 shares authorized;	2	2
shares issued and outstanding - 54,669,695 in 2006 and 54,092,268 in 2005	55	54
Additional paid-in capital	713,419	700,011
Uncarned compensation Accumulated deficit	(620.226.)	(315)
Accumulated other comprehensive loss	(629,236) (473)	(585,280) (470)
Total stockholders' equity	83,767	114,002
Total liabilities and stockholders' equity	\$ 378,332	\$ 423.501
Four naturnes and stockholes equity	<u> </u>	<u># 140,001</u>

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share data)

	Three months e	ended June 30, 2005	Six months ended June 30, 2006 2005
Revenues Contract research and development Contract manufacturing	\$ 14,991 <u>4,267</u>	\$ 13,545 2,821	\$ 29,578 \$ 27,047 7,899 5,528
	19,258	16,366	<u>37,477</u> <u>32,575</u>
Expenses Research and development	34,398	40,642	66,482 76,554
Contract manufacturing General and administrative	2, 810 6,299	1,675 6,216	4,662 4,166 12,24512,362
	43,507	48,533	83,389 93,082
Loss from operations	(24,249)	(32,167)	(45,912)(60,507)
Other income (expense) Other contract income		5,640	30,640
Investment income Interest expense	3,6 84 (3,011)	2,539 (3,011)	7,165 4,769 (6,022) (6,024)
·	673	5,168	1,143 29,385
Net loss before cumulative effect of a change in accounting principle Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")	(23,576)	(26,999)	(44,769) (31,122) 81 3
Net loss	\$ (23,576)	\$ (26,999)	<u>\$ (43,956</u>) <u>\$ (31,122</u>)
Net loss per share amounts, basic and diluted: Net loss before cumulative effect of a change in accounting principle Cumulative effect of adopting SFAS 123R	\$ (0.41)	\$ (0.48)	\$ (0.79) \$ (0.56) 0.02
Net loss	\$ (0.41)	\$ (0.48)	<u>\$ (0.77)</u> <u>\$ (0.56)</u>
Weighted average shares outstanding, basic and diluted	56,915	55,917	56,821 55,866

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) For the six months ended June 30, 2006 (In thousands)

	Class A Stock Shares Amount	Common Stock Shares Amount	Additional Paid-in Capital	Unearned Compensation	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity	Comprehensive Loss
Balance, December 2005	2,347 \$2	54,092 \$54	\$700,011	\$(315)	\$(585,280)	\$(470)	\$114,002	
Issuance of								
Common Stock in								
connection								
with								
exercise of								
stock options,								
net of								
shares								
tendered		409 1	3,812				3,813	
Issuance of Common Stock in connection with Company								
401(k) Savings Plan contributio		121	1,884				1,884	
Conversion								
of Class A Stock to								
Common								
Stock Forfeitures of restricted Common Stock under Long-Term Incentive Plan	(50)	50						
Stock-based compensation	nn							
expense	/ 		8,840				8,840	
Adjustment to reduce unearned compensati upon adoption of SFAS 123R Cumulative			(315)	315				
effect of adopting SFAS 123R Net foss Change in net			(813)		(43,956)		(813) (43,956)	\$ (43,956)
unrealized loss on marketable securities						(3)	(3)	(3)
Balance, June 30, 2006	2,297 \$2	54,670 \$55	\$713,419		\$(629,236)	\$(473)	\$ 83,767	\$(43,959)

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Six	months en 2006	ded June 30, 2005
Cash flows from operating activities Net loss	\$	(43,956)	\$ (31,122)
Adjustments to reconcile net loss to net cash provided by operating activities Depreciation and amortization		7.488	7,689
Non-cash compensation expense		8,779	11,703
Cumulative effect of a change in accounting principle		(813)	000000000000000000000000000000000000000
Changes in assets and liabilities Decrease in accounts receivable		24.380	26,272
Decrease in accounts receivable Decrease (increase) in prepaid expenses and other assets		24,500 627	(1,246)
Decrease in inventory		1,279	141
Decrease in deferred revenue		(8.063)	(6,848)
Decrease in accounts payable, accrued expenses, and other liabilities	60000000	(5,118)	(2,040)
Total adjustments	<u> </u>	28,559	35,671
Net cash (used in) provided by operating activities	_	(15,397)	4,549
Cash flows from investing activities			
Purchases of marketable securities Sales or maturities of marketable securities	8888888	(152,660) 95,292	(60,392) 107,6 8 0
Capital expenditures		(986)	(2,897)
Net cash (used in) provided by investing activities		(58,354)	44,391
	<u></u>		
Cash flows from financing activities	00000000	000000000000000000000000000000000000000	000000000000000000000000000000000000000
Net proceeds from the issuance of stock Other		3, 81 3 390	1,032
Net cash provided by financing activities		4,203	1,032
Net (decrease) increase in cash and cash equivalents		(69,548)	49,972
	2222222		
Cash and cash equivalents at beginning of period		184,508	95,229
Cash and cash equivalents at end of period	<u>\$</u>	114,960	<u>\$ 145,201</u>

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2005 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. For the three and six months ended June 30, 2006 and 2005, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months	Ended June 30,
	2006	2005
Net loss (Numerator)	\$(23,576)	\$(26,999)
Weighted-average shares, in thousands (Denominator)	56,915	55,917
Basic and diluted net loss per share	\$ (0.41)	\$ (0.48)
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REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

	Six Months E	nded June 30,
	2006	2005
Net loss (Numerator)	\$(43,956_)	\$(31,122)
Weighted-average shares, in thousands (Denominator)	56,821	55,866
Basic and diluted net loss per share	\$ (0.77)	\$ (0.56)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the June 30, 2006 and 2005 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months	s ended June 30,
Stock Options.	2006	2005
Weighted average number, in thousands Weighted average exercise price	14,181 \$ 14.32	13,295 \$ 14.55
	Ø 14.34	\$ 14.22
Restricted Stock: Weighted average number, in thousands	40	204
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25
	Six months	ended June 30,
Stock Options:	2006	2005
Stock Options: Weighted average number, in thousands Weighted average exercise price		
Weighted average number, in thousands	2006 14,291	2005 13,385
Weighted average number, in thousands Weighted average exercise price	2006 14,291	2005 13,385
Weighted average number, in thousands Weighted average exercise price Restricted Stock: Weighted average number, in thousands Convertible Debt:	2006 14,291 \$ 14.29 47	2005 13,385 \$ 14.64
Weighted average number, in thousands Weighted average exercise price Restricted Stock: Weighted average number, in thousands	2006 14,291	2005 13,385 \$ 14.64

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

3. Stock-based Employee Compensation

Adoption of Statement of Financial Accounting Standards Nos. 123 and 123R

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, Accounting for Stock-Based Compensation, using the modified prospective method as described in SFAS 148, Accounting for Stock-Based Compensation — Transition and Disclosure. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, Share-Based Payment, which is a revision of SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by \$813 and is included in the Company's operating results for the six months ended June 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on the Company's loss from operations, net loss, and net loss per share for the three and six months ended June 30, 2006 was not significant, and there was no impact to the Company's cash flows for these respective periods.

Long-Term Incentive Plans

The Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan"), as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, certain shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals,

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. The 1990 Incentive Plan, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. The 1990 Incentive Plan has expired and there will be no future awards from the 1990 Incentive Plan. The Company has issued Incentive Stock Options ("ISOS") and Nonqualified Stock Options, and shares of Restricted Stock from the 1990 and 2000 Incentive Plans. The terms of the awards are determined by the Compensation Committee of the board of directors; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the ISO is granted and no ISO is exercisable more than ten years after the date of grant. As of June 30, 2006, there were 6,495,452 shares available for future grants under the 2000 Incentive Plan.

a. Stock Options

At June 30, 2006, there were 14,150,178 stock options outstanding with exercise prices ranging from \$4.83 to \$51.56. Options granted to employees generally vest annually on a pro rata basis over a four to five year period beginning one year from the date of grant. Certain performance-based options granted to the Company's executive vice president and senior vice presidents in January 2005 vest if both (i) the Company's products have achieved defined sales targets and (ii) the option recipient has remained employed by the Company for at least three years from the date of grant. Options granted to members of the Company's board of directors vest annually on a pro rata basis over three years beginning one year from the date of grant. A summary of the Company's stock option activity for the six months ended June 30, 2006 is presented in the following table:

		Weighted		
		Average	Weighted	
		Remaining	Average	Intrinsic
	Number	Contractual	Exercise	Value (in
	Outstanding	Life	Price	thousands)
Stock options outstanding at January 1, 2006	14,719,492		\$ 14,23	
Stock options granted	206,500		\$ 15.32	
Stock options exercised	(438,031)		\$ 9,82	
Stock options forfeited	(201,135)		\$ 10.62	
Stock options expired	(136,648)		\$ 25,24	
Stock options outstanding at June 30, 2006	14,150,178	6.5	\$ 14.32	\$ 28,313
Stock options vested and exercisable	7,193,872	5.1	\$ 17,70	\$ 12,185

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

The total intrinsic value of stock options exercised during the first six months of 2006 and 2005 was \$2,863 and \$200, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

For the three months ended June 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") totaled \$4,610 and \$5,398, respectively, of which \$4,585 and \$5,348 was recognized in operating expenses and \$25 and \$50 was capitalized into inventory, respectively. For the six months ended June 30, 2006 and 2005, Stock Option Expense totaled \$8,541 and \$10,939, respectively, of which \$8,481 and \$10,727 was recognized in operating expenses and \$60 and \$212 was capitalized into inventory, respectively. As of June 30, 2006, there was \$23,243 of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.7 years. In addition, there are 723,092 options which are unvested as of June 30, 2006 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2,688 and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Fair Value Assumptions:

The fair value of each option granted during the three and six months ended June 30, 2006 and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and board directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The weighted-average fair value of the options granted during the three months ended June 30, 2006 and 2005 was \$8.23 and \$4.04 per option, respectively. The weighted-average fair value of the options granted during the six months ended June 30, 2006 and 2005 was \$10.28 and \$5.81 per option, respectively. The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Three months	ended June 30,
	2006	2005
Expected volatility	65 %	70 %
Expected lives from grant date	5.2 years	5.0 years
Expected dividend yield	0 %	0 %
Risk-free interest rate	4,95 %	3.78 %
	Six months er	nded June 30,
	Six months er	nded June 30, 2005
Expected volatility		
Exposted volatifity	2006	2005
Expected volatility Expected lives from grant date Expected dividend yield	2006 68 %	2005 75 %

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the six months ended June 30, 2006 is presented in the following table:

		Weighted
	Number	Average Grant
	of Shares	Date Fair Value
Restricted stock outstanding as of January 1, 2006	95,188	\$ 11.16
Restricted stock released	(93,485)	\$ 11.18
Restricted stock forfeited	(1,703)	\$ 9.74
Restricted stock outstanding as of June 30, 2006		

In accordance with generally accepted accounting principles, the Company recorded unearned compensation in Stockholders' Equity related to these Restricted Stock awards. The amount was based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restrictions lapse, which is approximately two years for grants issued in 2003 and 18 months for grants issued in 2004. No Restricted Stock awards were granted in 2005 or during the six months ended June 30, 2006. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation was combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

For the three months ended June 30, 2006 and 2005, the Company recognized compensation expense related to Restricted Stock awards of \$115 and \$474, respectively. For the six months ended June 30, 2006 and 2005, the Company recognized

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

compensation expense related to Restricted Stock awards of \$299 and \$976, respectively. As of June 30, 2006, there were no unvested shares of restricted stock outstanding and all compensation expense related to these awards had been recognized.

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2006 and December 31, 2005 are \$216 and \$234, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 2005 and December 31, 2004 are \$1,393 and \$550, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2005 and 2004 are \$1,884 and \$632, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2006 and 2005, the Company contributed 120,960 and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at June 30, 2006 and December 31, 2005 are \$840 and \$1,228, respectively, of accrued interest income. Included in marketable securities at June 30, 2005 and December 31, 2004 are \$2,562 and \$2,601, respectively, of accrued interest income.

5. Severance Costs

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the expected completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005, with the remainder planned for 2006 following the completion of the Company's contract manufacturing activities for Merck

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and are being expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, Accounting for Costs Associated with Exit or Disposal Activities. The Company

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

estimates that total costs associated with the 2005 and planned 2006 workforce reductions will approximate \$2.6 million, including \$0.2 million of non-cash expenses in 2005.

Severance costs associated with the workforce reduction plan that were charged to expense during the three and six months ended June 30, 2006 consist of the following:

		Three months ended June 30, 2006				
	Accrued liability at	Costs	Costs paid	Accrued liability at		
	March 31,	charged to	or settled in	June 30,		
	2006	expense	2006	2006		
Employee severance, payroll taxes, and benefits	\$ 4 25	\$ 197	\$ 159	\$ 463		
Other severance costs	<u></u>	<u> </u>		<u> </u>		
Total	<u>\$ 425</u>	<u>\$ 203</u>	<u>\$ 164</u>	<u>\$ 464</u>		
		Six mor	nths ended			
			nths ended 30, 2006			
	Accrued	June 3	30, 2006	Accrued		
	liability at	Costs June 2	30, 2006 Costs paid	liability at		
	liability at December 31,	Costs charged to	Costs paid or settled in	liability at June 30,		
E. I	liability at December 31,	Costs charged to expense	Costs paid or settled in 2006	liability at June 30, 2006		
Employee severance, payroll taxes, and benefits	liability at December 31, 2005 \$ 907	Costs charged to expense \$ 356	Costs paid or settled in 2006	liability at June 30,		
Employee severance, payroll taxes, and benefits Other severance costs Total	liability at December 31,	Costs charged to expense	Costs paid or settled in 2006	liability at June 30, 2006		

These severance costs are included in the Company's Statement of Operations for the three and six months ended June 30, 2006 as follows:

	Research &
Three months ended June 30, 2006	development
Employee severance, payroll taxes, and benefits	S 197
Other severance costs	6
Total	<u>\$ 203</u>

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Research &	General &
Six months ended June 30, 2006	development	administrative
Employee severance, payroll taxes, and benefits	\$ 358	\$ (2)
Other severance costs	19	_
Total	<u>\$ 377</u>	<u>\$ (2</u>)

For segment reporting purposes (see Note 10), all severance-related expenses are included in the Research & Development segment.

6. Accounts Receivable

Accounts receivable as of June 30, 2006 and December 31, 2005 consist of the following:

	June 30,	December 31,
	2006	2005
Receivable from the sanofi-aventis Group	\$ 11,773	\$ 36,412
Receivable from Merck & Co., Inc.	368	27
Other		
	\$ 12,141	\$ 36,521

7. Inventories

Inventories consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which will expire in October 2006.

Inventories as of June 30, 2006 and December 31, 2005 consist of the following:

	June 30,	December	31,
	2006	2005	
Raw materials		- S 2	78
Work-in-process		- 1,4	123
Finished products	C 1110	<u>8</u> <u>1,2</u>	03
	\$ 2,128	<u>\$ 2,9</u>	04

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

8 Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2006 and December 31, 2005 consist of the following:

	June 30,	December 31,
	2006	2005
Accounts payable	\$ 2,840	\$ 4,203
Accrued payroll and related costs	6,223	10,713
Accrued clinical trial expense	3,434	3,081
Accrued expenses, other	1,677	3,048
Interest payable on convertible notes	2,292	2,292
	<u>\$ 16,466</u>	<u>\$ 23,337</u>

9. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three and six months ended June 30, 2006 and 2005, the components of comprehensive loss are:

	Three months ende	d June 30,
	2006	2005
Net loss S	\$ (23,576)	\$ (26,999)
Change in net unrealized gain (loss) on marketable securities	(102)	401
Total comprehensive loss	§ (23,678 ₎	\$ (26,598)
•	·	
	Six months ended	June 30,
	2006	2005
Net loss S	8 (43,956)	\$ (31,122)
Change in net unrealized gain (loss) on marketable securities	(3)	60
Total comprehensive loss	<u>(43,959</u>)	\$ (31,062)

10. Segment Information

The Company's operations are managed in two business segments: research and development, and contract manufacturing.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and (ii) the supply of research materials based on Regeneron-developed proprietary technology.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. The Company produces an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which will expire in October 2006.

The table below presents information about reported segments for the three and six months ended June 30, 2006 and 2005.

		i nree months ended	June 30, 2006	
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 14,991	\$4,267		\$ 19,258
Depreciation and amortization	3,429	(1)	\$ 261	3,690
Non-cash compensation expense	4,603	97	<u></u> -	4,700
Interest expense	_	_	3,011	3,011
Net (foss) income	(25,706)	1,457	673 (2)	(23,576)
Capital expenditures	323	_	_	323
		Three months ended	June 30, 2005	
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 13,545	\$2,821		\$ 16,366
Depreciation and amortization	3,570	(1)	\$ 261	3,831
Non-cash compensation expense	5,732	90	<u></u>	5,822
Other contract income	5,640			5,640
Interest expense		<u></u> -	3,011	3,011
Net (loss) income	(27,673)	1,146	(472)(2)	(26,999)
Capital expenditures	2,115			2,115

Three months ended June 30, 2006

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Six months ended June 30, 2006			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 29,578	\$7,899		\$ 37,477
Depreciation and amortization	6,966	(1)	\$ 522	7,488
Non-cash compensation expense	8,587	192	(813)(3)	7,966
Interest expense	_	_	6,022	6,022
Net (loss) income	(49,149)	3,237	1,956 (2)	(43,956)
Capital expenditures	968	_	_	968
Total assets	64,543	3,580	310,209 (4)	378,332

	Six months ended June 30, 2005			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 27,047	\$5,528		\$ 32,575
Depreciation and amortization	7,167	(1)	\$ 522	7,689
Non-cash compensation expense	11,613	90	<u></u> -	11,703
Other contract income	30,640		_	30,640
Interest expense			6,024	6,024
Net (loss) income	(31,229)	1,362	$(1,255)^{(2)}$	(31,122)
Capital expenditures	3,752		<u> </u>	3,752
Total assets	81,936	6,006	359,006 (4)	446,948

⁽¹⁾ Depreciation and amortization related to contract manufacturing is capitalized into inventory and included in contract manufacturing expense when the product is shipped.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the six months ended June 30, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 3).

⁽³⁾ Represents the cumulative effect of adopting SFAS 123R (see Note 3).

⁽⁴⁾ Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: VEGF Trap in oncology, VEGF Trap eye formulation (VEGF Trap-Eye) in eye diseases using intraocular delivery, and IL-1 Trap in various inflammatory indications. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse pipeline of product candidates that we believe has the potential to address a variety of serious medical conditions. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the strength of the VelocImmune platform, which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move two new antibody candidates into clinical trials each year going forward beginning in 2007. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Clinical Programs:

Below is a summary of the clinical status of our clinical candidates as of June 30, 2006:

1. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PIGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis, as described below. In September 2005, we and sanofi-aventis announced plans to expand our joint development program, and we have subsequently initiated a broad set of clinical trials in oncology.

In the first half of 2006, we and sanofi-aventis initiated our phase 2 single-agent program for the VEGF Trap in cancer. Patient enrollment is now underway in studies in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the United States Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for the treatment of SMA.

The companies also plan to conduct three phase 3 efficacy/safety trials using the VEGF Trap in combination with standard chemotherapy regimens, the first of which is planned to begin in late 2006 or early 2007, once the supporting safety and tolerability studies have been completed. The companies are working to finalize plans with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) to conduct at least ten additional cancer trials, several of which are planned to begin in 2006.

Currently there are five safety and tolerability studies underway for the VEGF Trap in combination with standard chemotherapy regimens designed to support subsequent phase 3 clinical trials in a variety of cancer types. At the annual meeting of the American Society of Clinical Oncology (ASCO) in May 2006, the companies reported abstracts summarizing information from two of these studies. The first study is evaluating the VEGF Trap plus oxaliplatin, 5-flourouracil, and leucovorin (FOLFOX4) in a phase 1 trial of patients with advanced solid tumors. The second study is evaluating the VEGF Trap plus irinotecan, 5-fluorouracil, and leucovorin (LV5FU2-CPT11) in a phase 1 trial of patients with advanced solid tumors. In both trials, patients have been treated in combination with chemotherapy in doses ranging up to 4.0 milligrams per kilogram (mg/kg) of the VEGF Trap. The abstracts, published in the 2006 ASCO Annual Meeting Proceedings, reported that the VEGF Trap could be safely combined with either FOLFOX4 or LV5FU2-CPT11 at the dose levels studied. The maximum tolerated doses in these studies have not yet been reached, and dose escalation is continuing.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to \$400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another \$40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. (See "The sanofi-aventis Group Agreement" below.)

2. VEGF Trap — Eye Diseases

We are developing the VEGF Trap-Eye for the treatment of certain eye diseases. This product candidate has been purified and formulated in concentrations suitable for direct injection into the eye. We retain the exclusive right to develop and commercialize the VEGF Trap-Eye for the treatment of eye diseases utilizing local (intravitreal) delivery to the eye. In May 2006, we

announced that we had initiated a phase 2 trial of the VEGF Trap-Eye delivered intravitreally in patients with the neovascular form of age-related macular degeneration (wet AMD).

At the May 2006 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO), we reported positive preliminary results from a phase 1 trial of the VEGF Trap-Eye in patients with wet AMD. A total of 21 patients received a single dose of VEGF Trap-Eye at doses of 0.05, 0.15, 0.5, 1, 2, and 4 milligrams (mg) intravitreally (direct injection into the eye). Patients were evaluated for six weeks to measure the durability of effects and provide guidance for dosing regimens to be used in future trials. All dose levels were generally well tolerated, and a maximum tolerated dose was not reached in the study. In wet AMD, the leakiness of the abnormal blood vessels in the eye can lead to increased retinal thickness. On average, patients receiving the VEGF Trap-Eye demonstrated large, rapid, and sustained (at least six weeks) reductions in retinal thickness. Excess retinal thickness, as determined by ocular coherence tomography (OCT), is a clinical measure of disease activity in wet AMD. As measured by the OCT reading center (posterior pole OCT scans), the median excess retinal thickness resulting from the disease process was 194 microns at baseline. Following a single intravitreal dose of the VEGF Trap-Eye, median excess retinal thickness was reduced to 60 microns, an improvement that was sustained over a six week period. As measured by the computerized Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline, which was reduced to 27 microns at six weeks after the single dose of the VEGF Trap-Eye.

Of the 20 patients evaluable for efficacy, 95 percent had stabilization or improvement in visual acuity, defined as \leq 15 letter loss on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. Patients were also evaluated for best-corrected visual acuity (BCVA), the best acuity a person can achieve with glasses. BCVA for all patients in the study increased by a mean of 4.8 letters at six weeks. In the two highest dose groups (2 mg and 4 mg), the mean improvement in BCVA was 13.5 letters, with three of six patients showing an improvement in BCVA of 15 or more letters.

In the second quarter of 2006, we initiated a 150 patient, 12 week, phase 2 trial of the VEGF Trap-Eye in wet AMD. The trial is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. A phase 3 trial of the VEGF Trap-Eye in wet AMD is planned to begin in early 2007.

Also in the second quarter of 2006, we initiated a small pilot study of the VEGF Trap in patients with diabetic macular edema.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and LucentisTM (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal

edema and neovascular proliferation. It is estimated that in the U.S. 6% of individuals aged 65-74 and 20% of those older than 75 are affected with wet AMD. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

3. IL-1 Trap — Inflammatory Diseases

The IL-1 Trap is a protein-based product candidate designed to bind the interleukin-I (called IL-1) cytokine and prevent its interaction with cell surface receptors.

We are evaluating the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called CIAS1-Associated Periodic Syndrome (CAPS) and diseases associated with inflammation. These include Systemic Juvenile Idiopathic Arthritis (SJIA) and certain inflammatory vascular diseases.

In April 2006, we completed enrollment of the pivotal study of the IL-1 Trap in patients with CAPS. Patients in the trial are receiving a 160 mg dose of the IL-1 Trap once a week through subcutaneous self-administration. The six-month, placebo-controlled, double-blind, efficacy phase of the study is expected to be completed and preliminary data available by the end of 2006. This phase will be followed by a six-month open-label extension phase. We plan to file a Biologics License Application (BLA) for the IL-1 Trap for the treatment of CAPS in early 2007. In addition, Regeneron has ongoing proof-of-concept studies in other indications, such as SJIA. The FDA has granted Orphan Drug and Fast Track designations to the IL-1 Trap for the treatment of CAPS. In April 2005, the FDA also granted an Orphan Drug designation to the IL-1 Trap for the treatment of SJIA.

An IL-1 receptor antagonist, Kineret® (Amgen Inc.), has been approved by the FDA for the treatment of rheumatoid arthritis. It has been publicly reported that in small trials Kineret appears to reduce the symptoms in CAPS patients and SJIA patients, which supports the role of IL-1 in these diseases. CAPS includes rare genetic disorders, such as Familial Cold Auto-Inflammatory Syndrome (FCAS), Muckle Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disorder (NOMID), which affect a small group of people. Patients with these disorders develop fever, joint aches, headaches, and rashes. In certain indications, these symptoms can be extremely serious. There are no currently approved therapies for CAPS. SJIA is a severe inflammatory disorder which may be debilitating or fatal. It is estimated that there are between 5,000 and 10,000 children with SJIA in the United States.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we

are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our IL-1 Trap currently in clinical development.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through June 30, 2006, we had a cumulative loss of \$629.2 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the IL-1 Trap; advance new product candidates into clinical development from our existing research programs; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events for 2006 and plans over the next 12 months are as follows:

Product Candidate	2006 Events to Date	2006-7 Plans
VEGF Trap — Oncology	 Initiated phase 2 studies of the VEGF Trap as a single agent in AOC and NSCLA patients, and in AOC patients with SMA. Initiated two safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens Reported encouraging preliminary results of the safety and tolerability of intravenous VEGF Trap plus FOLFOX4 and of intravenous VEGF Trap plus LV5FU2-CPT11 in separate phase 1 trials of patients with advanced solid tumors 	 Initiate up to three efficacy/safety studies of the VEGF Trap in combination with standard chemotherapy regimens in different cancer indications Sponsor with the NCI/CTEP at least ten exploratory efficacy/safety studies evaluating the VEGF Trap in a variety of cancer types
VEGF Trap-Eye	 Reported positive preliminary results from phase 1 trial in wet AMD utilizing intravitreal injections in 21 patients up to a top dose of 4 mg Initiated phase 2 trial in wet AMD utilizing intravitreal injections Initiated phase 1 trial in DME 	 Report preliminary results of phase 2 trial in wet AMD utilizing intravitreal injections Initiate phase 3 trial in wet AMD utilizing intravitreal injections Explore additional eye disease indications
IL-1 Trap	 Completed enrollment of pivotal trial of IL-1 Trap in CAPS Reported positive preliminary results from ongoing phase 1 trial in SJIA 	 Complete efficacy portion of pivotal study in CAPS and, if results show positive efficacy and safety, file Biologics License Application (BLA) with the FDA Initiate advanced efficacy trial, evaluating the IL-1 Trap for SJIA

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Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, Accounting for Stock-Based Compensation, using the modified prospective method as described in SFAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by \$0.8 million and is included in our operating results for the six months ended June 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123R on our loss from operations, net loss, and net loss per share for the three and six months ended June 30, 2006 was not significant, and there was no impact to our cash flows for these respective periods.

Non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") totaled \$4.6 million for the three months ended June 30, 2006, which was recognized in operating expenses, and \$5.4 million for the three months ended June 30, 2005, of which \$5.3 million was recognized in operating expenses and \$0.1 million was capitalized into inventory. For the six months ended June 30, 2006 and 2005, Stock Option Expense totaled \$8.6 million and \$10.9 million, respectively, of which \$8.5 million and \$10.7 million was recognized in operating expenses and \$0.1 million and \$0.2 million was capitalized into inventory, respectively. As of June 30, 2006, there was \$23.2 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.7 years. In addition, there are 723,092 options which are unvested as of June 30, 2006 and would become vested upon the attainment of certain performance and service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2.7 million and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and Board Directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The

expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average values of the assumptions we used in computing the fair value of option grants during the three and six months ended June 30, 2006 and 2005:

	Three months	<u>ended June 30, </u>
	2006	2005
Expected volatility	65%	70%
Expected lives from grant date	5.2 years	5.0 years
Expected dividend yield		0%
Risk-free interest rate	4.95%	3.78%
	Six months en	nded June 30,
	2006	2005
Expected volatility	68 %	75 %

Changes in any of these estimates may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

Expected lives from grant date

Expected dividend yield

Risk-free interest rate

Results of Operations

Three Months Ended June 30, 2006 and 2005

Net Loss:

Regeneron reported a net loss of \$23.6 million, or \$0.41 per share (basic and diluted), for the second quarter of 2006 compared to a net loss of \$27.0 million, or \$0.48 per share (basic and diluted), for the second quarter of 2005.

Revenues:

Revenues for the three months ended June 30, 2006 and 2005 consist of the following:

			Increase
(In millions)	2006	2005	(Decrease)
Contract research & development revenue			
The sanofi-aventis Group	\$ 14.8	\$ 9.4	\$ 5.4
The Procter & Gamble Company		2.9	(2.9)
Other	0.2	1.3	(1.1)
Total contract research & development revenue	15.0	13.6	1.4
Contract manufacturing revenue	4.3	2.8	1.5
Total revenue	<u>\$ 19.3</u>	<u>\$ 16.4</u>	<u>\$ 2.9</u>

6.8 years

0%

4.76 %

6.2 years

3.96 %

0 %

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104).

Sanofi-aventis Contract Research & Development Revenue

	i nree montus ena	ea June 30,
(In millions)	2006	2005
Regeneron expense reimbursement	\$ 11.8	§ 7.1
Recognition of deferred revenue related to up-front payments	3.0	2.3
Total	<u>5 14.8</u>	<u>\$ 9,4</u>

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses increased in the second quarter of 2006 from the same period in 2005, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in the second quarter of 2006 from the same period in 2005, due to our January 2006 receipt of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan. As of June 30, 2006, \$75.2 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract research and development revenue earned from Procter & Gamble decreased in the second quarter of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

Contract manufacturing revenue relates to our long-term agreement with Merck & Co., Inc., which expires in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Contract manufacturing revenue increased in the second quarter of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Revenue and the related manufacturing expense are recognized as product is shipped, after acceptance by Merck. Included in contract manufacturing revenue in the second quarter of 2006 and 2005 were \$0.4 million and \$0.3 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. As of June 30, 2006, the remaining deferred balance of Merck's capital improvement reimbursements totaled \$0.4 million, which will be recognized as revenue as product is shipped based upon Merck's order quantities through October 2006.

Expenses:

Total operating expenses decreased to \$43.5 million in the second quarter of 2006 from \$48.5 million in the same period of 2005, due, in part, to our lower headcount. Our average headcount declined to 583 in the second quarter of 2006 from 731 in the same period of 2005 primarily as a

result of workforce reductions made in the fourth quarter of 2005. (See "Severance Costs" below.)

Operating expenses in the second quarter of 2006 and 2005 include a total of \$4.6 million and \$5.3 million of Stock Option Expense, respectively, as detailed below:

(In millions)	For the three months ended June 30, 2006					
Expenses	inclusio	ses before n of Stock Expense		Option pense	-	enses as
Research and development	8	31.8	\$	2.6	\$	34.4
Contract manufacturing General and administrative	<u> </u>	2.7 4.4		0.1 1.9	<u></u>	2.8 6.3
Total operating expenses	\$	38.9	\$	4.6	\$	43.5
(In millions)		For the three	months e	nded June 3	0, 2005	
	•	ses before n of Stock	Stock	Option	Evne	enses as
Expenses		Expense		ense	•	orted_
Research and development	8	37,3	\$	3,3	\$	40.6
Contract manufacturing General and administrative		1.6 4.3		0.1 <u>1.9</u>		1,7 6,2
Total operating expenses	\$	43,2	\$	5,3	\$	48.5

Research and Development Expenses:

Research and development expenses decreased to \$34.4 million in the second quarter of 2006 from \$40.6 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2006 and 2005:

(In millions)		Three months	ended Ju	ne 30,
				Increase
Research and development expenses	2006		005	(Decrease)
Payroll and benefits (1)	\$ 11.7	7 \$	14.0	\$ (2,3)
Clinical trial expenses	4.4	ļ	6.4	(2.0)
Clinical manufacturing costs (2)	9,1			0,9
Research and preclinical development costs	4.3	3	5.8	(1.5)
Occupancy and other operating costs	4.6	<u> </u>	6.2	(1.3)
Total research and development	\$ 34.4	<u>\$</u>	40.6	\$ (6.2)

⁽¹⁾ Includes \$2.2 million and \$2.9 million of Stock Option Expense for the three months ended June 30, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in the second quarter of 2006, as described above. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006, as we discontinued clinical development of IL-1 Trap in adult rheumatoid arthritis

⁽²⁾ Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.4 million of Stock Option Expense for both the three months ended June 30, 2006 and 2005.

and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs as we initiated a phase 2 clinical trial in wet AMD. Clinical manufacturing costs increased because of higher costs in 2006 related to manufacturing VEGF Trap clinical supplies, which were partially offset by lower costs related to manufacturing IL-1 Trap clinical supplies. Research and preclinical development costs decreased primarily because of our lower 2006 headcount and lower preclinical IL-1 Trap development costs in 2006. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to \$2.8 million in the second quarter of 2006 from \$1.7 million in the comparable quarter of 2005 primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses increased to \$6.3 million in the second quarter of 2006 from \$6.2 million in the same period of 2005 as higher administrative personnel-related costs were offset primarily by lower facility-related expenses and consulting costs in the second quarter of 2006.

Other Income and Expense:

In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble agreed to make a one-time \$5.6 million payment to us, which we recognized as other contract income in the second quarter of 2005.

Investment income increased to \$3.7 million in the second quarter of 2006 from \$2.5 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was \$3.0 million in the second quarter of 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Six Months Ended June 30, 2006 and 2005

Net Loss:

Regeneron reported a net loss of \$44.0 million, or \$0.77 per share (basic and diluted), for the first half of 2006 compared to a net loss of \$31.1 million, or \$0.56 per share (basic and diluted), for the same period of 2005. Results for the first half of 2005 included a \$25.0 million one-time, non-recurring payment from sanofi-aventis, which was recognized as other contract income, in connection with the January 2005 amendment to our collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap-Eye.

Revenues:

Revenues for the six months ended June 30, 2006 and 2005 consist of the following:

			Increase
(In millions)	2006	2005	(Decrease)
Contract research & development revenue			
The sanofi-aventis Group	\$ 28.7	\$ 19.2	\$ 9.5
The Procter & Gamble Company	—	6.0	(6.0)
Other	0.9	1.9	(1.0)
Total contract research & development revenue	29,6	27.1	2.5
Contract manufacturing revenue	7.9	5.5	2.4
Total revenue	<u>\$ 37.5</u>	<u>\$ 32.6</u>	<u>\$ 4.9</u>

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with SAB 104.

Sanofi-aventis Contract Research & Development Revenue

	Six months	ended June 30,
(In millions)	2006	2005
Regeneron expense reimbursement	\$ 22.6	S 14.5
Recognition of deferred revenue related to up-front payments	6.1	4.7
Total	<u> 28.7</u>	<u>\$ 19.2</u>

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses increased in the first half of 2006 from the same period in 2005, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in the first half of 2006 from the same period in 2005, due to our January 2006 receipt of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

Contract research and development revenue earned from Procter & Gamble decreased in the first half of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

Contract manufacturing revenue increased in the first half of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Included in contract manufacturing revenue in the first half of 2006 and 2005 were \$0.8 million and \$0.6 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production.

Expenses:

Total operating expenses decreased to \$83.4 million in the first half of 2006 from \$93.1 million in the same period of 2005, due, in part, to our lower headcount, as previously described above. (Also see "Severance Costs" below.)

Operating expenses in the first half of 2006 and 2005 include a total of \$8.5 million and \$10.7 million of Stock Option Expense, respectively, as detailed below:

(In millions)	For the six months ended June 30, 2006		
	Expenses before		
	inclusion of Stock	Stock Option	Expenses as
Expenses	Option Expense	<u>Expense</u>	<u>Reported</u>
Research and development	s 61.9	\$ 4.6	\$ 66.5
Contract manufacturing	4.5	0.2	4.7
General and administrative	<u>8,5</u>	3.7	12.2
Total operating expenses	\$ 74,9	\$ 8,5	\$ 83,4
(In millions)	For the six i	nonths ended June 30,	2005
	Expenses before		
	Expenses before inclusion of Stock	Stock Option	Expenses as
Expenses	•	<u>Expense</u>	Expenses as Reported
Expenses Research and development	inclusion of Stock	-	•
	inclusion of Stock Option Expense	<u>Expense</u>	Reported
Research and development	inclusion of Stock Option Expense \$ 69.8	<u>Expense</u> \$ 6.7	Reported \$ 76.5
Research and development Contract manufacturing	inclusion of Stock Option Expense \$ 69.8 4.1	Expense	Reported \$ 76.5 4.2

Research and Development Expenses:

Research and development expenses decreased to \$66.5 million in the second half of 2006 from \$76.5 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2006 and 2005:

(In millions)	Six r	nonths ended June	30,
			Increase
Research and development expenses	2006	2005	(Decrease)
Payroll and benefits (1)	\$ 21.7	\$ 28.4	\$ (6.7)
Clinical trial expenses	7.8	8.5	(0.7)
Clinical manufacturing costs (2)	18.4	17.3	1.1
Research and preclinical development costs	7.8	10.7	(2.9)
Occupancy and other operating costs	10,8	11.6	(0,8)
Total research and development	\$ 66.5	<u>\$ 76.5</u>	<u>\$ (10.0</u>)
Clinical trial expenses Clinical manufacturing costs (2) Research and preclinical development costs Occupancy and other operating costs	\$ 21.7 7.8 18.4 7.8 10.8 \$ 66.5	\$ 28.4 8.5 17.3 10.7 11.6 \$ 76.5	\$ (0.7 1.1 (2.9 (0.8 \$ (10.0

⁽¹⁾ Includes \$3.8 million and \$5.9 million of Stock Option Expense for the six months ended June 30, 2006 and 2005, respectively.

⁽²⁾ Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.7 million and \$0.8 million of Stock Option Expense for the six months ended June 30, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in the first half of 2006. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006 as we discontinued clinical development of IL-1 Trap in adult rheumatoid arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs primarily in connection with initiating a phase 2 clinical trial in wet AMD. Clinical manufacturing costs increased because of higher costs in 2006 related to manufacturing VEGF Trap clinical supplies, which were partially offset by lower costs related to manufacturing IL-1 Trap clinical supplies. Research and preclinical development costs decreased primarily because of our lower 2006 headcount and lower preclinical IL-1 Trap development costs in 2006. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount offset, in part, by higher costs for utilities in 2006.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to \$4.7 million in the first half of 2006 from \$4.2 million in the comparable period of 2005 primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses decreased to \$12.2 million in the first half of 2006 from \$12.4 million in the same period of 2005. In 2006, lower facility-related expenses and consulting costs were partly offset by higher patent-related and administrative personnel-related expenses.

Other Income and Expense:

As described above, in January 2005 we received a one-time \$25.0 million payment from sanofi-aventis, which was recognized as other contract income in the first half of 2005. In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble agreed to make a one-time \$5.6 million payment to us, which we recognized as other contract income in the first half of 2005.

Investment income increased to \$7.2 million in the first half of 2006 from \$4.8 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was \$6.0 million in the first half of 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis and Merck, and investment income.

Six Months Ended June 30, 2006 and 2005

Cash (Used in) Provided by Operations:

At June 30, 2006, we had \$304.1 million in cash, cash equivalents, and marketable securities compared with \$316.7 million at December 31, 2005. In January 2006, we received a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

In the first half of 2006, our net loss was \$44.0 million; however, cash used in our operations was only \$15.4 million, principally because the above-described \$25.0 million payment from sanofi-aventis was receivable at December 31, 2005 and paid in January 2006. In the first half of 2005, our net loss was \$31.1 million; however, cash provided by our operations was \$4.5 million, principally due to receipts during this period from the sanofi-aventis Group for (i) reimbursement of VEGF Trap development expenses incurred by us and (ii) a \$25.0 million clinical milestone payment earned in December 2004.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was \$58.4 million in the first half of 2006 compared to net cash provided by investing activities of \$44.4 million in the same period in 2005, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first half of 2006, purchases of marketable securities exceeded sales or maturities by \$57.4 million, whereas in the first half of 2005, sales or maturities of marketable securities exceeded purchases by \$47.3 million.

Cash Provided by Financing Activities:

Cash provided by financing activities increased to \$4.2 million in the first half of 2006 from \$1.0 million in the same period in 2005 due primarily to an increase in issuances of Common Stock in connection with exercises of stock options.

The sanofi-aventis Group Agreement:

Under our collaboration agreement with sanofi-aventis, agreed upon worldwide VEGF Trap development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of a VEGF Trap product for intraocular delivery to the eye predates the first commercial sale of a VEGF Trap product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of VEGF Trap development expenses in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of VEGF Trap development expenses will terminate and we will retain all rights to the VEGF Trap.

Severance Costs:

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of our collaboration with Procter & Gamble, and the expected completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005, with the remainder planned for 2006 following the completion of our contract manufacturing activities for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included \$0.2 million of non-cash expenses. Estimated termination costs associated with the planned workforce reduction in 2006 were measured in October 2005 and are being expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. We estimate that total costs associated with the 2005 and planned 2006 workforce reductions will approximate \$2.6 million, of which \$2.2 million was charged to expense in the fourth quarter of 2005 and \$0.4 million was charged to expense in the first half of 2006. We anticipate cost savings of approximately \$8 million in 2006 resulting from the implementation of our workforce reduction.

Capital Expenditures:

Our additions to property, plant, and equipment totaled \$1.0 million and \$3.8 million for the first half of 2006 and 2005, respectively. During the remainder of 2006, we expect to incur approximately \$2 million to \$4 million in capital expenditures which will primarily consist of equipment for our manufacturing, research, and development activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from sanofi-aventis, we currently anticipate that approximately 55%-65% of our expenditures for 2006 will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap; approximately 20%-25% of our expenditures for 2006 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2006 will be used for capital expenditures and general corporate purposes.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaboration with sanofiaventis. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least mid-2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of June 30, 2006, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In January 2005, we filed a shelf registration statement on Form S-3 to sell, in one or more offerings, up to \$200.0 million of equity or debt securities, together or separately, which registration statement was declared effective in February 2005. However, there is no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

During the six months ended June 30, 2006, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2005.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in an approximately \$0.9 million and \$1.1 million change in the fair market value of our investment portfolio at June 30, 2006 and 2005, respectively. The decrease in the impact of an interest rate change at June 30, 2006, compared to June 30, 2005, is due to decreases in our investment portfolio's balance and duration to maturity at the end of June 2006 versus the end of June 2005.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and

uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2005 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through June 30, 2006, we had a cumulative loss of \$629.2 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We currently receive contract manufacturing revenue from our agreement with Merck and, until June 30, 2005, we received contract research and development revenue from our agreement with The Procter & Gamble Company. Our agreement with Procter & Gamble expired in June 2005 and our agreement with Merck will expire before the end of 2006. The expiration of these agreements results in a significant loss of revenue to the Company.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least mid-2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October

2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial. lack

of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of the IL-1 Trap in different diseases after a phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate (s), and our business, financial condition, and results of operations may be materially harmed.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions, referred to as infusion reactions. These and other

complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

Although the IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events in the phase 2 rheumatoid arthritis study completed in 2003, safety or tolerability concerns may arise as we test higher doses of the IL-1 Trap in patients with other inflammatory diseases and disorders. Like TNF-antagonists such as Enbrel® (Amgen) and Remicade® (Centocor), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, there may be an increased risk for infections to develop in patients treated with the IL-1 Trap. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the IL-1 Trap.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created at a later date — in some cases even after pivotal clinical trials have been completed. Subjects who received the IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap develop antibodies to the product candidate.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap-Eye or in a damage award.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be

prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials.

The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs,

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2005, which report was included in our Annual Report on Form 10-K for the year ended December 31, 2005. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide

commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply

with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. Under a long-term manufacturing agreement with Merck, which expires in October 2006, we produce an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. We also use our facilities to produce API for our own clinical and preclinical candidates. When we no longer use our facilities to manufacture the Merck intermediate or if clinical candidates are discontinued, we will have to absorb overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using

these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Onyx Pharmaceuticals and Bayer have received approval from the FDA to market and sell the first oral medication that targets tumor cell growth and new vasculature

formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the Onyx/Bayer kinase inhibitor, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye diseases is also very competitive. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor (Macugen®) for age-related macular degeneration (wet AMD). Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (LucentisTM) for the treatment of wet AMD and other eye indications that was approved by the FDA in June 2006. In addition, it has been reported that ophthalmologists are using a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The marketing approval of Macugen and Lucentis and the potential off-label use of Avastin make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis or Macugen, because doctors and patients will have significant experience using these medicines. Moreover, the relatively low cost of therapy with Avastin in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Amgen), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Novartis is developing an antibody to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the CIAS1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers.

Sales of biopharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the governments or third-party payers, the market for any biopharmaceutical product will be limited. These third-party payers increasingly challenge the price and examine the cost-effectiveness of products and services. Significant uncertainty exists as to the reimbursement status of any new therapeutic, particularly if there exist lower-cost standards of care. Third-party payers may not reimburse sales of our products, which would harm our business.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, Murray A. Goldberg, our Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, Neil Stahl, Ph.D., our Senior Vice President, Preclinical Development and Biomolecular Science, and Randall G. Rupp, Ph.D., our Senior Vice President, Manufacturing Operations. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;

- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- · arrivals and departures of key personnel; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of April 13, 2006, our seven largest shareholders, including sanofi-aventis, beneficially owned 47.9% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 13, 2006. As of April 13, 2006, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 5.1% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, through September 5, 2006, sanofi-aventis may sell no more than 250,000 of these shares in any calendar quarter. After September 5, 2006, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofiaventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 13, 2006, holders of Class A Stock held 4.1% of all shares of Common Stock and Class A Stock then outstanding, and had 29.7% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 13, 2006:

- our current officers and directors beneficially owned 14.6% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2006, and 33.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 13, 2006; and
- our seven largest shareholders beneficially owned 47.9% of our outstanding shares of Common Stock assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 13, 2006. In addition, these seven shareholders held 54.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of April 13, 2006.

The anti-takeover effects of provisions of our charter, by-laws, and rights agreement, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws, our rights agreement and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the
 outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining
 directors:
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and

• under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

We have a shareholder rights plan which could make it more difficult for a third party to acquire us without the support of our board of directors and principal shareholders. In addition, many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of the Company, as defined in the plan.

Item 4. Submission of Matters to a Vote of Security Holders

On June 9, 2006, we conducted our Annual Meeting of Shareholders pursuant to due notice. A quorum being present either in person or by proxy, the shareholders voted on the following matters:

- 1. To elect four Directors to hold office for a three-year term as Class III directors, and until their successors are duly elected and qualified.
- 2. To ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for our fiscal year ending December 31, 2006.

No other matters were voted on. The number of votes cast was:

	For	Withheld
Election of Class II Directors		
Charles A. Baker.	68,193,948	1,341,920
Michael S. Brown, M.D.	68,530,409	1,005,459
Arthur F. Ryan	68,681,939	853,929
George L. Sing	68,239,673	1,296,195

The terms of office of Leonard S. Schleifer, M.D., Ph.D., Eric M. Shooter, Ph.D., George D. Yancopoulos, M.D., Ph.D., Alfred G. Gilman, M.D., Ph.D., Joseph L. Goldstein, M.D., and P. Roy Vagelos, M.D. continued after the meeting.

	For	Against	Abstain
2. Ratification of the Appointment of Independent Registered Public Accounting Firm	69,093,166	105,312	337,390
52			

Item 6. Exhibits

(a) Exhibits

Exhibit <u>Number</u> 12.1	Description - Statement re: computation of ratio of earnings to combined fixed charges.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
	53

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: August 8, 2006

By: /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

54

Six months

Regeneron Pharmaceuticals, Inc. Computation of Ratio of Earnings to Combined Fixed Charges

(Dollars in thousands)

		ended June 30,				
	2001	2002	rs ended December 3 2003	2004	2005	2006
Earnings: Income (loss) from continuing operations before income (loss) from equity investee	\$(75,178)	\$(124,350)	\$(107,395)	\$41,565	\$(95,456)	(44,769)
Fixed charges Amortization of capitalized interest Interest capitalized	3,888	13,685 — (222)	14,108 33 (276)	14,060 78	13,687 78	6,817 39
Adjusted earnings	\$(71,290)	\$(110,887)	\$ (93,530)	\$55,703	\$(81,691)	\$(37,913)
Fixed charges: Interest expense Interest capitalized Assumed interest component of	\$ 2,657 —	\$ 11,859 222	\$ 11,932 276	\$12,175 —	\$ 12,046 —	\$ 6,022
rental charges	1,231	1,604	1,900	1,885	1,641	795
Total fixed charges	\$ 3,888	\$ 13,685	\$ 14,108	\$14,060	\$ 13,687	\$ 6,817
Ratio of earnings to fixed charges	(A)	(A)	(A)	3.96	(A)	(A)

(A) Due to the registrant's losses for the years ended December 31, 2001, 2002, 2003, and 2005, and for the six months ended June 30, 2006, the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

					ended	
		Years ended December 31,				
	2001	2002	2003	2005	2006	
Coverage deficiency	\$ 75,178	\$124,572	\$107,638	\$ 95,378	\$ 44,730	

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions
 about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such
 evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2006 /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f)) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2006 /s/ Murray A. Goldberg

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer August 8, 2006

/s/ Murray A. Goldberg

Murray A. Goldberg Chief Financial Officer August 8, 2006

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 11/6/2006

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)				
✓	-	SUANT TO SECTIO EXCHANGE ACT (ON 13 OR 15(d) OF THE SECURITIES OF 1934	
	For the quarterly period ended September 30,	<u>2006</u>		
		OR		
_				
		UANT TO SECTIO EXCHANGE ACT (N 13 OR 15 (d) OF THE SECURITIES OF 1934	
	For the transition period from to			
	Commiss	sion File Number <u>0-1903</u> 4	<u>1</u>	
<u>]</u>	REGENERON PHA	ARMACE egistrant as specified in its		
	New York		13-3444607	
	(State or other jurisdiction of incorporation or organization)		(I.R.S. Employer Identification No.)	
	777 Old Saw Mill River Road Tarrytown, New York		10591-6707	
(1	Address of principal executive offices)		(Zip Code)	
		(914) 347-7000		
	(Registrant's telep	phone number, including a	rea code)	
1934 during the			y Section 13 or 15(d) of the Securities Exchange Actuired to file such reports), and (2) has been subject	
	k mark whether the registrant is a large accelerate r and large accelerated filer" in Rule 12b-2 of the l Large accelerated filer □	Exchange Act.	r, or a non-accelerated filer. See definition of Non-accelerated filer □	
Indicate by check	k mark whether the registrant is a shell company	(as defined in Rule 12b-2	of the Exchange Act).	
Indicate the num	nber of shares outstanding of each of the issuer's	classes of common stock	s as of October 31, 2006:	
	Class of Common Stock	<u></u>	Number of Shares	
	Class A Stock, \$0.001 par value Common Stock, \$0.001 par value		2,296,928 55,153,986	

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2006 AND DECEMBER 31, 2005 (Unaudited)

(In thousands, except share data)

	September 30, 2006	December 31, 2005
ASSETS		
Current assets Cash and cash equivalents	\$ 167,662	\$ 184,508
Marketable securities	94,227	114.037
Accounts receivable	7,940	36,521
Prepaid expenses and other current assets	3,920	3,422
Inventory Total current assets	273,749	2,904 341,392
Total current assets	273,749	341,392
Marketable securities	27,708	18,109
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	51,035	60,535
Other assets Total assets	\$ 355,186	3,465 \$ 423,501
Total assets	333,180	\$ 423,301
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable and accrued expenses	\$ 19,054	\$ 23,337
Deferred revenue, current portion	13,644	17,020
Total current liabilities	32,698	40,357
Deferred revenue	60,015	69,142
Notes payable	200,000	200,000
Total liabilities	292,713	309,499
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and outstanding-none		
Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,296,928 in 2006 and 2,347,073 in 2005	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized;	2	2
shares issued and outstanding - 54,784,449 in 2006 and 54,092,268 in 2005	55	54
Additional paid-in capital Unearned compensation	719,157	700,011 (31 5)
Accumulated deficit	(656,646)	(585,280)
Accumulated other comprehensive loss	(95)	(470)
Total stockholders' equity	62,473	114,002
Total liabilities and stockholders' equity	<u>\$ 355,186</u>	<u>\$ 423,501</u>

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share data)

	Three months ended 5	September 30, 2005	Nine months en	ded September 30
Revenues Contract research and development	\$ 11.448	\$ 11,533	\$ 41.026	\$ 38,580
Contract research and development Contract manufacturing	4,176	4,661	12,075	10,189
	15,624	16,194	53,101	48,769
Expenses Research and development	34.808	41.116	101.290	117,670
Contract manufacturing	3,054	3,246	7,716	7,412
General and administrative	6,019	6,219	18,264	18,581
	43,881	50,581	127,270	143,663
Loss from operations	(28,257)	(34,387)	(74,169)	(94,894)
Other income (expense)				
Other contract income	2.2.2.2			30,640
Investment income Interest expense	3,858 (3,011)	2,746 (3,011)	11,023 (9,033)	7,515 (9,035)
microsi expense	847	(265)	1,990	29,120
Net loss before cumulative effect of a change in accounting principle	(27,410)	(34,652)	(72,179)	(65,774)
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")			813	
Standards No. 123K (SFAS 123K)			013	<u></u> :
Net loss	\$ (27,410)	\$ (34,652)	\$ (71,366)	<u>\$ (65,774)</u>
Net loss per share amounts, basic and diluted:				
Net loss before cumulative effect of a change in accounting principle	\$ (0.48)	\$ (0.62)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	\$ (1.18)
Cumulative effect of adopting SFAS 123R	<u> </u>	···· <u>······</u> ·	0.02	<u></u>
Net loss	<u>\$ (0.48</u>)	\$ (0.62)	<u>\$ (1.25)</u>	<u>\$ (1.18)</u>
Weighted average shares outstanding, basic and diluted	57,011	55,978	56,884	55,903

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REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) For the nine months ended September 30, 2006 (In thousands)

					Additional			Accumulated Other	Total	
	Class A S	Amount	Common Shares	-	Paid-in Capital	Unearned Compensation	Accumulated Deficit	Comprehensive Loss	Stockholders'	Comprehensive
Balance, December 31, 2005	2.347	\$2	54.092	Amount \$54	\$700.011	\$(315.)	\$(585,280)	\$(470)	Equity \$114,002	Loss
Issuance of Common Stock in	000 00 88000000000000000000000000000000	00000 0055 0000000	::::::::::::::::::::::::::::::::::::::	50000 %6.6 60.5000000		::::::::::::::::::::::::::::::::::::::	·*(*************			000000000000000000000000000000000000000
connection with exercise of										
stock options, net of shares										
tendered			523	1	4,882				4,883	
Issuance of Common Stock in										
connection with Company										
401(k) Savings Plan										
contribution			121		1,884				1,884	
Conversion of Class A Stock to	(50)		50							
Common Stock Forfeitures of restricted	(50)		50							
Common Stock under Long-										
Term Incentive Plan			(2)							
Stock-based compensation									•	
expense					13,508				13,508	
Adjustment to reduce uncarned										
compensation upon										
adoption of SFAS 123R					(315)	315				
Cumulative effect of adopting					(010)				(014)	
SFAS 123R					(813)		/m1 022 s		(813)	ውን ግ ቱ ግረረ
Net loss Change in net unrealized loss on							(71,366)		(71,366)	\$(71,366_)
marketable securities								375	375	375
marketable securities								515	373	373
Balance, September 30,	3 207	e a	71 - 01	.	\$510.155			4 .07	Ф ко 4772	ф/да.001
2006	2,297	\$2	54,784	\$55	\$719,157		\$(656,646)	\$ (95)	\$ 62,473	\$(70,991_)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Nine months endo	ed September 30, 2005
Cash flows from operating activities		
Net loss	\$ (71,366)	<u>\$ (65,774</u>)
Adjustments to reconcile net loss to net cash provided by operating activities		
Depreciation and amortization	11,196	11,624
Non-cash compensation expense	13,542	17,624
Cumulative effect of a change in accounting principle	(813)	
Changes in assets and liabilities	00 5 01	22.766
Decrease in accounts receivable	28,581	32,566
Decrease (increase) in prepaid expenses and other assets	364	(956)
Decrease in inventory Decrease in deferred revenue	3,524 (12,503.)	1,208
(Decrease) increase in accounts payable, accrued expenses, and other liabilities	(2,753)	(9,398) 2,657
Total adjustments	41,138	55,325
Net cash used in operating activities	(30,228)	(10,449)
Cash flows from investing activities		
Purchases of marketable securities	(252,037)	(91,078)
Sales or maturities of marketable securities	261,749	185,882
Capital expenditures	(1,603)	(4,613)
Net cash provided by investing activities	8,109	90,191
Cash flows from financing activities		
Net proceeds from the issuance of stock	4,883	1,122
Other	390	
Net cash provided by financing activities	5,273	1,122
Net (decrease) increase in cash and cash equivalents	(16,846)	80,864
Cash and cash equivalents at beginning of period	184,508	95,229
Cash and cash equivalents at end of period	\$ 167,662	\$ 176,093
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REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2005 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2005.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. For the three and nine months ended September 30, 2006 and 2005, the Company reported net losses and, therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended September 30,	
	2006	2005
Net loss (Numerator)	\$(27,410)	\$(34,652)
Weighted-average shares, in thousands (Denominator)	57,011	55,978
Basic and diluted net loss per share	\$ (0.48)	\$ (0.62)

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Nine Months Ended September 30,	
	2006	2005
Net loss (Numerator)	\$(71,366)	\$(65,774)
Weighted-average shares, in thousands (Denominator)	56,884	55,903
Basic and diluted net loss per share	\$ (1.25)	S (1.18)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the September 30, 2006 and 2005 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months en	ded September 30,
	2006	2005
Stock Options:	11.000	12.226
Weighted average number, in thousands	14,082	13,236
Weighted average exercise price	\$ 14.35	\$ 14.54
Restricted Stock:		
Weighted average number, in thousands		149
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25
	Nine months er	ded September 30
	Nine months en	ded September 30,
Stock Options:		
Stock Options: Weighted average number, in thousands		
	2006	2005
Weighted average number, in thousands Weighted average exercise price	2006 14,220	2005 13,335
Weighted average number, in thousands Weighted average exercise price Restricted Stock:	2006 14,220 \$ 14.31	2005 13,335 \$ 14.61
Weighted average number, in thousands Weighted average exercise price	2006 14,220	2005 13,335
Weighted average number, in thousands Weighted average exercise price Restricted Stock: Weighted average number, in thousands	2006 14,220 \$ 14.31	2005 13,335 \$ 14.61
Weighted average number, in thousands Weighted average exercise price Restricted Stock: Weighted average number, in thousands Convertible Debt:	2006 14,220 \$ 14.31	2005 13,335 \$ 14.61
Weighted average number, in thousands Weighted average exercise price Restricted Stock: Weighted average number, in thousands	2006 14,220 \$ 14.31	2005 13,335 \$ 14.61

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

3. Stock-based Employee Compensation

Adoption of Statement of Financial Accounting Standards Nos. 123 and 123R

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, Accounting for Stock-Based Compensation, using the modified prospective method as described in SFAS 148, Accounting for Stock-Based Compensation — Transition and Disclosure. As a result, in 2005, the Company recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced the Company's loss by \$813 and is included in the Company's operating results for the nine months ended September 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on the Company's loss from operations, net loss, and net loss per share for the three and nine months ended September 30, 2006 was not significant, and there was no impact to the Company's cash flows for these respective periods.

Long-Term Incentive Plans

The Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan ("2000 Incentive Plan"), as amended, provides for the issuance of up to 18,500,000 shares of Common Stock in respect of awards. In addition, certain shares of Common Stock previously approved by shareholders for issuance under the Regeneron Pharmaceuticals,

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

Inc. 1990 Long-Term Incentive Plan ("1990 Incentive Plan") that are not issued under the 1990 Incentive Plan, may be issued as awards under the 2000 Incentive Plan. The 1990 Incentive Plan, as amended, provided for a maximum of 6,900,000 shares of Common Stock in respect of awards. The 1990 Incentive Plan has expired and there will be no future awards from the 1990 Incentive Plan. The Company has issued Incentive Stock Options ("ISOs") and Nonqualified Stock Options, and shares of Restricted Stock from the 1990 and 2000 Incentive Plans. The terms of the awards are determined by the Compensation Committee of the board of directors; however, in the case of an ISO, the option exercise price will not be less than the fair market value of a share of Common Stock on the date the ISO is granted and no ISO is exercisable more than ten years after the date of grant. As of September 30, 2006, there were 6,563,402 shares available for future grants under the 2000 Incentive Plan.

a. Stock Options

At September 30, 2006, there were 13,967,474 stock options outstanding with exercise prices ranging from \$4.83 to \$51.56. Options granted to employees generally vest annually on a pro rata basis over a four to five year period beginning one year from the date of grant. Certain performance-based options granted to the Company's executive vice president and senior vice presidents in January 2005 vest if both (i) the Company's products have achieved defined sales targets and (ii) the option recipient has remained employed by the Company for at least three years from the date of grant. Options granted to members of the Company's board of directors vest annually on a pro rata basis over three years beginning one year from the date of grant. A summary of the Company's stock option activity for the nine months ended September 30, 2006 is presented in the following table:

		Weighted		
		Average	Weighted	
		Remaining	Average	Intrinsic
	Number	Contractual	Exercise	Value (in
	Outstanding	Life	Price	thousands)
Stock options outstanding at January 1, 2006	14,719,492		\$14.23	
Stock options granted	280,900		\$14.90	
Stock options exercised	(552,785)		\$ 9.72	
Stock options forfeited	(315,115)		\$10.47	
Stock options expired	(165,018)		\$24.17	
Stock options outstanding at September 30, 2006	13,967,474	6.30	\$14.39	\$59,450
Stock options vested and exercisable	7 087 863	4.89	\$17.79	\$24 221

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

The total intrinsic value of stock options exercised during the first nine months of 2006 and 2005 was \$3,548 and \$220, respectively. The intrinsic value represents the amount by which the market price of the underlying stock exceeds the exercise price of an option.

For the three months ended September 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") recognized in operating expenses totaled \$4,762 and \$5,439, respectively, which included \$94 and \$65, respectively, of Stock Option Expense previously capitalized in inventory. Stock Option Expense recognized in operating expenses for the nine months ended September 30, 2006 and 2005 totaled \$13,243, which included \$34 previously capitalized in inventory, and \$16,166, respectively. In addition, for the nine months ended September 30, 2005, \$147 of Stock Option Expense was capitalized into inventory. As of September 30, 2006, there was \$19,132 of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. The Company expects to recognize this compensation cost over a weighted-average period of 1.43 years. In addition, there are 723,092 options which are unvested as of September 30, 2006 and would become vested upon the Company's products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2,688 and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Fair Value Assumptions:

The fair value of each option granted during the three and nine months ended September 30, 2006 and 2005 was estimated on the date of grant using the Black-Scholes option-pricing model. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of the Company's Common Stock price, (ii) the periods of time over which employees and members of the Company's board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on the Company's Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in the Company's stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on the Company's limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as the Company has never paid dividends and does not currently anticipate paying any in the foreseeable future. The weighted-average fair value of the options granted during the three months ended September 30, 2006 and 2005 was \$8.30 and \$5.12 per option, respectively. The weighted-average fair value of the options granted during the nine months ended September 30, 2006 and 2005 was \$9.75 and \$5.79 per option, respectively. The following table summarizes the weighted average values of the assumptions used in computing the fair value of option grants.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Three months er	nded September 30,
	2006	2005
Expected volatility	65%	70%
Expected lives from grant date	5.5 years	5.0 years
Expected dividend yield	0%	0%
Risk-free interest rate	4.74%	4.00%
	Nine months er	nded September 30,
	Nine months er	nded September 30, 2005
Expected volatility		
Expected lives from grant date	2006	2005
Expected volatility Expected lives from grant date Expected dividend yield	2006 67%	2005 75%

b. Restricted Stock

A summary of the Company's activity related to Restricted Stock awards for the nine months ended September 30, 2006 is presented in the following table:

		Weighted
	Number	Average Grant Date Fair Value
	Of Shares	Date Fair Value
Restricted stock outstanding as of January 1, 2006	95,188	\$11.16
Restricted stock released	(93,485)	\$11.18
Restricted stock forfeited		\$ 9.74
Restricted stock outstanding as of September 30, 2006		

In accordance with generally accepted accounting principles, the Company recorded unearned compensation in Stockholders' Equity related to these Restricted Stock awards. The amount was based on the fair market value of shares of the Company's Common Stock on the date of grant and is expensed, on a pro rata basis, over the period that the restrictions lapse, which is approximately two years for grants issued in 2003 and 18 months for grants issued in 2004. No Restricted Stock awards were granted in 2005 or during the nine months ended September 30, 2006. Prior to the adoption of SFAS 123R, unearned compensation was included as a separate component of Stockholders' Equity. Effective January 1, 2006, unearned compensation was combined with additional paid-in capital in accordance with the provisions of SFAS 123R.

For the three months ended September 30 2005, the Company recognized compensation expense related to Restricted Stock awards of \$482. For the nine months ended September 30, 2006 and 2005, the Company recognized compensation expense

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

related to Restricted Stock awards of \$299 and \$1,458, respectively. As of September 30, 2006, there were no unvested shares of restricted stock outstanding and all compensation expense related to these awards had been recognized.

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2006 and December 31, 2005 are \$439 and \$234, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2005 and December 31, 2004 are \$252 and \$550, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2005 and 2004 are \$1,884 and \$632, respectively, of accrued Company 401 (k) Savings Plan contribution expense. In the first quarter of 2006 and 2005, the Company contributed 120,960 and 90,385 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2006 and December 31, 2005 are \$354 and \$1,228, respectively, of accrued interest income. Included in marketable securities at September 30, 2005 and December 31, 2004 are \$1,110 and \$2,607, respectively, of accrued interest income.

5. Severance Costs

In September 2005, the Company announced plans to reduce its workforce by approximately 165 employees in connection with narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the June 2005 expiration of the Company's collaboration with The Procter & Gamble Company, and the completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions have been occurring in 2006 as the Company completes activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005. Estimated termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

2006 workforce reductions will approximate \$2.6 million, including \$0.2 million of non-cash expenses in 2005.

Severance costs associated with the workforce reduction plan that were charged to expense, or credited to adjust original cost estimates, during the three and nine months ended September 30, 2006 consist of the following:

		Three mon September		
	Accrued	Costs		Accrued
	liability at	charged	Costs paid	liability at
	June 30, 2006	(credited) to expense	or settled in 2006	September 30, 2006
Employee severance, payroll taxes, and benefits	\$ 463	\$ (44)	§ (273)	\$ 146
Other severance costs	<u> </u>	6	<u>(7</u>)	<u></u>
Total	\$ 464	\$ (38)	\$ (280)	\$ 146
		Nine mon		
	Accrued	September		Accrued
	liability at	Costs	Costs paid	liability at
	December	charged to	or settled	September 30,
	31, 2005	expense	<u>in 2006</u>	2006
Employee severance, payroll taxes, and benefits	\$ 907	\$ 312	\$ (1,073)	\$ 146
Other severance costs	<u> 176</u>	26	(202)	
Total	<u>\$ 1,083</u>	\$ 338	<u>\$ (1,275</u>)	<u>\$ 146</u>

These severance costs are included in the Company's Statement of Operations for the three and nine months ended September 30, 2006 as follows:

	Research &
Three months ended September 30, 2006	development
Employee severance, payroll taxes, and benefits	S (44)
Other severance costs	6
Total	<u>\$ (38)</u>

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Research &	General &
Nine months ended September 30, 2006	development	administrative
Employee severance, payroll taxes, and benefits	S 314	\$ (2)
Other severance costs	26	
Total	\$ 340	<u>\$ (2)</u>

For segment reporting purposes (see Note 11), all severance-related expenses are included in the Research & Development segment.

6. Accounts Receivable

Accounts receivable as of September 30, 2006 and December 31, 2005 consist of the following:

	September 30,	December 31,
	2006	2005
Receivable from the sanofi-aventis Group	5 7.326	\$ 36.412
Receivable from Merck & Co., Inc.	511	27
Other		
	\$ 7,940	\$ 36,521

7. Inventories

Inventories consist of raw materials, work-in process, and finished products associated with the production of an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which expired in October 2006.

The Company held no inventories at September 30, 2006. Inventories as of December 31, 2005 consist of the following:

Dec	ember 31,
	2005
Raw materials 5	278
Work-in-process	1,423
Finished products	
<u>\$</u>	2,904

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

8. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2006 and December 31, 2005 consist of the following:

	September 30,	December 31,
	2006	2005
Accounts payable	\$ 3,657	\$ 4,203
Accrued payroll and related costs	5,952	10,713
Accrued clinical trial expense	2,145	3,081
Accrued expenses, other	2,258	3,048
Interest payable on convertible notes	5,042	2,292
	\$ 19,054	\$ 23,337

9. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three and nine months ended September 30, 2006 and 2005, the components of comprehensive loss are:

	Three months end	led September 30,
	2006	2005
Net loss	\$ (27,410)	\$ (34,652)
Change in net unrealized gain (loss) on marketable securities	378	27
Total comprehensive loss	\$ (27,032)	\$ (34,625)
	Nine months ende	ed September 30,
	2006	2005
Net loss	\$ (71,366)	\$ (65,774)
Change in net unrealized gain (loss) on marketable securities	<u>375</u>	87
Total comprehensive loss	\$ (70,991)	<u>\$ (65,687)</u>

10. National Institutes of Health Grant

In September 2006, the Company was awarded a grant from the National Institutes of Health ("NIH") as part of the NIH's Knockout Mouse Project. The NIH grant provides a minimum of \$17.9 million in funding over a five-year period, subject to compliance with

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

its terms and annual funding approvals, for the Company's use of its VelociGene® technology to generate a collection of targeting vectors and targeted mouse embryonic stem cells ("ES Cells") which can be used to produce knockout mice. The Company will also receive another \$1.0 million in funding to optimize certain existing technology for use in the Knockout Mouse Project. In September 2006, we recognized contract research and development revenue of \$57 from the NIH Grant.

11. Segment Information

The Company's operations are managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to (i) the development of manufacturing processes prior to commencing commercial production of a product under contract manufacturing arrangements, and (ii) the supply of research materials based on Regeneron-developed proprietary technology.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. The Company produced an intermediate for a Merck & Co., Inc. pediatric vaccine under a long-term manufacturing agreement which expired in October 2006.

The table below presents information about reported segments for the three and nine months ended September 30, 2006 and 2005.

	Three months ended September 30, 2006			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 11,448	\$4,176		\$ 15,624
Depreciation and amortization	3,447	(1)	\$ 261	3,708
Non-cash compensation expense	4,632	130		4,762
Interest expense		_	3,011	3,011
Net (loss) income	(29,379)	1,122	847 (2)	(27,410)
Capital expenditures	441	_	_	441

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended September 30, 2005			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 11,533	\$4,661		\$ 16,194
Depreciation and amortization	3,674	(1)	\$ 261	3,935
Non-cash compensation expense	5,703	218		5,921
Interest expense		_	3,011	3,011
Net (loss) income	(35,802)	1,415	(265-)(2)	(34,652)
Capital expenditures	575	_		575

	Nine months ended September 30, 2006			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 41,026	\$12,075		\$ 53,101
Depreciation and amortization	10,413	(1)	\$ 783	11,196
Non-cash compensation expense	13,220	322	(813)(3)	12,729
Interest expense	_	_	9,033	9,033
Net (loss) income	(78,528)	4,359	2,803 (2)	(71,366)
Capital expenditures	1,409	_	_	1,409
Total assets	57,530	1,445	296,211 (4)	355,186

	Nine months ended September 30, 2005			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 38,580	\$10,189	<u></u>	\$ 48,769
Depreciation and amortization	10,841	(1)	\$ 783	11,624
Non-cash compensation expense	17,316	308		17,624
Other contract income	30,640	_	_	30,640
Interest expense		<u></u>	9,035	9,035
Net (loss) income	(67,031)	2,777	$(1,520)^{(2)}$	(65,774)
Capital expenditures	4,327			4,327
Total assets	72,037	5,380	341,858 (4)	419,275

Depreciation and amortization related to contract manufacturing was capitalized into inventory and included in contract manufacturing expense when the product was shipped.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

- 2) Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the nine months ended September 30, 2006, also includes the cumulative effect of adopting SFAS 123R (see Note 3).
- (3) Represents the cumulative effect of adopting SFAS 123R (see Note 3).
- (4) Includes cash and cash equivalents, marketable securities, prepaid expenses and other current assets, and other assets.

12. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

13. Future Impact of Recently Issued Accounting Standards

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company will be required to adopt FIN 48 effective for the fiscal year beginning January 1, 2007. Management is currently evaluating the potential impact of adopting FIN 48 on the Company's financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles ("GAAP"), and expands disclosures about fair value measurements. The Company will be required to adopt SFAS 157 effective for the fiscal year beginning January 1, 2008. Management is currently evaluating the potential impact of adopting SFAS 157 on the Company's financial statements.

14. Subsequent Event — New Research and Development Agreement

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC ("Bayer") to globally develop, and commercialize outside the United States, the Company's Vascular Endothelial Growth Factor ("VEGF") Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer made a non-refundable up-front payment to the Company of \$75.0 million. In addition, the Company is eligible to receive up to \$110.0 million in

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

development and regulatory milestones, including a total of \$40.0 million upon the initiation of Phase 3 trials in defined major indications. The Company is also eligible to receive up to an additional \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

The Company will share equally with Bayer in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. Within the United States, the Company is responsible for any future commercialization of the VEGF Trap-Eye and has retained exclusive rights to any future profits arising therefrom.

Agreed upon development expenses incurred by both companies under a global development plan will be shared as follows:

2007: Up to \$50.0 million shared equally, we are solely responsible for up to the next \$40.0 million; over \$90.0 million shared equally.

2008: Up to \$70.0 million shared equally, we are solely responsible for up to the next \$30.0 million; over \$100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, the Company will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and the Company's share of the collaboration profits, or at a faster rate at the Company's option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, the Company retains all rights to the VEGF Trap-Eye.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: VEGF Trap in oncology, VEGF Trap eye formulation (VEGF Trap-Eye) in eye diseases using intraocular delivery, and the IL-1 Trap (rilonacept) in various inflammatory indications. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. In October 2006, we entered into a collaboration with Bayer HealthCare LLC for the development of the VEGF Trap-Eye. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. Our efforts have yielded a diverse pipeline of product candidates that we believe has the potential to address a variety of serious medical conditions. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the strength of the VelocImmune platform, which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move two new antibody candidates into clinical trials each year going forward beginning in 2007. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Clinical Programs:

Below is a summary of the clinical status of our clinical candidates as of September 30, 2006:

1. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis. Currently, the collaboration is conducting three Phase 2 studies, with patient enrollment underway in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the United States Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for the treatment of SMA. In addition, four new Phase 2 single-agent studies are beginning in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) in metastatic breast cancer, metastatic or unresectable kidney cancer, recurrent ovarian cancer, and recurrent malignant gliomas. We and sanofi-aventis are working to finalize plans with NCI/CTEP for at least six additional trials in different cancer types.

Sanofi-aventis and Regeneron intend to conduct three Phase 3 trials evaluating the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer types, the first of which is planned to begin in early 2007. Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are in progress in a variety of cancer types to support the planned Phase 3 clinical program. The companies have previously summarized information from two of these safety and tolerability trials. One study is evaluating the VEGF Trap in combination with oxaliplatin, 5-flourouracil, and leucovorin (FOLFOX4) in a Phase 1 trial of patients with advanced solid tumors. Another study is evaluating the VEGF Trap in combination with irinotecan, 5-fluorouracil, and leucovorin (LV5FU2-CPT11) in a Phase 1 trial of patients with advanced solid tumors. Abstracts published in the 2006 ASCO Annual Meeting Proceedings reported that the VEGF Trap could be safely combined with either FOLFOX4 or LV5FU2-CPT11 at the dose levels studied. The maximum tolerated doses in these studies have not yet been reached, and dose escalation is continuing.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular

system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to \$400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another \$40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. (See "The sanofi-aventis Group Agreement" below.)

2. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 2 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and in a small pilot study in patients with diabetic macular edema (DME).

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States, of the VEGF Trap-Eye. Under the agreement we and Bayer will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic

eye diseases, and other diseases and disorders. The companies will share equally in profits from any future sales of the VEGF Trap-Eye outside the United States. Within the United States, we retained exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare and can earn up to \$110.0 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135.0 million in sales milestones if total annual sales of the VEGF Trap outside the United States achieve certain specified levels starting at \$200 million. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Detailed information about this agreement is included in the section below entitled "Collaboration with Bayer HealthCare."

In the second quarter of 2006, we initiated a 150 patient, 12 week, Phase 2 trial of the VEGF Trap-Eye in wet AMD. The trial is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. Regeneron is initiating a Phase 1 safety and tolerability trial of a new formulation of the VEGF Trap-Eye in AMD. A Phase 3 trial of the VEGF Trap-Eye in wet AMD utilizing the new formulation is planned to begin in early 2007.

Also in the second quarter of 2006, we initiated a small pilot study of the VEGF Trap in patients with DME.

At the 2006 American Society of Retinal Specialists (ASRS) annual meeting in France, we updated the positive preliminary results from a Phase 1 trial of the VEGF Trap-Eye in patients with wet AMD. A total of 21 patients received a single dose of VEGF Trap-Eye at doses of 0.05, 0.15, 0.5, 1, 2, and 4 milligrams (mg) intravitreally (direct injection into the eye). Patients were evaluated for six weeks to measure the durability of effects and provide guidance for dosing regimens to be used in future trials. All dose levels were generally well tolerated, and a maximum tolerated dose was not reached in the study. In wet AMD, the leakiness of the abnormal blood vessels in the eye can lead to increased retinal thickness. On average, patients receiving the VEGF Trap-Eye demonstrated large, rapid, and sustained (at least six weeks) reductions in retinal thickness. Excess retinal thickness, as determined by ocular coherence tomography (OCT), is a clinical measure of disease activity in wet AMD. As measured by the OCT reading center (posterior pole OCT scans), the median excess retinal thickness resulting from the disease process was 194 microns at baseline. Following a single intravitreal dose of the VEGF Trap-Eye, median excess retinal thickness was reduced to 60 microns, an improvement that was sustained over a six week period. As measured by the computerized Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline, which was reduced to 27 microns at six weeks after the single dose of the VEGF Trap-Eye.

Of the 20 patients evaluable for efficacy, 95 percent had stabilization or improvement in visual acuity, defined as \leq 15 letter loss on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. Patients were also evaluated for best-corrected visual acuity (BCVA), the best acuity a person can achieve with glasses. BCVA for all patients in the study increased by a mean of 4.8 letters at six weeks. In the two highest dose groups (2 mg and 4 mg), the mean

improvement in BCVA was 13.5 letters, with three of six patients showing an improvement in BCVA of 15 or more letters.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and LucentisTM (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. It is estimated that in the U.S. 6% of individuals aged 65-74 and 20% of those older than 75 are affected with wet AMD. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

3. IL-1 Trap (rilonacept) — Inflammatory Diseases

The IL-1 Trap (rilonacept) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called CIAS1-related Autoinflammatory Periodic Syndromes (CAPS) and other diseases associated with inflammation.

In October 2006, we announced positive data from a Phase 3 clinical program designed to provide two separate demonstrations of efficacy for the IL-1 Trap within a single group of adult patients suffering from CAPS. The Phase 3 program of the IL-1 Trap included two studies (Part A and Part B). Both studies met their primary endpoints (Part A: p < 0.0001 and Part B: p < 0.001). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

We plan to file a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) in the second quarter of 2007, following completion of a 24-week open-label extension phase. The FDA has granted Orphan Drug status and Fast Track designation to the IL-1 Trap for the treatment of CAPS.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive the IL-1 Trap had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo (p<0.0001). Following a 9-week interval during which all patients received the IL-1 Trap, a "randomized withdrawal" study (Part B) was performed, in which the same patients were re-randomized to either switch to placebo or continue treatment with the IL-1 Trap in a double-

blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on the IL-1 Trap who had no significant change (p<0.001). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on the IL-1 Trap than on placebo. In these studies, the IL-1 Trap appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study. The 24-week open-label extension phase is ongoing.

CAPS is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID). These syndromes are characterized by spontaneous systemic inflammation and are termed autoinflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS are caused by a range of mutations in the gene *CIASI* (also known as NALP3) which encodes a protein named cryopyrin ("icy-fire"). Currently, there are no medicines approved for the treatment of CAPS.

We are also evaluating the potential use of the IL-1 Trap in other indications. In particular, based on preclinical evidence that IL-1 appears to play a critical role in gout, we are preparing to initiate an exploratory study in gout in early 2007. In an ongoing pilot study in systemic juvenile idiopathic arthritis (SJIA), we observed evidence of biological activity and clinical response, but also noted clinical variability across the SJIA patients. While we continue to evaluate the IL-1 Trap in these patients, no new studies are currently planned.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our IL-1 Trap currently in clinical development.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In

addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2006, we had a cumulative loss of \$656.6 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and IL-1 Trap; advance new product candidates into clinical development from our existing research programs; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend, among other factors, on the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events for 2006 and plans over the next 12 months are as follows:

Product Candidate

VEGF Trap — Oncology

2006 Events to Date

- Initiated Phase 2 studies of the VEGF Trap as a single agent in AOC and NSCLA patients, and in AOC patients with SMA.
- Initiated two safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens
- Reported encouraging preliminary results of the safety and tolerability of intravenous VEGF Trap plus FOLFOX4 and of intravenous VEGF Trap plus LV5FU2-CPT11 in separate Phase 1 trials of patients with advanced solid tumors
- NCI/CTEP finalized protocols for Phase 2 trials of the VEGF Trap in metastatic breast cancer, metastatic or unresectable kidney cancer, recurrent ovarian cancer, and recurrent malignant gliomas

2006-7 Plans

- Initiate up to three efficacy/safety studies of the VEGF Trap in combination with standard chemotherapy regimens in different cancer indications
- Sponsor with the NCI/CTEP at least six additional exploratory efficacy/safety studies evaluating the VEGF Trap in a variety of cancer types

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Product Candidate VEGF Trap-Eye	 Reported positive preliminary results from Phase 1 trial in wet AMD utilizing intravitreal injections in 21 patients up to a top dose of 4 mg Initiated Phase 2 trial in wet AMD utilizing intravitreal injections Initiated safety and tolerability study of the new formulation of the VEGF Trap-Eye in patients with AMD Initiated Phase 1 trial in DME Initiated collaboration with Bayer HealthCare 	 2006-7 Plans Report preliminary results of Phase 2 trial in wet AMD utilizing intravitreal injections Initiate Phase 3 trial in wet AMD utilizing intravitreal injections of the VEGF Trap-Eye Explore additional eye disease indications
IL-1 Trap (rilonacept)	 Reported positive results from efficacy portion of Phase 3 trial of the IL-1 Trap in CAPS Reported positive preliminary results from ongoing Phase 1 trial in SJIA 	 File Biologics License Application with the FDA for CAPS Evaluate the IL-1 Trap in other disease indications in which IL-1 may play an important role

Collaboration with Bayer Healthcare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare to globally develop, and commercialize outside the United States, the VEGF Trap-Eye. Under the terms of the agreement, Bayer made a non-refundable up-front payment to us of \$75.0 million. In addition, we are eligible to receive up to \$110.0 million in development and regulatory milestones, including a total of \$40.0 million upon the initiation of Phase 3 trials in defined major indications such as wet AMD and DME. We are also eligible to receive up to an additional \$135.0 million in sales milestones when and if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

We will share equally with Bayer in any future profits arising from the commercialization of the VEGF Trap-Eye outside the United States. Within the United States, we are responsible for any future commercialization of the VEGF Trap-Eye and have retained exclusive rights to any future profits arising therefrom.

Agreed upon development expenses incurred by both companies under a global development plan will be shared as follows:

2007: Up to \$50.0 million shared equally; we are solely responsible for up to the next \$40.0 million; over \$90.0 million shared equally.

2008: Up to \$70.0 million shared equally, we are solely responsible for up to the next \$30.0 million; over \$100.0 million shared equally.

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2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and our share of the collaboration profits, or at a faster rate at our option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We will use our VelociGene® technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We have also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our VelociGene technology in the Knockout Mouse Project. We will generate a collection of targeting vectors and targeted mouse embryonic stem cells (ES cells) which can be used to produce knockout mice. These materials will be made widely available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, we will be entitled to receive a minimum of \$17.9 million over a five-year period. We will receive another \$1.0 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which will be supplied to the research consortium for its use in the Knockout Mouse Project. We will have the right to use, for any purpose, all materials generated by us and the research consortium.

Accounting for Stock-based Employee Compensation

Effective January 1, 2005, we adopted the fair value based method of accounting for stock-based employee compensation under the provisions of Statement of Financial Accounting Standards No. ("SFAS") 123, Accounting for Stock-Based Compensation, using the modified prospective method as described in SFAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure. As a result, in 2005, we recognized compensation expense, in an amount equal to the fair value of share-based payments (including stock option awards) on their date of grant, over the vesting period of the awards using graded vesting, which is an accelerated expense recognition method. Under the modified prospective method, compensation expense for Regeneron is recognized for (a) all share based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, we adopted the provisions of SFAS 123R, *Share-Based Payment*, which is a revision of SFAS 123. SFAS 123R focuses primarily on accounting for transactions

in which an entity obtains employee services in share-based payment transactions, and requires the recognition of compensation expense in an amount equal to the fair value of the share-based payment (including stock options and restricted stock) issued to employees. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, we recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, we were required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the SFAS 123R adoption date. This adjustment reduced our loss by \$0.8 million and is included in our operating results for the nine months ended September 30, 2006 as a cumulative-effect adjustment of a change in accounting principle. Exclusive of the cumulative-effect adjustment, the effect of the change from applying the provisions of SFAS 123 to applying the provisions of SFAS 123R on our loss from operations, net loss, and net loss per share for the three and nine months ended September 30, 2006 was not significant, and there was no impact to our cash flows for these respective periods.

For the three months ended September 30, 2006 and 2005, non-cash stock-based employee compensation expense related to stock option awards ("Stock Option Expense") recognized in operating expenses totaled \$4.8 million and \$5.4 million, respectively, which, in both periods, included \$0.1 million in each period of Stock Option Expense previously capitalized in inventory. Stock Option Expense recognized in operating expenses for the nine months ended September 30, 2006 and 2005 totaled \$13.2 million and \$16.2 million, respectively. In addition, for the nine months ended September 30, 2005, \$0.1 million of Stock Option Expense was capitalized into inventory. As of September 30, 2006, there was \$19.1 million of stock-based compensation cost related to outstanding nonvested stock options, net of estimated forfeitures, which had not yet been recognized in operating expenses. We expect to recognize this compensation cost over a weighted-average period of 1.43 years. In addition, there are 723,092 options which are unvested as of September 30, 2006 and would become vested upon our products achieving certain sales targets and the optionee satisfying certain service conditions. Potential compensation cost, measured on the grant date, related to these performance options totals \$2.7 million and will begin to be recognized only if, and when, these options' performance condition becomes probable of attainment.

Assumptions

We use the Black-Scholes model to estimate the fair value of each option granted under the Regeneron Pharmaceuticals, Inc. 2000 Long-Term Incentive Plan. Using this model, fair value is calculated based on assumptions with respect to (i) expected volatility of our Common Stock price, (ii) the periods of time over which employees and members of our board of directors are expected to hold their options prior to exercise (expected lives), (iii) expected dividend yield on our Common Stock, and (iv) risk-free interest rates, which are based on quoted U.S. Treasury rates for securities with maturities approximating the options' expected lives. Expected volatility has been estimated based on actual movements in our stock price over the most recent historical periods equivalent to the options' expected lives. Expected lives are principally based on our limited historical exercise experience with option grants with similar exercise prices. The expected dividend yield is zero as we have never paid dividends and do not currently anticipate paying any in the foreseeable future. The following table summarizes the weighted average

values of the assumptions we used in computing the fair value of option grants during the three and nine months ended September 30, 2006 and 2005:

	Inree months ended September 30,			
	2006	2005		
Expected volatility	65%	70%		
Expected lives from grant date	5.5 years	5.0 years		
Expected dividend yield	0%	0%		
Risk-free interest rate	4.74%	4.00%		

	Nine months ended September 30,			
	2006	2005		
Expected volatility	67%	75%		
Expected lives from grant date	6.5 years	6.2 years		
Expected dividend yield	0%	0%		
Risk-free interest rate	4.76%	3.96%		

Changes in any of these estimates may materially affect the fair value of stock options granted and the amount of stock-based compensation recognized in any period.

Results of Operations

Three Months Ended September 30, 2006 and 2005

Net Loss:

We reported a net loss of \$27.4 million, or \$0.48 per share (basic and diluted), for the third quarter of 2006 compared to a net loss of \$34.7 million, or \$0.62 per share (basic and diluted), for the third quarter of 2005.

Revenues:

Revenues for the three months ended September 30, 2006 and 2005 consist of the following:

					I	Increase	
(In millions)	2	2006		2005		(Decrease)	
Contract research & development revenue							
The sanofi-aventis Group	\$	10.0	\$	11.2	\$	(1.2)	
Other			_	0,3		1,1	
Total contract research & development revenue		11.4		11.5		(0.1)	
Contract manufacturing revenue		4.2	_	4,7		(0.5)	
Total revenue	\$	15.6	<u>\$</u>	16.2	\$	(0.6)	

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and

2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104).

Sanofi-aventis Contract Research & Development Revenue

	Three months end	led September 30,
(In millions)	2006	2005
Regeneron expense reimbursement	\$ 7.0	S 8.9
Recognition of deferred revenue related to up-front payments	3.0	2.3
Total	\$ 10.0	<u>\$ 11,2</u>

Sanofi-aventis' reimbursement of our VEGF Trap expenses decreased in the third quarter of 2006 from the same period in 2005, primarily due to lower costs in the third quarter of 2006 related to our manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments increased in the third quarter of 2006 from the same period in 2005, due to our January 2006 receipt of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan. As of September 30, 2006, \$72.2 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Contract manufacturing revenue relates to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Contract manufacturing revenue decreased in the third quarter of 2006 from the same period of 2005 as we shipped less product to Merck in 2006. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the third quarter of 2006 and 2005 were \$0.4 million and \$0.5 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. Merck deferred revenue has been recognized as product is shipped, based upon Merck's order quantities during the term of the agreement. In September 2006, we made the final shipment of product to Merck under the Merck agreement and the remaining deferred revenue associated with the capital improvement reimbursements was recognized. Subsequent to the October 2006 expiration of the Merck agreement, we do not expect to receive any further contract manufacturing revenue from Merck.

Expenses:

Total operating expenses decreased to \$43.9 million in the third quarter of 2006 from \$50.6 million in the same period of 2005, due, in part, to our lower headcount. Our average headcount declined to 574 in the third quarter of 2006 from 728 in the same period of 2005 primarily as a result of workforce reductions made in the fourth quarter of 2005. (See "Severance Costs" below.)

Operating expenses in the third quarter of 2006 and 2005 include a total of \$4.7 million and \$5.5 million of Stock Option Expense, respectively, as detailed below:

(In millions)	ions) For the three months ended September 30, 2006			<u> </u>		
Expenses	inclusion	es before 1 of Stock Expense		Option pense	-	enses as ported
Research and development	\$	32.1	\$	2.7	S	34.8
Contract manufacturing		3.0		0.1		3.1
General and administrative		4.1		1.9		6,0
Total operating expenses	\$	39.2	\$	4.7	\$	43.9
(In millions)	F	or the three m	onths ende	d September	r 30, 2005	<u>; </u>
	-	es before 1 of Stock	Stock	Option	Expe	enses as
Expenses	<u>Option</u>	Expense_	Ex	pense	Rej	ported
Research and development	S	37.8	\$	3.3	\$	41.1
Contract manufacturing		3.0		0.3		3.3
General and administrative		4,3		1,9	<u></u>	6.2
Total operating expenses	\$	45.1	\$	5.5	\$	50.6

Research and Development Expenses:

Research and development expenses decreased to \$34.8 million in the third quarter of 2006 from \$41.1 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2006 and 2005:

(In millions)	Three months ended September 30,		nber 30,
			Increase
Research and development expenses	2006	2005(1)	(Decrease)
Payroll and benefits (2)	\$ 11.0	\$ 12.8	(\$1,8)
Clinical trial expenses	3.1	7.5	(4.4)
Clinical manufacturing costs (3)	10,0	10.8	(0.8)
Research and preclinical development costs	5.5	4.5	1.0
Occupancy and other operating costs	5.2	5.5	(0.3)
Total research and development	\$ 34.8	<u>\$ 41.1</u>	(\$6.3)

⁽¹⁾ For the major categories of research and development expenses, amounts for the three months ended September 30, 2005 have been reclassified to conform with, and be comparable to, the current period's presentation. Total research and development expenses for the three months ended September 30, 2005 are unchanged from amounts previously reported.

Payroll and benefits decreased principally due to our lower headcount in the third quarter of 2006, as described above. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006, as we discontinued clinical development of the IL-1 Trap in adult rheumatoid

⁽²⁾ Includes \$2.3 million and \$2.8 million of Stock Option Expense for the three months ended September 30, 2006 and 2005, respectively.

⁽³⁾ Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.5 million of Stock Option Expense for both the three months ended September 30, 2006 and 2005.

arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased as we were not actively manufacturing clinical supplies of our drug candidates during the third quarter of 2006. Research and preclinical development costs increased primarily due to higher third-party pre-clinical testing costs in connection with our VEGF Trap and VEGF Trap-Eye programs. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased to \$3.1 million in the third quarter of 2006 from \$3.3 million in the comparable quarter of 2005 primarily because we shipped less product to Merck.

General and Administrative Expenses:

General and administrative expenses decreased to \$6.0 million in the third quarter of 2006 from \$6.2 million in the same period of 2005, primarily due to lower professional fees for accounting and other administrative advisory services and lower facility-related costs, which were partly offset by higher patent-related costs and legal expenses related to general corporate matters.

Other Income and Expense:

Investment income increased to \$3.9 million in the third quarter of 2006 from \$2.7 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was \$3.0 million in the third quarter of 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Nine Months Ended September 30, 2006 and 2005

Net Loss:

We reported a net loss of \$71.4 million, or \$1.25 per share (basic and diluted), for the first nine months of 2006 compared to a net loss of \$65.8 million, or \$1.18 per share (basic and diluted), for the same period of 2005. Results for the first nine months of 2005 included a \$25.0 million one-time, non-recurring payment from sanofi-aventis, which was recognized as other contract income, in connection with the January 2005 amendment to our collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap-Eye.

Revenues:

Revenues for the nine months ended September 30, 2006 and 2005 consist of the following:

			Increase
(In millions)	2006	2005	(Decrease)
Contract research & development revenue			
The sanofi-aventis Group	\$ 38.7	\$ 30.4	\$ 8.3
The Procter & Gamble Company		6.0	(6.0)
Other	2.3	2.2	0.1
Total contract research & development revenue	41.0	38.6	2.4
Contract manufacturing revenue	12.1	10.2	1.9
Total revenue	\$ 53.1	\$ 48.8	<u>§ 4.3</u>

We earn contract research and development revenue from sanofi-aventis in connection with the companies' VEGF Trap collaboration which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable, up-front payments are recorded as deferred revenue and recognized ratably over the period over which we are obligated to perform services in accordance with SAB 104.

Sanofi-aventis Contract Research & Development Revenue

(In millions)	Nine months ended	l September 30,
	2006	2005
Regeneron expense reimbursement	\$ 29.6	\$ 23.4
Recognition of deferred revenue related to up-front payments	9.1	7.0
Total	\$ 38.7	<u>\$ 30.4</u>

Sanofi-aventis' reimbursement of our VEGF Trap expenses increased in the first nine months of 2006 from the same period in 2005, primarily due to higher costs related to our manufacture of VEGF Trap clinical supplies during the first half of 2006. Recognition of deferred revenue related to sanofi-aventis' up-front payments also increased in the first nine months of 2006 from the same period in 2005, due to our January 2006 receipt of a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

Contract research and development revenue earned from Procter & Gamble decreased in the first nine months of 2006 compared to the same period of 2005, as the research activities being pursued under our December 2000 collaboration agreement with Procter & Gamble, as amended, were completed on June 30, 2005. Since the second quarter of 2005, we have not received, and do not expect to receive, any further contract research and development revenue from Procter & Gamble.

Contract manufacturing revenue increased in the first nine months of 2006 from the same period of 2005 as we shipped more product to Merck in 2006. Included in contract manufacturing revenue in the first nine months of 2006 and 2005 were \$1.2 million and \$1.1 million, respectively, of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production.

Expenses:

Total operating expenses decreased to \$127.3 million in the first nine months of 2006 from \$143.7 million in the same period of 2005, due, in part, to our lower headcount, as previously described above. (Also see "Severance Costs" below.)

Operating expenses in the first nine months of 2006 and 2005 include a total of \$13.2 million and \$16.2 million of Stock Option Expense, respectively, as detailed below:

(In millions)	For the nine months ended September 30, 2006		
	Expenses before		
	inclusion of Stock	Stock Option	Expenses as
Expenses	Option Expense	Expense	Reported_
Research and development	\$ 94.0	\$ 7.3	\$ 101.3
Contract manufacturing	7.4	0.3	7.7
General and administrative	12.7	5,6	18,3
Total operating expenses	<u>\$ 114.1</u>	\$ 13.2	<u>\$ 127.3</u>
(In millions)	For the nine mo	nths ended September	30, 2005
	Expenses before		
	inclusion of Stock	Stock Option	Expenses as
Expenses	Option Expense	Expense	Reported
Research and development	\$ 107.6	\$ 10.1	\$ 117.7

Research and Development Expenses:

Contract manufacturing

General and administrative

Total operating expenses

Research and development expenses decreased to \$101.3 million in the first nine months of 2006 from \$117.7 million in the same period of 2005. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2006 and 2005:

7.1

12.8

127.5

\$

0.3

5.8

16.2

7.4

18.6

143.7

(In millions) Nine months ended September		mber 30,	
			Increase
Research and development expenses	2006	2005(1)	(Decrease)
Payroll and benefits (2)	\$ 32.7	\$ 38.4	\$ (5.7)
Clinical trial expenses	11.0	16.1	(5.1)
Clinical manufacturing costs (3)	28.3	32.1	(3.8)
Research and preclinical development costs	13.3	14.5	(1.2)
Occupancy and other operating costs	<u>16.0</u>	<u>16.6</u>	(0.6)
Total research and development	\$ 101.3	<u>\$ 117.7</u>	<u>\$ (16.4)</u>

- (1) For the major categories of research and development expenses, amounts for the nine months ended September 30, 2005 have been reclassified to conform with, and be comparable to, the current period's presentation. Total research and development expenses for the nine months ended September 30, 2005 are unchanged from amounts previously reported.
- (2) Includes \$6.1 million and \$8.4 million of Stock Option Expense for the nine months ended September 30, 2006 and 2005, respectively.
- (3) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$1.2 million and \$1.6 million of Stock Option Expense for the nine months ended September 30, 2006 and 2005, respectively.

Payroll and benefits decreased principally due to our lower headcount in the first nine months of 2006. Clinical trial expenses decreased primarily due to lower IL-1 Trap costs in 2006 as we discontinued clinical development of the IL-1 Trap in adult rheumatoid arthritis and osteoarthritis in the second half of 2005. This decrease was partly offset by higher 2006 VEGF Trap-Eye costs related to Phase 1 and Phase 2 clinical trials that we are conducting in wet AMD. Clinical manufacturing costs decreased because of lower costs in 2006 related to manufacturing IL-1 Trap clinical supplies, which were partially offset by higher costs related to manufacturing VEGF Trap clinical supplies. Research and preclinical development costs decreased primarily because of our lower 2006 headcount and lower preclinical IL-1 Trap development costs in 2006. Occupancy and other operating costs decreased primarily due to our lower 2006 headcount.

Contract Manufacturing Expenses:

Contract manufacturing expenses increased to \$7.7 million in the first nine months of 2006 from \$7.4 million in the comparable period of 2005 primarily because we shipped more product to Merck.

General and Administrative Expenses:

General and administrative expenses decreased to \$18.3 million in the first nine months of 2006 from \$18.6 million in the same period of 2005, primarily due to lower professional fees for accounting and other administrative advisory services and lower facility-related costs, which were partly offset by higher patent-related costs and administrative personnel-related costs.

Other Income and Expense:

As described above, in January 2005 we received a one-time \$25.0 million payment from sanofi-aventis, which was recognized as other contract income in the first nine months of 2005.

In June 2005, we and Procter & Gamble amended our collaboration agreement and agreed that the research activities of both companies under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble agreed to make a one-time \$5.6 million payment to us, which we recognized as other contract income in the first nine months of 2005.

Investment income increased to \$11.0 million in the first nine months of 2006 from \$7.5 million in the same period of 2005 due primarily to higher effective interest rates on investment securities in 2006. Interest expense was \$9.0 million in the first nine months of 2006 and 2005. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis and Merck, and investment income.

Nine Months Ended September 30, 2006 and 2005

Cash Used in Operations:

At September 30, 2006, we had \$289.6 million in cash, cash equivalents, and marketable securities compared with \$316.7 million at December 31, 2005. In January 2006, we received a \$25.0 million non-refundable, up-front payment from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration to include Japan.

In the first nine months of 2006, our net loss was \$71.4 million; however, cash used in our operations was only \$30.2 million, principally because (i) the above-described \$25.0 million payment from sanofi-aventis was receivable at December 31, 2005 and paid in January 2006, and (ii) we recognized non-cash compensation expense of \$13.5 million and depreciation and amortization of \$11.2 million for the first nine months of 2006. In the first nine months of 2005, our net loss was \$65.8 million; however, cash used in our operations was only \$10.4 million, principally due to (i) receipts during this period from the sanofi-aventis Group for reimbursement of VEGF Trap development expenses incurred by us and a \$25.0 million clinical milestone payment earned in December 2004 and (ii) recognition of non-cash compensation expense of \$17.6 million and depreciation and amortization of \$11.6 million for the first nine months of 2005.

Cash (Used in) Provided by Investing Activities:

Net cash provided by investing activities was \$8.1 million in the first nine months of 2006 compared to \$90.2 million in the same period of 2005, due primarily to a decrease in sales or maturities of marketable securities net of purchases. In the first nine months of 2006, sales or maturities of marketable securities exceeded purchases by \$9.7 million, whereas in the same period of 2005, sales or maturities of marketable securities exceeded purchases by \$94.8 million.

Cash Provided by Financing Activities:

Cash provided by financing activities increased to \$5.3 million in the first nine months of 2006 from \$1.1 million in the same period in 2005 due primarily to an increase in payments in connection with exercises of stock options.

The sanofi-aventis Group Agreement:

Under our collaboration agreement with sanofi-aventis, agreed upon worldwide VEGF Trap development expenses incurred by both companies during the term of the agreement, including costs associated with the manufacture of clinical drug supply, will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of these development expenses, including 50% of the \$25.0 million payment received in connection with the January 2005 amendment to our collaboration agreement, in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option. In addition, if the first commercial sale of a VEGF Trap product for intraocular delivery to the eye predates the first commercial sale of a VEGF Trap product under the collaboration by two years, we will begin reimbursing sanofi-aventis for up to \$7.5 million of VEGF Trap development expenses in accordance with a formula until the first commercial VEGF Trap sale under the collaboration occurs.

Sanofi-aventis has the right to terminate the agreement without cause with at least twelve months advance notice. Upon termination of the agreement for any reason, any remaining obligation to reimburse sanofi-aventis for 50% of VEGF Trap development expenses will terminate and we will retain all rights to the VEGF Trap.

The Bayer Healthcare Agreement:

Under our collaboration agreement with Bayer, Bayer made a non-refundable, up-front payment of \$75.0 million to us in October 2006. Agreed upon development expenses incurred by both companies during the term of the collaboration will be shared as follows:

2007: Up to \$50.0 million shared equally, we are solely responsible for up to the next \$40.0 million; over \$90.0 million shared equally.

2008: Up to \$70.0 million shared equally, we are solely responsible for up to the next \$30.0 million; over \$100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States and the collaboration becomes profitable, we will be obligated to reimburse Bayer for 50% of the agreed upon development expenses that Bayer has incurred in accordance with a formula based on the amount of development expenses that Bayer has incurred and our share of the collaboration profits, or at a faster rate at our option.

Bayer has the right to terminate the agreement without cause with at least six months or twelve months advance notice depending on defined circumstances at the time of termination. In the event of termination of the agreement for any reason, we retain all rights to the VEGF Trap-Eye.

Severance Costs:

In September 2005, we announced plans to reduce our workforce by approximately 165 employees in connection with narrowing the focus of our research and development efforts, substantial improvements in manufacturing productivity, the September 2005 expiration of our collaboration with Procter & Gamble, and the completion of contract manufacturing for Merck in late 2006. The majority of the headcount reduction occurred in the fourth quarter of 2005. The remaining headcount reductions have been occurring in 2006 as we complete activities related to contract manufacturing for Merck.

Costs associated with the workforce reduction are comprised principally of severance payments and related payroll taxes, employee benefits, and outplacement services. Termination costs related to 2005 workforce reductions were expensed in the fourth quarter of 2005, and included \$0.2 million of non-cash expenses. Estimated termination costs associated with the workforce reduction in 2006 were measured in October 2005 and expensed ratably over the expected service period of the affected employees in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. Total costs associated with the 2005 and 2006 workforce reductions will approximate \$2.6 million, of which \$2.2 million was charged to expense in the fourth quarter of 2005 and \$0.4 million was charged to expense in the first nine months of 2006.

Capital Expenditures:

Our additions to property, plant, and equipment totaled \$1.8 million and \$4.3 million for the first nine months of 2006 and 2005, respectively. During the remainder of 2006, we expect to incur approximately \$2 million in capital expenditures which will primarily consist of equipment for our manufacturing, research, and development activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55%-65% of our expenditures for 2006 will be directed toward the preclinical and clinical development of product candidates, including the VEGF Trap-Eye, and IL-1 Trap; approximately 20%-25% of our expenditures for 2006 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2006 will be used for capital expenditures and general corporate purposes.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer. We have entered into discussions regarding a new long-term operating lease for our laboratory and office facilities in Tarrytown, New York, as the operating lease for our current Tarrytown facilities expires in December of 2007 and 2009. We expect to continue to

incur significant lease costs in future years. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least mid-2009, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. We have no off-balance sheet arrangements and do not guarantee the obligations of any other entity. As of September 30, 2006, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In January 2005, we filed a shelf registration statement on Form S-3 to sell, in one or more offerings, up to \$200.0 million of equity or debt securities, together or separately, which registration statement was declared effective in February 2005. However, there is no assurance that we will be able to complete any such offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

During the nine months ended September 30, 2006, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2005.

Future Impact of Recently Issued Accounting Standards

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes an interpretation of FASB Statement No. 109*. This interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. We will be required to adopt FIN 48 effective for the fiscal year beginning January 1, 2007. Our management is currently evaluating the potential impact of adopting FIN 48 on our financial statements.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles ("GAAP"), and expands disclosures about fair value measurements. We will be required to adopt SFAS 157 effective for the fiscal year beginning January 1, 2008. Our management is currently evaluating the potential impact of adopting SFAS 157 on our financial statements.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in an approximately \$0.5 million and \$0.8 million change in the fair market value of our investment portfolio at September 30, 2006 and 2005, respectively. The decrease in the impact of an interest rate change at September 30, 2006, compared to September 30, 2005, is due to decreases in our investment portfolio's balance and duration to maturity at the end of September 2006 versus the end of September 2005.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2005 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2006, we had a cumulative loss of \$656.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. Until October 31, 2006, we received contract manufacturing revenue from our agreement with Merck and, until June 30, 2005, we received contract research and development revenue from our agreement with The Procter & Gamble Company. Our agreement with Procter & Gamble expired in June 2005 and our agreement with Merck expired in October 2006. The expiration of these agreements results in a significant loss of revenue to the Company.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least mid-2009, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of the IL-1 Trap in different diseases after a phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

The data from the phase 3 clinical program for the IL-1 Trap in CAPS (CIAS1-related Autoinflammatory Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of the IL-1 Trap.

The efficacy and safety data from the phase 3 clinical program for the IL-1 Trap in CAPS may be inadequate to support approval for its commercialization in this indication. Moreover, if the safety data from the ongoing clinical trials testing the IL-1 Trap are not satisfactory, we may not proceed with the filing of a biological license application, or BLA, for the IL-1 Trap or we may be forced to delay the filing. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance. Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for the IL-1 Trap, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize the IL-1 Trap profitably.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the IL-1 Trap in those countries.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses,

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injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions, referred to as infusion reactions. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

Although the IL-1 Trap was generally well tolerated and was not associated with any drug-related serious adverse events in the phase 2 rheumatoid arthritis study completed in 2003, safety or tolerability concerns may arise as we test higher doses of the IL-1 Trap in patients with other inflammatory diseases and disorders. Like TNF-antagonists such as Enbrel® (Amgen) and Remicade® (Centocor), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, there may be an increased risk for infections to develop in patients treated with the IL-1 Trap. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions, referred to as infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of the IL-1 Trap.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be created

at a later date — in some cases even after pivotal clinical trials have been completed. Subjects who received IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap and VEGF Trap-Eye develop antibodies to these product candidates, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye in a Phase 1 Trial. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap-Eye, and IL-1 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have

blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap-Eye or in a damage award.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an

unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2005, which report was included in our Annual Report on Form 10-K for the year ended December 31, 2005. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

If our collaboration with Bayer HealthCare for the VEGF Trap-Eye is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap-Eye in the time expected, or at all, would be harmed.

We will rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, provide assistance with the enrollment and monitoring of clinical trials conducted outside the United States, obtaining regulatory approval outside the United States, and provide sales, marketing and commercial support for the product outside the United States. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration

agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap-Eye development program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce API for our own clinical and preclinical candidates. Under a long-term manufacturing agreement with Merck, which expired in October 2006, we also produced an intermediate for a Merck pediatric vaccine at our facility in Rensselaer, New York. Since we no longer use our facilities to manufacture the Merck intermediate, and if clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Onyx Pharmaceuticals and Bayer have received approval from the FDA to market and sell the first oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings.

This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the Onyx/Bayer kinase inhibitor, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor (Macugen®) for age-related macular degeneration (wet AMD). Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (LucentisTM) for the treatment of wet AMD and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, it has been reported that ophthalmologists are using a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin, with success for the treatment of wet AMD. The National Eye Institute has recently received funding for a Phase 3 trial to compare Lucentis to Avastin in the treatment of wet AMD. The marketing approval of Macugen and Lucentis and the potential off-label use of Avastin make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis or Macugen, because doctors and patients will have significant experience using these medicines. Moreover, the relatively low cost of therapy with Avastin in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Amgen), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Novartis is developing an antibody to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the CIAS1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We intend to file an application with the FDA seeking approval to market the IL-1 Trap for the treatment of a spectrum of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize the IL-1 Trap. Physicians may not prescribe the IL-1 Trap and CAPS patients may not be able to afford the IL-1 Trap if third party payers do not agree to reimburse the cost of IL-1 Trap therapy and this would adversely affect our ability to commercialize the IL-1 Trap profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including the IL-1 Trap, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, Murray A. Goldberg, our Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary, Neil Stahl, Ph.D., our Senior Vice President, Therapeutics and Clinical Program Development, Randall G. Rupp, Ph.D., our Senior Vice President, Manufacturing Operations, and Peter Powchik, M.D., our Senior Vice President, Clinical Development. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners,
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of September 30, 2006, our seven largest shareholders, including sanofi-aventis, beneficially owned 46.6% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of September 30, 2006. As of September 30, 2006, sanofiaventis owned 2,799,552 shares of Common Stock, representing approximately 5.1% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofiaventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2006, holders of Class A Stock held 29.5% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of September 30, 2006:

- our current officers and directors beneficially owned 14.4% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2006, and 33.1% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2006; and
- our seven largest shareholders beneficially owned 46.6% of our outstanding shares of Common Stock assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of September 30, 2006. In addition, these seven shareholders held 53.4% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of September 30, 2006.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote

for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;

- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

In addition, we have a Change in Control Severance Plan and many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of the Company, as defined in the plan.

Item 6. Exhibits

(a) Exhibits

Exhibit Number	Descri	ption
10.1	_	License and Collaboration Agreement, dated as of October 18, 2006, by and between Bayer HealthCare LLC and Regeneron Pharmaceuticals, Inc.
12.1	_	Statement re: computation of ratio of earnings to combined fixed charges.
31.1	_	Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	_	Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	_	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: November 6, 2006

By: /s/ Murray A. Goldberg

Murray A. Goldberg

Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

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LICENSE AND COLLABORATION AGREEMENT By and Between BAYER HEALTHCARE LLC

and

REGENERON PHARMACEUTICALS, INC.

Dated as of October 18, 2006

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LICENSE AND COLLABORATION AGREEMENT

THIS LICENSE AND COLLABORATION AGREEMENT ("<u>Agreement</u>"), dated as of October 18, 2006 (the "<u>Effective Date</u>"), is by and between BAYER HEALTHCARE LLC, a Delaware limited liability company having a principal place of business at 511 Benedict Avenue, Tarrytown, New York 10591 ("<u>Company</u>"), and REGENERON PHARMACEUTICALS, INC., a New York corporation having a principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591 ("<u>Regeneron</u>") (with each of Company and Regeneron referred to herein individually as a "<u>Party</u>" and collectively as the "<u>Parties</u>").

WHEREAS, Regeneron owns and has licensed certain Patents, Know-How and other rights related to the VEGF Trap in the Territory;

WHEREAS, Company and its Affiliates possess knowledge and expertise in, and resources for, developing and commercializing pharmaceutical products in the Field in the Territory; and

WHEREAS, Regeneron and Company desire to collaborate on the Development and Manufacture of Products in the Field, and the Commercialization of Products in the Field in the Territory under the terms and conditions set forth herein (the "Collaboration").

NOW, THEREFORE, in consideration of the following mutual covenants contained herein, and for other good and valuable consideration the adequacy and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, except as expressly set forth herein, shall have the meanings set forth below:

1.1 "Affiliate" shall mean, with respect to any Person, another Person which controls, is controlled by or is under common control with such Person. A Person shall be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. Without limiting the generality of the foregoing, a Person shall be deemed to control another Person if any of the following conditions is met: (a) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors, and (b) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by

law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, provided that such foreign investor has the power to direct the management and policies of such entity.

- 1.2 "Agreement" shall have the meaning set forth in the introductory paragraph, including all Schedules and Exhibits.
- 1.3 "Anticipated First Commercial Sale" shall mean, with respect to a Licensed Product in the Field, the date agreed upon by the JSC in advance as the expected date of First Commercial Sale of such Licensed Product in the Field in a country in the Territory.
- 1.4 "Approval" shall mean, with respect to each Licensed Product, any approval (including Marketing Approvals and Pricing Approvals), registration, license or authorization from any Regulatory Authority required for the Development, Manufacture or Commercialization of such Product in the Field in a regulatory jurisdiction anywhere in the world, and shall include, without limitation, an approval, registration, license or authorization granted in connection with any Registration Filing.
 - 1.5 "Aventis" shall mean sanofi-aventis US LLC (successor in interest to Aventis Pharmaceuticals, Inc.
- 1.6 "Aventis Agreement" shall mean the Collaboration Agreement, dated as of September 3, 2003, by and between Aventis and Regeneron Pharmaceuticals, Inc., as amended by the First Amendment, dated as of December 31, 2004, the Second Amendment, dated as of January 7, 2005, the Third Amendment, dated as of December 21, 2005, and the Fourth Amendment, dated as of January 31, 2006, as the same may be further amended from time to time.
 - 1.7 "Business Day" shall mean a day on which commercial banking institutions in New York, New York are open for business.
- 1.8 "Change of Control" shall mean, with respect to Regeneron, any of the following events: (a) any Person is or becomes the "beneficial owner" (as such term is used in Section 13(d) of the Securities Exchange Act of 1934, as amended, and Rule 13d-3 thereunder, except that a Person shall be deemed to have "beneficial ownership" of all shares that any such Person has the right to acquire, whether such right may be exercised immediately or only after the passage of time), directly or indirectly, of a majority of the total voting power represented by all classes of capital stock then outstanding of Regeneron normally entitled to vote in elections of directors; (b) Regeneron consolidates with or merges into another corporation or entity, or any corporation or entity consolidates with or merges into Regeneron, other than (i) a merger or consolidation which would result in the voting securities of Regeneron outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or any parent thereof) a majority of the combined voting power of the voting securities of Regeneron or such surviving entity or any parent thereof outstanding immediately after such merger or consolidation, or (ii) a

merger or consolidation effected to implement a recapitalization of Regeneron (or similar transaction) in which no Person becomes the beneficial owner, directly or indirectly, of voting securities of Regeneron representing a majority of the combined voting power of Regeneron's then outstanding securities; or (c) Regeneron conveys, transfers or leases all or substantially all of its assets to any Person other than a wholly-owned Affiliate of Regeneron.

- 1.9 "Class A Stock" shall mean the Class A Stock of Regeneron, par value \$0.001 per share.
- 1.10 "Clinical Supply Cost" shall mean (a) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture Formulated Bulk Product for Clinical Supply Requirements under the Development Plans, (b) the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost to Manufacture, comparator agent or placebo requirements for activities contemplated under the Development Plans, (c) the Out-of-Pocket Cost and/or the Manufacturing Cost for filling, packaging and labeling such Clinical Supply Requirements, comparator agent and/or placebo, as the case may be, for activities contemplated under the Development Plans and (d) any VAT or similar taxes actually paid with respect to the Manufacture or delivery of Clinical Supply Requirements.
- 1.11 "Clinical Supply Requirements" shall mean, with respect to a Licensed Product, the quantities of such Licensed Product which are required by a Party or the Parties for Development in the Field under this Agreement, including, without limitation, the conduct of research, preclinical studies and clinical trials in connection with a Development Plan and quantities of such Licensed Product which are required by a Party for submission to a Regulatory Authority in connection with any Registration Filing or Approval in the Field in any regulatory jurisdiction in the Territory.
- 1.12 "COGS" for a Quarter shall mean cost (calculated in accordance with GAAP or IAS/IFRS) of Manufacturing the Licensed Products sold in the Field in the Territory in the Quarter.
- 1.13 "Commercialize" or "Commercialization" shall mean any and all activities directed to marketing, promoting, detailing, distributing, importing, offering for sale, having sold and/or selling a Licensed Product in the Field in the Territory, including, without limitation, market research, pre-launch marketing and educational activities, sampling and Non-Approval Trials in the Territory.

- 1.15 "Commercially Reasonable Efforts" shall mean, with respect to the efforts to be expended by a Party with respect to any objective, reasonable, diligent, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that such efforts shall be consistent with the Collaboration Purpose and substantially equivalent to those efforts and resources commonly used by a Party for a product owned by it, which product is at a similar stage in its development or product life and is of similar market potential (taking into consideration both anticipated total sales and overall profitability). Commercially Reasonable Efforts shall be determined on a market-by-market and product-by-product basis in view of conditions prevailing at the time, and evaluated taking into account all relevant factors, including without limitation, the efficacy, safety, anticipated regulatory authority approved labeling, competitiveness of the product or alternative products that are in the marketplace or under development by Third Parties and other technical, scientific, legal, medical marketing and competitiveness factors. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. In determining whether a Party has used Commercially Reasonable Efforts, neither the Territory Profit Split nor other payments made or required to be made from one Party to the other under this Agreement shall be considered in determining market potential (that is, a Party may not apply lesser resources or efforts in support of a Licensed Product because it must pay the Territory Profit Split or make milestone or any other payments hereunder to the other Party). By way of example, for purposes of determining whether Company uses Commercially Reasonable Efforts to Commercialize a Licensed Product in a Major Market Country, a basis for comparison shall be the efforts used by Company to commercialize in such Major Market Country another Company product that is wholly owned by Company, is at a similar stage of commercialization to the Licensed Product and has both anticipated total sales and overall profitability to Company in such Major Market Country substantially similar to that of the Licensed Product, taking into account total sales and total profitability of the Licensed Product in such Major Market Country, but without consideration of any of the payments required to be made from one Party to the other under this Agreement.
- 1.16 "Commercial Supply Cost" shall mean the Out-of-Pocket Cost for purchasing and/or the Manufacturing Cost for the Manufacture of the Commercial Supply Requirements, including, without limitation, any filling, packaging and labeling costs, and any VAT or similar taxes actually paid with respect to the Manufacture or delivery of such Commercial Supply Requirements.
- 1.17 "Commercial Supply Requirements" shall mean, with respect to each Licensed Product, quantities of Finished Product as are required by Company to fulfill its (or its Affiliate's or Sublicensee's) requirements for commercial sales, Non-Approval Trials and Product sampling with respect to such Licensed Product in the Field in the Territory.
- 1.18 "Committee" means any of the JSC, JDC, JCC or JFC, each as described in Article 3 (together with Working Groups or other committees contemplated herein or established in accordance with this Agreement).

- 1.19 "Common Stock" shall mean the common stock of Regeneron, par value \$0.001 per share.
- 1.20 "Company Excluded Territory Intellectual Property" shall mean Company Patent Rights and Know-How that cover, claim or are used for the Development, Manufacture and/or Commercialization of Regeneron Products under the Plans, but excluding (a) any Company Patent Rights covering the composition of any Company Products, and (b) any New Information or Party Information arising from the Development, Manufacture and/or Commercialization of Company Products.
 - 1.21 "Company Intellectual Property" shall mean the Company Patent Rights and any Know-How of Company or any of its Affiliates.
- 1.22 "Company Patent Rights" shall mean those Patent Rights which (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Company or any of its Affiliates (other than pursuant to this Agreement), including, without limitation, Patent Rights covering any formulation and delivery technologies, with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Product in the Field.
- 1.23 "Consolidated Payment Report" shall mean a consolidated Quarterly report prepared by Company (based on information reported under Sections 5.4 and 9.3) setting forth in reasonable detail, for each Major Market Country in the Territory, for each Region in the Territory, and in the aggregate for all countries in the Territory, (a) Net Sales, COGS and Shared Promotion Expenses incurred by each Party for such Quarter, (b) Development Costs incurred by each Party for such Quarter under the Global Development Plan and the Territory Development Plan, (c) Other Shared Expenses incurred by each Party for such Quarter, including the allocation of global costs pursuant to Section 3.4(b)(xii), (d) Commercial Supply Costs incurred by each Party for such Quarter and (e) the Quarterly True-Up, and the component items and calculations in determining such Quarterly True-Up, calculated in accordance with Schedule 2.
- 1.24 "Contract Year" shall mean the period beginning on the Effective Date and ending on December 31, 2007, and each succeeding consecutive twelve (12) month period thereafter during the Term. The last Contract Year of the Term shall begin on January 1 for the year during which termination or expiration of the Agreement will occur, and the last day of such Contract Year shall be the effective date of such termination or expiration.
- 1.25 "Controlling Party" shall mean Regeneron with respect to the filing, prosecution and maintenance of a Joint Patent Right that claims or covers a Regeneron Product (or the Manufacture or use thereof), and Company in the case of all other Joint Patent Rights.
- 1.26 "Country Commercialization Budget" shall mean the three-year rolling budget(s) approved by the JCC for a particular Country Commercialization Plan.

- 1.27 "Country Commercialization Plan" shall mean, for each Major Market Country in the Territory, the three-year rolling plan for Commercializing Licensed Products in the Field in such country, including the applicable Country Commercialization Budget, developed and approved by the JCC, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Each Country Commercialization Plan shall set forth, for each Licensed Product, the information, plans and forecasts set forth in Section 6.3.
- 1.28 "Country Commercialization Report" shall mean, for each Major Market Country in the Territory, a written report summarizing the marketing, detailing, selling and promotional activities undertaken by Company (or its Affiliate) during the previous Quarter in connection with the applicable Country Commercialization Plan, including the number of details for the Licensed Product in the Field in the country, together with a detailed project-level statement of Shared Promotion Expenses (calculated in U.S. dollars and local currency) incurred by Company (or its Affiliate) during such Quarter in the country.
- 1.29 "CPI" for the Excluded Territory shall mean the Consumer Price Index Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984 = 100, published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index). For countries and Regions in the Territory (other than Japan), "CPI" shall mean the "EU15 CPI" (or its successor equivalent index), which is published monthly and available via Bloomberg Professional, as published by Bloomberg L.P. In Japan, "CPI" shall mean such other inflation measure or rate agreed upon by the Parties.
- 1.30 "Develop" or "Development" shall mean (a) activities directly and specifically relating to research, pre-clinical and clinical drug development of a Licensed Product in the Field, including, without limitation, test method development and stability testing, assay development, toxicology, pharmacology, formulation, quality assurance/quality control development, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, clinical studies (including research to design clinical studies), regulatory affairs, project management, drug safety surveillance activities related to clinical studies, the preparation, submission and maintenance of Registration Filings and Approvals (including post-marketing clinical trials imposed by applicable Law or as required by a Regulatory Authority) and activities necessary to obtain a Pricing Approval, reimbursement and/or listing on health care providers' and payers' formularies, and (b) any other development activities with respect to a Licensed Product in the Field, including, without limitation, activities to support new product formulations, delivery technologies and/or new indications in the Field either before or after the First Commercial Sale.
- 1.31 "<u>Development Costs</u>" shall mean costs incurred by a Party in connection with the Development of Licensed Products in the Field in accordance with this Agreement and the Development Plan(s) (or prior to the first Development Plan, the Initial Development Plan), including without limitation:

- (a) all Out-of-Pocket Costs, including, without limitation, fees and expenses associated with obtaining and maintaining Registration Filings and Approvals (including Pricing Approvals) necessary for the Development and Commercialization of the Licensed Products in the Field under this Agreement;
- (b) Development FTE Costs;
- (c) Clinical Supply Costs;
- (d) the costs and expenses incurred in connection with (i) Manufacturing process, formulation, cleaning, and shipping development and validation, (ii), Manufacturing scale-up and improvements, (iii) stability testing, (iv) quality assurance/quality control development (including management of Third Party fillers, packagers and labelers), and (v) internal and Third Party costs and expenses incurred in connection with (A) qualification and validation of Third Party contract manufacturers and vendors and (B) subject to the terms of this Agreement, establishing a primary or secondary source supplier, including, without limitation, the transfer of process and Manufacturing technology and analytical methods, scale-up, process and equipment validation, cleaning validation and initial Manufacturing licenses, approvals and Regulatory Authority inspections (in each case, to the extent not included in Clinical Supply Costs or Commercial Supply Costs);
- (e) Pre-Launch Marketing Expenses;
- (f) any license fees and other payments under Existing Licenses and New Licenses to the extent attributable to the Manufacture of Clinical Supply Requirements and/or the Development of Licensed Products in the Field under the Plans for the Territory (which, for the avoidance of doubt, include activities in the Excluded Territory performed under the Global Development Plan); and
- (g) any other costs or expenses specifically identified and included in the applicable Development Plan or included as Development Costs under this Agreement.

1.32 "Development FTE Cost" shall mean, for all Development activities performed in accordance with the Development Plan(s), including regulatory activities, the

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product of (a) the number of FTEs required for such Development activity as set forth in the approved Development Plan and (b) the Development FTE Rate.

- 1.33 "Development FTE Rate" for the Excluded Territory, the Territory (other than Japan) and Japan shall mean [*******] in the first Contract Year, such amount to be adjusted as of January 1, 2008 and annually thereafter by the percentage increase or decrease, if any, in the applicable CPI (determined based on the location of the Development personnel) since the Effective Date or the latest adjustment date hereunder, whichever is later, through June 30 of the prior calendar year. The Development FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.
 - 1.34 "Development Plan(s)" shall mean the Global Development Plan and the Territory Development Plan.
 - 1.35 "Effective Date" shall have the meaning set forth in the introductory paragraph.
 - 1.36 "EMEA" shall mean the European Medicines Evaluation Agency or any successor agency thereto.
 - 1.37 "Excluded Territory" shall mean the United States.
- 1.38 "Executive Officers" shall mean the Chief Executive Officer of Regeneron and the Chief Executive Officer of Bayer HealthCare AG, a German corporation having a principal place of business at 51368 Leverkusen, Germany.
 - 1.39 "Existing Licenses" shall mean the agreements listed in Schedule 4.
 - 1.40 "FDA" shall mean the United States Food and Drug Administration and any successor agency thereto.
- 1.41 "Field" shall mean the treatment and/or diagnosis of any ocular disease or disorder through the local administration of any product to the eye, including, without limitation, by topical, intravitreal, periorbital, implants or other means of local administration to the eye.
- 1.42 "Finished Product" shall mean a Licensed Product in the Field in its finished, labeled and packaged form, ready for sale to the market or use in clinical or pre-clinical trials, as the case may be.
- 1.43 "<u>First Commercial Sale</u>" shall mean, with respect to a Licensed Product in a country in the Territory (or, solely for purposes of Section 19.7(c), in the Excluded Territory), the first commercial sale of the Finished Product to non-Sublicensee Third Parties for use in the Field in such country (or group of countries) following receipt of Marketing Approval. Sales for test marketing or clinical trial purposes or compassionate or similar use shall not constitute a First Commercial Sale.

- 1.44 "Formulated Bulk Product" shall mean Licensed Product in the Field formulated into solution or in a lyophilized form, ready for storage or shipment to a manufacturing facility, to allow processing into the final dosage form.
- 1.45 "FTE" shall mean a full time equivalent employee (<u>i.e.</u>, one fully-committed or multiple partially-committed employees aggregating to one full-time employee) employed or contracted by a Party and assigned to perform specified work, with such commitment of time and effort to constitute one employee performing such work on a full-time basis, which for purposes hereof shall be [********] per year.
 - 1.46 "GAAP" shall mean generally accepted accounting principles in the United States.
 - 1.47 "Global Development Budget" shall mean the three-year rolling budget(s) approved by the JSC in the Global Development Plan.
- 1.48 "Global Development Plan" shall mean the three-year rolling plan approved by the JSC for Developing Licensed Products in the Field as part of an integrated worldwide Development program, including the related Global Development Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. Global Development Plan activities may be undertaken entirely or partially in the Excluded Territory if approved by the JSC. For the avoidance of doubt, the Global Development Plan will not include (a) any Development activities that are conducted or sponsored by a Party which are only required for a specific Approval in the Territory (including activities under the Territory Development Plan) or the Excluded Territory, (b) Non-Approval Trials or (c) any studies conducted for Pricing Approval or formulary approval.
- 1.49 "Good Practices" shall mean compliance with the applicable standards contained in then-current "Good Laboratory Practices," "Good Manufacturing Practices" and/or "Good Clinical Practices," as promulgated by the FDA and all analogous guidelines promulgated by the EMEA or the ICH, as applicable.
- 1.50 "Governmental Authority" shall mean any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or any supranational organization of which any such country is a member.
- 1.51 "IAS/IFRS" shall mean International Accounting Standards/International Financial Reporting Standards of the International Accounting Standards Board.
- 1.52 "ICH" shall mean the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- 1.53 "IND" shall mean, with respect to each Licensed Product in the Field, an Investigational New Drug Application filed with respect to such Product, as

described in the FDA regulations, including all amendments and supplements to the application, and any equivalent filing with any Regulatory Authority outside the United States.

- 1.54 "Joint Patent Rights" shall mean Patent Rights that cover a Joint Invention.
- 1.55 "Know-How" shall mean any and all proprietary technical or scientific information, know-how, data, test results, knowledge, techniques, discoveries, inventions, specifications, designs, trade secrets, regulatory filings and other information (whether or not patentable or otherwise protected by trade secret Law) which (a) are now or hereafter during the Term owned by, licensed to or otherwise held by (i) a Party, (ii) any Affiliate of Company that is engaged in the Development or Commercialization of Licensed Products pursuant to this Agreement or (iii) any of Regeneron's Affiliates, with the rights to license or sublicense the same, and (b) relate to a Product in the Field and are necessary or useful for the Development, Manufacture or Commercialization of a Product in the Field, including, without limitation, New Information.
- 1.56 "Law" or "Laws" shall mean all laws, statutes, rules, regulations, orders, judgments, injunctions and/or ordinances of any Governmental Authority.
- 1.57 "<u>Lead Regulatory Party</u>" shall mean the Party having responsibility for preparing, prosecuting and maintaining Registration Filings and any Approvals for Licensed Products in the Field under this Agreement, and for related regulatory duties.
- 1.58 "<u>Legal Dispute</u>" shall mean any dispute, controversy or claim related to compliance with this Agreement or the validity, breach, termination or interpretation of this Agreement.
 - 1.59 "Licensed Products" shall mean Regeneron Products and Company Products.
 - 1.60 "Major Market Country" shall mean [********************* and [******].
- 1.61 "Manufacture" or "Manufacturing" shall mean activities directed to producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping and/or storage of Formulated Bulk Product, Finished Product, placebo or a comparator agent, as the case may be.
- 1.62 "Marketing Approval" shall mean an approval of the applicable Regulatory Authority necessary for the marketing and sale of a Licensed Product in an indication in the Field in any country, but excluding any separate Pricing Approval.
- 1.63 "Medical Affairs Cost" shall mean, for each country in the Territory, the product of (a) the number of office-based FTEs supporting the coordination of Non-Approval Trials related to the Licensed Products in the Field as agreed upon in the

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Country Commercialization Plan or Territory Commercialization Plan and (b) the applicable Medical Affairs FTE Rate.

- 1.64 "Medical Affairs FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis in the Territory (determined based on the location of the medical affairs professional), a rate agreed upon in local currency by the Parties prior to the expected start of the first Non-Approval Trial in such Region or Major Market Country, as applicable, based upon the fully burdened cost of medical affairs professionals of pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Medical Affairs FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.
- 1.65 "Net Sales" shall mean the gross amount invoiced for bona fide arms' length sales of Licensed Products in the Field in the Territory by or on behalf of Company or its Affiliates or Sublicensees to Third Parties, less the following deductions determined in accordance with Company's standard methods as generally and consistently applied by Company:
 - (a) normal and customary trade, cash and/or quantity discounts allowed and taken with respect to Licensed Product sales;
 - (b) amounts repaid or credited by reason of defects, rejections, recalls, returns, rebates and allowances;
 - (c) chargebacks and other amounts paid on sale or dispensing of Licensed Products;
 - (d) Third Party cash rebates and chargebacks related to sales of the Licensed Product, to the extent allowed;
 - (e) retroactive price reductions that are actually allowed or granted;
 - (f) compulsory payments and rebates directly related to the sale of Licensed Products, accrued, paid or deducted pursuant to agreements (including, but not limited to, managed care agreements) or government regulations;
 - (g) freight, insurance and other transportation charges, to the extent included in the invoice price;
 - (h) tariffs, duties, excise, value-added, consumption or other taxes (other than taxes based on income), to the extent included in the invoice price; and

(i) any other specifically identifiable costs or charges included in the gross invoiced sales price of such Licensed Product falling within categories substantially equivalent to those listed above.

Sales between the Parties, or between the Parties and their Affiliates or Sublicensees, for resale, shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to, and paid by, Third Parties shall not be deducted from the invoice price in the calculation of Net Sales. In the case of any sale of a Licensed Product for consideration other than cash, such as barter or countertrade, Net Sales shall be calculated on the fair market value of the consideration received as agreed by the Parties. Solely for purposes of calculating Net Sales, if Company or its Affiliate or Sublicensee sells such Licensed Products in the form of a combination product containing any Product and one or more active ingredients (whether combined in a single formulation or package, as applicable, or formulated or packaged separately but sold together for a single price in a manner consistent with the terms of this Agreement) (a "Combination Product"), Net Sales of such Combination Product for the purpose of determining the Territory Profit Split pursuant to this Agreement will be calculated by multiplying actual Net Sales of such Combination Product as determined in the first paragraph of this definition of "Net Sales" by the fraction A/(A+B), where A is the invoice price of such Licensed Product if sold separately, and B is the total invoice price of the other active ingredient(s) in the combination if sold separately. If, on a country-by-country basis, such other active ingredient(s) in the Combination Product is not sold separately in such country, but the Licensed Product component of the Combination Product is sold separately in such country. Net Sales for the purpose of determining Territory Profit Split pursuant to this Agreement for the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction A/C, where A is the invoice price of the Licensed Product component if sold separately, and C is the invoice price of the Combination Product. If, on a country-by-country basis, the Licensed Product component is not sold separately in that country, Net Sales for the purpose of determining the Territory Profit Split pursuant to this Agreement for the Combination Product shall be calculated by multiplying actual Net Sales of the Combination Product by the fraction D/ (D+E), where D is the fair market value of the portion of the Combination Product that contains the Licensed Product and E is the fair market value of the portion of the Combination Product containing the other active ingredient(s) included in such Combination Product, as such fair market values are determined by mutual agreement of the Parties through the JFC.

1.66 "New Information" shall mean any and all ideas, inventions, data, writings, protocols, discoveries, improvements, trade secrets, materials or other proprietary information not generally known to the public, which may arise or be conceived or developed by (a) either Party,(b) any Affiliate of Company that is engaged in the Development or Commercialization of Licensed Products pursuant to this Agreement, (c) any of Regeneron's Affiliates or (d) the Parties or their Affiliates jointly, during the Term pursuant to this Agreement to the extent specifically related to any Licensed Product in the Field, including, without limitation, information and data included in any Plans or Registration Filings made under this Agreement.

- 1.67 "New License" shall mean any license approved by the JSC, other than Existing Licenses, required for the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement.
- 1.68 "Other Shared Expenses" shall mean those costs and expenses specifically referred to in Sections 3.4(b)(xii), 7.7, 12.2(e), 12.3(b), 13.1(c), 13.3(b), 13.3(d) and 17.1(c) which, except as set forth in Section 3.4(b)(xii) or elsewhere in this Agreement, shall be shared equally between the Parties.
- 1.69 "Out-of-Pocket Costs" shall mean costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with GAAP or IAS/IFRS) by either Party and/or its Affiliates in accordance with the applicable Plan.
- 1.70 "Party Information" shall mean any and all trade secrets or other proprietary information, including, without limitation, any proprietary data, inventions, ideas, discoveries and materials (whether or not patentable or protectable as a trade secret) not generally known to the public regarding a Party's or its Affiliates' technology, products, business or objectives, in each case, other than New Information, which are disclosed or made available by a Party or such Party's Affiliates to the other Party or the other Party's Affiliates in connection with this Agreement. For the avoidance of doubt, all confidential information disclosed by Regeneron under the terms of the confidentiality agreement between the Parties dated July 6, 2006 is hereby deemed Party Information of Regeneron.
 - 1.71 "Patent Application" shall mean any application for a Patent.
 - 1.72 "Patent Rights" shall mean unexpired Patents and Patent Applications.
- 1.73 "Patents" shall mean patents and all substitutions, divisions, continuations, continuations-in-part, reissues, reexaminations and extensions thereof and supplemental protection certificates relating thereto, and all counterparts thereof in any country in the world.
- 1.74 "Person" shall mean and include an individual, partnership, joint venture, limited liability company, corporation, firm, trust, unincorporated organization and government or other department or agency thereof.
- 1.75 "Phase 2 Trial" shall mean a controlled dose ranging clinical trial to evaluate further the efficacy and safety of a Licensed Product in the Field in the targeted patient population and to help define the optimal dose and/or dosing regimen.
- 1.76 "Phase 3 Trial" shall mean a clinical trial that is designed to gather further evidence of safety and efficacy of a Licensed Product in the Field (and to help evaluate its overall risks and benefits) and is intended to support Marketing Approval for a Licensed Product in the Field in one or more countries in the Territory. A Phase 3 Trial typically follows at least one Phase 2 Trial.

- 1.77 "Plan" shall mean any Country Commercialization Plan, Territory Commercialization Plan, Global Development Plan, Territory Development Plan, Manufacturing Plan or other plan approved through the Committee process relating to the Development, Manufacture or Commercialization of Licensed Products in the Field under this Agreement.
- 1.78 "<u>Pre-Launch Marketing Expenses</u>" shall mean, on a country-by-country basis in the Territory, with respect to each Licensed Product, all Commercialization expenses to support the Licensed Products in the Field incurred prior to the First Commercial Sale of such Licensed Product in the Field in the country.
- 1.79 "<u>Pricing Approval</u>" shall mean such approval, agreement, determination or governmental decision establishing prices for a Licensed Product that can be charged to consumers and will be reimbursed by Governmental Authorities in countries in the Territory where Governmental Authorities or Regulatory Authorities of such country approve or determine pricing for pharmaceutical products for reimbursement or otherwise.
- 1.80 "Product" shall mean [**********************************. Except as expressly set forth herein, the defined term "Product" shall refer exclusively to any such molecule Manufactured, Developed and/or Commercialized in the Field.
- 1.81 "Product Trademark" shall mean, with respect to each Licensed Product in the Field in the Territory, the trademark(s) selected by the JCC and approved by the JSC for use on such Licensed Product throughout the Territory and/or accompanying logos, slogans, trade names, trade dress and/or other indicia of origin, in each case as selected by the JCC and approved by the JSC.
- 1.82 "Promotional Materials" shall mean, with respect to each Licensed Product, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, promotion and sale of such Licensed Product in the Field in the Territory, and the content thereof, and shall include, without limitation, promotional literature, product support materials and promotional giveaways.
- 1.83 "Quarter" or "Quarterly" shall refer to a calendar quarter, except that the first Quarter shall commence on the Effective Date and extend to the end of the then-current calendar quarter and the last calendar quarter shall extend from the first day of such calendar quarter until the effective date of the termination or expiration of the Agreement.
- 1.84 "Regeneron Excluded Territory Intellectual Property" shall mean Regeneron Patent Rights and Know-How that cover, claim or are used for the Development, Manufacture and/or Commercialization of Company Products under the Plans, but excluding (a) any Regeneron Patent Rights covering the composition of any Regeneron Products, including, without limitation, the VEGF Trap, and (b) any New

Information or Party Information arising from the Development, Manufacture and/or Commercialization of Regeneron Products.

- 1.85 "Regeneron Intellectual Property" shall mean the Regeneron Patent Rights and any Know-How of Regeneron or any of its Affiliates.
- 1.86 "Regeneron Patent Rights" shall mean those Patent Rights which, (a) at the Effective Date or at any time thereafter during the Term, are owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than pursuant to this Agreement), including, without limitation, Patent Rights covering formulation and delivery technologies, with the right to license or sublicense the same, and (b) include at least one Valid Claim which would be infringed by the Development, Manufacture or Commercialization of a Product in the Field.
- 1.87 "Regeneron Products" shall mean Products which are now or hereafter during the Term owned by, licensed to or otherwise held by Regeneron or any of its Affiliates (other than pursuant to this Agreement), including, without limitation, the VEGF Trap.
 - 1.88 "Region" shall mean [*********************** and [******].
- 1.89 "<u>Registration Filing</u>" shall mean the submission to the relevant Regulatory Authority of an appropriate application seeking any Approval, and shall include, without limitation, any IND or Marketing Approval application in the Field.
- 1.90 "Regulatory Authority" shall mean any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity anywhere in the world with authority over the Development, Manufacture or Commercialization of any Licensed Product in the Field under this Agreement. The term "Regulatory Authority" includes, without limitation, the FDA, the EMEA and the Japanese Ministry of Health, Labour and Welfare.
 - 1.91 "Rest of World Country" shall mean any country in the Territory other than the Major Market Countries.
- 1.93 "Sales Force FTE Rate" shall mean, on a Region-by-Region or one or more Major Market Countries basis (determined based on the location of the sales representative), a rate agreed upon in local currency by the Parties at least eighteen (18) months prior to the Anticipated First Commercial Sale in the Region or Major Market Country, as applicable, based upon the fully burdened cost of sales representatives of

pharmaceutical companies in the Field in the applicable country, such amount to be adjusted as of January 1 of each following Contract Year by the percentage increase or decrease, if any, in the applicable CPI through June 30 of the prior calendar year. The Sales Force FTE Rate shall be inclusive of Out-of-Pocket Costs and other expenses for the employee providing the services, including travel costs and allocated costs, such as, for example, allocated overhead costs.

- 1.94 "<u>Shared Promotion Expenses</u>" shall mean the sum of the following items, in each case to the extent attributable to Commercialization of Licensed Products in the Field in the Territory in accordance with an approved Country Commercialization Plan or Territory Commercialization Plan:

 - (b) bad debt attributable to Licensed Products in the Field sold in the Territory;
 - (c) Sales Force Cost;
 - (d) Medical Affairs Cost;
 - (e) Out-of-Pocket Costs related to (i) the marketing, advertising and/or promotion of Licensed Products in the Field in the Territory (including, without limitation, educational expenses, advocate development programs and symposia and Promotional Materials), (ii) market research for Licensed Products in the Field in the Territory and (iii) the preparation of training and communication materials for Licensed Products in the Field in the Territory;
 - (f) a portion of Out-of-Pocket Costs agreed upon by the Parties related to the marketing, advertising and promotion of Licensed Products in the Field in the Territory (including, without limitation, educational expenses, advocate development programs and symposia, and promotional materials) to the extent such marketing, advertising and promotion (i) relate to both Licensed Products and other Company products or (ii) relate to Licensed Products in the Field in both the Territory and the Excluded Territory, in each case, as agreed upon in an approved Territory Commercialization Plan or Country Commercialization Plan;
 - (g) Out-of-Pocket Costs related to Non-Approval Trials for Licensed Products in the Field in the Territory, including, without limitation, the Out-of-Pocket Cost of clinical research organizations, investigator and expert fees, lab fees and scientific service fees, the Out-of-Pocket Cost of shipping clinical supplies to centers or disposal of clinical supplies, in each case, to the extent not included in Commercial Supply Cost; and

(h) Commercial Overhead Charge.

The foregoing shall not include any costs which have been included in Development Costs. For clarity, it is the intent of the Parties that costs and headcount included in the foregoing will not be unfairly allocated to the Licensed Products in the Field in the Territory (to the extent that any Shared Promotion Expense is attributable, in part, to products or activities other than the Licensed Products in the Field in the Territory) and, in each case, will only be included once in the calculation of the Quarterly True-Up.

- 1.95 "Shares of Then Outstanding Capital Stock" shall mean, at any time, the issued and outstanding shares of Common Stock and Class A Stock of Regeneron at such time, as well as all capital stock issued and outstanding as a result of any stock split, stock dividend or reclassification of Common Stock or Class A Stock distributable, on a pro rata basis, to all holders of Common Stock and Class A Stock.
- 1.96 "Sublicensee" shall mean a Third Party or an Affiliate to whom Company will have granted a license or sublicense under Company's rights pursuant to Section 4.3 to Commercialize Licensed Products in the Field in the Territory. For the avoidance of doubt, a "Sublicensee" will include a Third Party to whom Company will have granted the right to distribute Licensed Products in the Field wherein such distributor pays to Company a royalty (or other amount) based upon the revenues received by the distributor for the sale (or resale) of Licensed Products by such distributor.
 - 1.97 "Territory Commercialization Budget" shall mean the three-year rolling budget(s) included in the Territory Commercialization Plan.
- 1.98 "<u>Territory Commercialization Plan</u>" shall mean the three-year rolling plan for Commercializing the Licensed Products in the Field in the Territory approved by the JSC, including the Territory Commercialization Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. The Territory Commercialization Plan shall set forth for each Licensed Product, the information, plans and forecasts set forth in Section 6.2.
 - 1.99 "Territory" shall mean all the countries of the world, except the Excluded Territory.
- 1.100 "Territory Development Plan" shall mean the three-year rolling plan approved by the JSC for Developing the Licensed Products in the Field for a specific country (or countries) in the Territory, including the related Territory Development Budget, as the same may be amended from time-to-time in accordance with the terms of this Agreement. For the avoidance of doubt, the Territory Development Plan will not include (a) any Development activities that are conducted as part of the Global Development Plan or (b) Non-Approval Trials, but will include any other clinical trials of the Licensed Products in the Field in the Territory, including any studies or other activities conducted for Pricing Approval.
 - 1.101 "Territory Development Budget" shall mean the three-year rolling budget(s) approved by the JSC in the Territory Development Plan.

- 1.102 "Third Party" shall mean any Person other than Company or Regeneron or any Affiliate of either Party.
- 1.103 "United States," "US" or "U.S." shall mean the United States of America (including its territories and possessions) and Puerto Rico.
- 1.104 "Valid Claim" shall mean a claim (a) of any issued, unexpired Patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (b) of any Patent Application that has not been cancelled, withdrawn or abandoned or pending for more than seven (7) years.
 - 1.105 "VEGF" shall mean vascular endothelial growth factor.
- 1.107 "Additional Definitions." Each of the following definitions is set forth in the Sections (or Schedules) of this Agreement indicated below:

DEFINITION	SECTION/SCHEDULE

Aggregate Regeneron Payment Amount	9.2(a)
Alliance Manager	3.2(a)
Collaboration	Preamble
Collaboration Purpose	3.1(b)
Company Products	2.6
Development Budget(s)	5.3
Development Overrun	9.11
Expert Panel	0.4
Global Brand	3.4(b)(i)
Global Development Balance	Schedule 2
Global True-Up	Schedule 2
Governance Dispute	10.2
Initial Development Plan	5.2
JCĈ	3.1(a)
JDC	3.1(a)
JFC	3.1(a)
JSC	3.1(a)
Joint Invention	12.1(b)
Manufacturing Cost	Schedule 1
Manufacturing Plan	8.4
Marketing Guidelines	3.4(b)(v)
Non-Approval Trials	6.2(j)

DEFINITION SECTION/SCHEDULE

Non-Incurred Amount
Project Manager

Regeneron Reimbursement Amount
Quarterly True-Up
Term
19.1(a)
Termination Notice Period
Territory Profit Split
Working Group

S.3
9
Schedule 2
Schedule 2
19.1(a)
19.2
Schedule 2
3.1(a)

ARTICLE II COLLABORATION

- 2.1 Scope of Collaboration. The Parties will cooperate in good faith under this Agreement and each Party will use Commercially Reasonable Efforts to Develop Licensed Products in the Field for the purpose of Commercializing Licensed Products in the Field in the Territory. Company will use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory. The Parties shall establish various Committees as set forth in Article 3 of this Agreement to oversee and/or coordinate the Development of Licensed Products in the Field and oversee the Commercialization of Licensed Products in the Field in the Territory, and each Party shall, subject to the terms and conditions set forth in Article 16, provide (or cause its Affiliates to provide) to any relevant Committee any necessary Party Information, New Information and such other information and materials as may be reasonably required for the Parties to effectively and efficiently Develop and Manufacture Licensed Products in the Field and for Company (and, if agreed to by Company or set forth in the Plans, Regeneron) to effectively and efficiently Commercialize the Licensed Products in the Field in the Territory under this Agreement.
- 2.2 <u>Compliance With Law.</u> Both Company and Regeneron, and their respective Affiliates, shall perform their obligations under this Agreement in an effort to Develop, Manufacture and Commercialize Licensed Products in the Field in the Territory in accordance with applicable Law. No Party or any of its Affiliates shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any applicable Law.
- 2.3 Further Assurances and Transaction Approvals. Upon the terms and subject to the conditions hereof, each of the Parties will use Commercially Reasonable Efforts to (a) take, or cause to be taken, all actions necessary, proper or advisable under applicable Laws or otherwise to consummate and make effective the transactions contemplated by this Agreement, (b) obtain from the requisite Governmental Authorities any consents, licenses, permits, waivers, approvals, authorizations or orders required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement and the consummation by such Party of the transactions contemplated by this Agreement and (c) make all necessary filings, and thereafter make any other advisable submissions, with respect to this Agreement and the transactions contemplated by this Agreement required to be made by such Party under applicable Laws. The Parties will cooperate with each other in connection with the making

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of all such filings. Each Party will furnish to the other Party all information in its possession or under its control required for any applicable or other filing to be made pursuant to the rules and regulations of any applicable Laws in connection with the transactions contemplated by this Agreement.

- 2.4 Compliance with Third Party Agreements. Each Party agrees to comply with the obligations set forth in (a) the Existing Licenses and the New Licenses to which it is a party and to notify the other Party of any terms or conditions in any such Existing License or New License with which such other Party is required to comply as a licensee or sublicensee, as the case may be, and (b) any other material agreement to which it is a party and that is related to the Collaboration, including, without limitation, any obligations to pay royalties, fees or other amounts due thereunder. Moreover, each Party shall take all actions reasonably necessary to ensure the other Party's ability to comply with (i) any such Existing License or New License (including any such terms and conditions with which such Party is required to comply as a sublicensee), and (ii) any such material agreement entered into pursuant to a Plan. Neither Party may terminate or amend any Existing License, New License or any other material agreement entered into pursuant to a Plan without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed, if the amendment or termination imposes any material liability or restriction on either Party with respect to the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory.
- 2.5 <u>Plans</u>. The Parties shall undertake all Development and Commercialization activities under this Agreement solely in accordance with the Committee approved Plans. The Parties may agree to amend all Plans and budgets from time to time as circumstances may require.
 - 2.6 Limitation on Exercise of Rights Outside of Collaboration.
- (a) During the Term, except as set forth in this Agreement, neither Party nor any of its Affiliates, either alone or through any Third Party, shall Develop or Commercialize any Product in the Field in the Territory, except pursuant to this Agreement. For the avoidance of doubt, nothing in the preceding sentence or elsewhere in this Agreement shall limit or restrict either Party's right to research, develop, make, have made, use, sell, offer to sell, have sold, import and export its Products outside the Field, including, without limitation, Regeneron's and Aventis' activities under the Aventis Agreement.
- (b) If a Party (the "Proposing Party") presents a proposal to the JDC to undertake additional clinical trials not contemplated in a Development Plan to support a Licensed Product in the Field and the JDC fails to approve the proposal within the timeframe established by the JDC pursuant to Section 5.5, then the Proposing Party may, at its option and at its sole expense, conduct such additional clinical trial(s) outside the scope of the Development Plans; provided, however, the Proposing Party must first present the proposed protocols and clinical trial designs to the other Party for approval, such approval not to be unreasonably withheld or delayed and, for other than

Non-Approval Trials or trials conducted solely for purposes of obtaining Approvals in the Excluded Territory, shall also present to the other Party the related budgets for Clinical Supply Costs and Out-of-Pocket Costs (provided that such budgets shall be provided for informational purposes only and may not be used to disapprove such protocols and designs). The other Party's representatives on the JDC may only disapprove any such protocols or clinical trial designs for material safety reasons. If, in compliance with this Section 2.6(b), the other Party does not approve any such protocols or clinical trial designs for material safety reasons, the Proposing Party may not proceed with the proposed clinical trials unless and until the dispute has been resolved as provided in Section 3.10(b) and, if necessary, Section 10.4. In the event that the Proposing Party conducts any such additional clinical trials, all results, Know-How and Patent Rights generated in or arising from any such clinical trial shall be subject to the grants of rights pursuant to Article 4 of this Agreement. For the avoidance of doubt, no consideration or reimbursement shall be paid to the Proposing Party with respect to the conduct of any such additional clinical trials; provided, however, that if the Parties subsequently agree to commence a further clinical trial based on the results of such additional clinical trial(s) or data is used from such additional clinical trials to support an Approval in the Territory, then the other Party shall be required to reimburse the Proposing Party for [**********] of the actual Out-of-Pocket Costs and Clinical Supply Costs incurred in connection with the conduct of such additional clinical trial(s) that are consistent with the budgets provided to the other Party pursuant to this Section 2.6(b) (if applicable) and the other terms of this Agreement. Nothing in this Section 2.6(b) shall permit Regeneron to make a Registration Filing in the Territory or seek an Approval in the Territory based on any results or data obtained in conducting the additional clinical trial(s) allowed under this Section 2.6(b), and publication of all data and results thereof shall be subject to Article 16.

(c) If Company determines that one of its or one of its Affiliates' internal product candidates constitutes a Product in the Field or if Company or its Affiliate acquires rights to a Product in the Field in the Territory from a Third Party, Company shall promptly present a proposal to the JDC to include such Product in the Collaboration based on the terms of this Agreement, and, as part of such presentation, shall provide the JDC with all information with respect to such Product reasonably available to Company and material to a decision by Regeneron's representatives on the JDC as to whether to approve the inclusion of such Product in the Collaboration. If Regeneron's representatives on the JDC, in their sole discretion, approve such inclusion of such Products being referred to as "Company Products"). If Regeneron's representatives on the JDC, in their sole discretion, do not approve such inclusion of such Product in the Collaboration, then, for such Products arising from Company's or its Affiliates' internal research and development activities or to which Company or its Affiliates acquire rights, Company or its Affiliates may continue to Develop such Product in the Field in the Territory up to the completion of Phase 2 Trials, at which time Company shall present to Regeneron's representatives on the JDC the available clinical data with respect to such Product for the approval by Regeneron's

representatives on the JDC of inclusion of such Product in the Collaboration as a Licensed Product under the terms of this Agreement. If Regeneron's representatives on the JDC do not, in their sole discretion, approve the inclusion of such Product in the Collaboration on the terms of this Agreement, then Company or its Affiliates may license or otherwise transfer rights to such Product in the Territory in the Field to a Third Party without any further consideration or payments to Regeneron. However, neither Company nor any of its Affiliates may participate in the further Development or Commercialization of such Products in the Field in the Territory. For the avoidance of doubt, any modification, derivative or new formulation of a Regeneron Product Developed by either Party shall be considered a Regeneron Product and not a Company Product.

2.7 Excluded Territory Activities. Notwithstanding that a Company Product or a Regeneron Product is deemed a Licensed Product hereunder, and for the avoidance of doubt, Company shall have the exclusive right and authority, in its discretion, to exploit Company Products in the Field in the Excluded Territory and Regeneron shall have the exclusive right and authority, in its discretion, to exploit Regeneron Products in the Field in the Excluded Territory, in each case, subject only to the terms of this Agreement that expressly apply to Licensed Products in the Field in the Excluded Territory. Each Party agrees to reasonably communicate and consult with the other Party (through the JDC or the other Party's representatives on the JDC, with respect to Development activities, and through the JCC or the other Party's representatives on the JCC, with respect to commercialization activities) on material Development and commercialization activities relating to Licensed Products in the Field in the Excluded Territory. Notwithstanding the foregoing or any other provision in this Agreement, neither Party nor any Committee shall have the right or authority to manage or control the internal operations of the other Party or to approve, modify, impede or delay any of the other Party's commercialization or Development plans or activities for its Products in the Excluded Territory (other than as contemplated under or in connection with the Global Development Plan). Each Party shall reasonably inform the JDC or the JCC or the other Party's representatives on the JDC or JCC, as applicable, of (a) all material clinical and regulatory matters directly relating to its Products in the Excluded Territory, whether or not addressed in the Global Development Plan, and (b) any other Development or commercialization activities directly relating to its Products in the Excluded Territory to the extent such matters or activities would be reasonably expected to materially adversely affect, or have a material impact on, the Development or Commercialization of Licensed Products in the Territory. To the extent any of the foregoing matters or activities in the Excluded Territory are undertaken pursuant to the Global Development Plan, each Party shall comply with the Global Development Plan; otherwise, the Party Developing and/or commercializing its Product(s) in the Excluded Territory shall consider in good faith all comments of the JDC and the JCC (or the other Party's representatives on the JDC or JCC) with respect to such matters and activities.

ARTICLE III MANAGEMENT

3.1 Committees/Management.

- (a) The Parties agree to establish, for the purposes specified herein, a Joint Steering Committee (the "JSC"), a Joint Development Committee (the "JDC"), a Joint Commercialization Committee (the "JCC"), a Joint Finance Committee (the "JFC") and such other Committees as the Parties deem appropriate. The roles and responsibilities of each Committee are set forth in this Agreement (or as may be determined by the JSC for Committees established in the future) and may be further designated by the JSC. From time to time, each Committee may establish working groups (each, a "Working Group") to oversee particular projects or activities, and each such Working Group shall be constituted and shall operate as the Committee which establishes the Working Group determines.
- (b) Each of the Committees and the Executive Officers shall exercise its decision-making authority hereunder in good faith and in a commercially reasonable manner for the purpose of optimizing the commercial potential of and financial returns from the Licensed Products in the Field in the Territory consistent with Commercially Reasonable Efforts and without regard to any other pharmaceutical product being developed or commercialized in the Field by or through a Party or any of its Affiliates (the "Collaboration Purpose"). The Parties acknowledge and agree that none of the Committees or the Executive Officers shall have the power to amend any of the terms or conditions of this Agreement, other than by mutual agreement of the Parties as set forth in Section 20.5.

3.2 Joint Steering Committee.

(a) Formation; Composition and Purpose. Within ten (10) days after the Effective Date, the Parties will establish the JSC, which shall have overall responsibility for the oversight of the Collaboration. The purpose of the JSC shall be (i) to review and approve the overall strategy for an integrated worldwide Development program; for the Manufacture of Licensed Products in the Field for use in activities under the Plans and for the Commercialization of Licensed Products in the Field in the Territory; (ii) to review the efforts of the Parties in performing their responsibilities under the Plans and (iii) to oversee the Committees and resolve matters pursuant to the provisions of Section 3.10 below on which such Committees are unable to reach consensus. The JSC shall be composed of at least three (3) senior executives of each Party; provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). In addition, each Party shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Alliance Manager ("Alliance Manager") to the JSC. Each Alliance Manager shall be charged with creating and maintaining a collaborative work environment within and among all Committees.

(b) Specific Responsibilities. In addition to its overall responsibility for overseeing the Collaboration, the JSC shall in particular (i) annually

review and approve the Development Plan(s), Manufacturing Plan(s) and Territory Commercialization Plan(s); (ii) at least semi-annually review the efforts of the Parties in performing their respective Development and Commercialization activities under the then effective Plans; (iii) attempt in good faith to resolve any disputes referred to it by any of the Committees and provide a single-point communication for seeking consensus regarding key global strategy and Plan issues; (iv) establish sub-committees of the JSC as the JSC deems appropriate and (v) consider and act upon such other matters as are specified in this Agreement or otherwise agreed to by the Parties.

3.3 Joint Development Committee.

- (a) <u>Formation; Composition and Purpose</u>. Within ten (10) days after the Effective Date, the Parties will establish the JDC. The purpose of the JDC shall be (i) to advise the JSC on the strategy for the Development of Licensed Products in the Field as part of an integrated worldwide Development program; (ii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Development Plan(s) (and related Development Budget(s)) and (iii) to oversee the implementation of the Development Plan(s) and the Development operational aspects of the Collaboration. The JDC shall be composed of at least three (3) senior executives of each Party; provided that each Party must appoint, as one of its representatives on the JDC, its Project Manager and provided further, that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).
 - (b) Specific Responsibilities. In particular, subject to Section 2.7, the JDC shall be responsible for:
 - (i) advising the JSC on the overall global Development strategy for the Licensed Products in the Field;
 - (ii) facilitating an exchange of Development data between the Parties and developing and updating the Development Plans (and related Development Budgets), as described in Sections 5.2 and 5.3, for final approval by the JSC;
 - (iii) developing (or overseeing the development of), reviewing, annually updating and overseeing the implementation of, and compliance with, the Development Plans (including the Development Budgets);
 - (iv) developing forecasts for Clinical Supply Requirements to enable the timely preparation of the Manufacturing Plan;
 - (v) overseeing clinical and regulatory matters pertaining to Licensed Products in the Field arising from the Plans; advising on material clinical and regulatory matters and other Development activities in the Excluded Territory that are reasonably expected to

materially adversely affect, or have a material impact on, the Development of Licensed Products in the Territory; and reviewing and approving protocols, statistical analysis plans, clinical study endpoints, clinical methodology and monitoring requirements for clinical trials of Licensed Products in the Field as contemplated under the Development Plans and for Non-Approval Trials;

- (vi) reviewing and approving proposed target Licensed Product labeling and reviewing, and to the extent set forth herein approving, proposed changes to Product labeling with respect to Licensed Products in the Field in accordance with Section 7.2(f);
- (vii) facilitating an exchange between the Parties of data, information, material and results relating to the Development of Licensed Products in the Field;
- (viii) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new formulations, delivery systems and improvements in concert with the JCC;
- (ix) establishing a regulatory Working Group responsible for overseeing, monitoring and coordinating the submission of Registration Filings in countries in the Territory, including coordinating material communications, filings and correspondence with Regulatory Authorities in the Territory in connection with the Licensed Products in the Field;
- (x) establishing a Working Group responsible for overseeing all basic research activities for Licensed Products in the Field conducted under the Global Development Plan; and
 - (xi) considering and acting upon such other matters as are specified in this Agreement or by the JSC.

3.4 Joint Commercialization Committee.

(a) <u>Formation</u>; <u>Composition and Purpose</u>. Within twenty (20) days after the Effective Date, the Parties will establish the JCC. The purpose of the JCC shall be (i) to develop and propose to the JDC and JSC the strategy for the Commercialization of Licensed Products in the Field in the Territory; (ii) to discuss and advise on certain commercialization activities for the Licensed Products in the Excluded Territory to the extent contemplated in Section 2.7; (iii) to develop (or oversee the development of), review and annually update and present to the JSC for approval the Territory Commercialization Plan (and related Territory Commercialization Budget); (iv) to develop (or oversee the development of), review and annually update and approve the Country Commercialization Plans (and related Country Commercialization Budgets) and (v) to oversee the implementation of the Territory Commercialization Plan and the

Commercialization operational aspects of the Collaboration. The JCC shall be composed of at least two (2) senior executives of each Party.

- (b) JCC Responsibilities. In particular, subject to Section 2.7, the JCC shall be responsible for:
- - (ii) developing and proposing to the JSC the strategy for the Commercialization of the Licensed Products in the Field in the Territory;
- (iii) commencing no later than three (3) years prior to the Anticipated First Commercial Sale anywhere in the Territory, (A) developing, and updating at least annually, the Territory Commercialization Plans (and related Territory Commercialization Budgets) for final approval by the JSC and (B) approving the Country Commercialization Plan(s) (and related Country Commercialization Budget(s));
- (iv) developing forecasts for Commercial Supply Requirements for the Territory to enable the timely preparation of the Manufacturing Plan for review by the JSC;
- - (vi) developing target profiles for the Licensed Products in the Field;
- (vii) developing (or overseeing the development of), reviewing, annually updating and overseeing the implementation of and compliance with the Territory Commercialization Plans (including the Territory Commercialization Budgets) and Country Commercialization Plans (including the Country Commercialization Budgets), including ensuring that country specific launch plans in the Territory are consistent with the Marketing Guidelines;
 - (viii) establishing, as necessary, sub-committees of the JCC;
 - (ix) if the Parties agree to use a Global Brand, selecting a Product Trademark for Licensed Products in the Field in accordance with

- (xi) developing and implementing plans and policies regarding journal and other publications with respect to Licensed Products in the Field in concert with the JDC;
- (xii) allocating the appropriate cost for Commercialization activities that support the Licensed Products in the Field in the Territory and the Excluded Territory as Other Shared Expenses and/or Shared Promotion Expenses, if applicable, in accordance with this Agreement and assigning responsibilities and approving budgets for such activities;
- (xiii) formulating a life-cycle management strategy for Licensed Products in the Field and evaluating new opportunities for new indications, formulations, delivery systems and improvements in concert with the JDC;
- (xiv) consulting on all commercialization activities for Licensed Products in the Field in the Excluded Territory that are reasonably expected to materially adversely affect, or have a material impact on, the Commercialization of Licensed Products in the Territory in accordance with, and subject to, Section 2.7 and Section 6.5; and
 - (xv) considering and acting upon such other matters as are specified in this Agreement or by the JSC or JDC.
- 3.5 Other Committees. Within ten (10) days after the Effective Date, the Parties will establish the JFC, which shall be responsible for accounting, financial (including planning, reporting and controls) and funds flow matters related to the Collaboration and this Agreement, including such specific responsibilities set forth in Article 9 and such other responsibilities determined by the JSC. The JFC also shall respond to inquiries from the JDC and the JCC, as needed.
- 3.6 <u>Membership</u>. Each of the Committees shall be composed of an equal number of representatives appointed by each of Regeneron and Company. Each Party may replace its Committee members upon written notice to the other Party. Each Committee will have two (2) cochairpersons, one designated by each of Regeneron and Company. Each co-chairperson shall be entitled to call meetings. The co-chairpersons shall coordinate activities to prepare and circulate an agenda in advance of the meeting and prepare and issue draft minutes of each meeting within seven (7) days thereafter and final minutes within thirty (30) days thereafter.

- 3.7 <u>Meetings</u>. Each Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than every Quarter during the Term. If possible, the meetings shall be held in person (to the extent practicable, alternating the site for such meetings between the Parties) or when agreed by the Parties, by video or telephone conference. Other representatives of each Party or of Third Parties involved in the Development, Manufacture or Commercialization of the Products (under obligations of confidentiality) may be invited by the Committee cochairs to attend meetings of the Committees as nonvoting participants. Each Party shall be responsible for all of its own expenses of participating in the Committees. Either Party's representatives on a Committee may call a special meeting of the applicable Committee upon at least five (5) Business Day's prior written notice, except that emergency meetings may be called with at least one (1) Business Day's prior written notice.
- 3.8 <u>Decision-Making</u>. The Committees shall operate by consensus. The representatives of each Party shall have collectively one (1) vote on behalf of such Party; provided that no such vote taken at a meeting shall be valid unless a representative of each Party is present and participating in the vote. Notwithstanding the foregoing, each Party, in its sole discretion, by written notice to the other Party, may choose not to have representatives on a Committee and leave decisions of such Committee(s) to representatives of the other Party.
- 3.9 <u>Project Manager</u>. Each of Company and Regeneron shall appoint a senior representative who possesses a general understanding of clinical, regulatory, manufacturing and marketing issues to act as its Project Manager ("<u>Project Manager</u>"). Each Project Manager will be responsible for:
- (a) coordinating the various functional activities of Company and Regeneron, as appropriate, in developing and executing strategies and Plans for the Licensed Products in the Field in an effort to ensure consistency and efficiency;
- (b) providing single-point communication for seeking consensus both within the respective Party's organization and with the other Party's organization regarding key strategy and Plan issues, as appropriate, including facilitating review of external corporate communications; and
 - (c) identifying and raising cross-country, cross-Party and/or cross-functional disputes to the appropriate Committee in a timely manner.
- 3.10 <u>Resolution of Governance Matters</u>. As provided in Section 10.2, this Section 3.10 shall apply to matters constituting, or which if not resolved would constitute, a Governance Dispute.
- (a) <u>Generally</u>. The Parties shall cause their respective representatives on the Committees to use their Commercially Reasonable Efforts to resolve all matters presented to them as expeditiously as possible:

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- (i) in the case of any matter which cannot be resolved by the JDC, JCC, JFC or any other committee established by the JSC, at the request of either Party, such matter shall promptly, and in any event within five (5) Business Days (or one (1) Business Day in the event of an urgent matter) after such request, be referred to the JSC with a request for resolution;

- (b) <u>Referral to Executive Officers</u>. In the event that the JSC is, after a period of five (5) Business Days from the date a matter is submitted to it for decision, unable to make a decision due to a lack of required unanimity, and one Party is not expressly allocated decision making authority over the matter as set forth in this Agreement, then either Party may require that the matter be submitted to the Executive Officers for a joint decision. In such event, either Party may, in a written notice to the other Party, formally request that the dispute be resolved by the Executive Officers, specifying the nature of the dispute with sufficient specificity to permit adequate consideration by such Executive Officers. The Executive Officers shall diligently and in good faith, attempt to resolve the referred dispute within five (5) Business Days of receiving such written notification, failing which, except for Legal Disputes (unless as jointly agreed by the Parties), either Party may by written notice to the other Party require the specific issue in dispute to be submitted for resolution by an Expert Panel pursuant to Section 10.4, if such dispute is with respect to a Technical Development Matter.
- (c) <u>Interim Budgets</u>. Pending resolution by the Executive Officers of any referred dispute under Section 3.10(b) and subject to the terms of Section 19.2, the Executive Officers shall negotiate in good faith in an effort to agree to appropriate interim budgets and plans to allow the Parties to continue to use

Commercially Reasonable Efforts to Develop, Manufacture and Commercialize the Licensed Products in the Field in the Territory pursuant to this Agreement. The most recent Committee approved Plan(s) shall be extended pending approval by the Executive Officers of the interim budget(s) and Plan(s) referred to in this Section 3.10(c).

(d) <u>Obligations of the Parties</u>. The Parties shall cause their respective designees on the Committees and their respective Executive Officers to take the actions and make the decisions provided herein to be taken and made by such respective designees and Executive Officers in the manner and within the applicable time periods provided herein.

ARTICLE IV LICENSE GRANTS

- 4.1 Regeneron License Grants. Subject to the terms and conditions of this Agreement (including, without limitation, Section 4.5) and any Existing License or New License to which Regeneron is a party, Regeneron hereby grants to Company (a) the nontransferable (except as permitted by Section 20.9), co-exclusive (with Regeneron and its Affiliates) right and license under the Regeneron Intellectual Property to make, have made, use, develop, import and export Licensed Products for use in the Field in the Territory, and (b) the nontransferable (except as permitted by Section 20.9), exclusive right and license under the Regeneron Intellectual Property to sell and offer to sell Licensed Products in the Field in the Territory, subject to Regeneron's right to supply Licensed Products to Company, as contemplated by this Agreement. Company will have the right to grant sublicenses under the foregoing license only as set forth in Section 4.3. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Regeneron is a party, Regeneron also grants to Company the nontransferable (except as permitted by Section 20.9), fully paid-up, royalty-free, non-exclusive, sublicensable right and license under Regeneron Excluded Territory Intellectual Property to make, have made, use, sell, offer to sell, have sold, import or export Company Products for use in the Field in the Excluded Territory.
- 4.2 Company License Grants. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Company or any of its Affiliates is a party, Company hereby grants to Regeneron the nontransferable (except as permitted by Section 20.9), royalty-free, co-exclusive (with Company and its Affiliates) right and license under the Company Intellectual Property to make, have made, develop, use, import and export Licensed Products for use in the Field in the Territory. Subject to the terms and conditions of this Agreement and any Existing License or New License to which Company or any of its Affiliates is a party, Company also grants to Regeneron the nontransferable (except as permitted by Section 20.9), fully paid-up, royalty-free, non-exclusive, sublicensable right and license under Company Excluded Territory Intellectual Property to make, have made, use, sell, offer to sell, have sold, import or export Regeneron Products for use in the Field in the Excluded Territory.

- 4.3 Sublicensing. Unless otherwise restricted by any Existing License or New License, Company will have the right to sublicense any of its rights under the first sentence of Section 4.1 only with the prior written consent of Regeneron, such consent not to be unreasonably withheld or delayed with respect to rights outside the Major Market Countries (and only with the prior written consent of Regeneron, which consent may be withheld for any reason, in the Major Market Countries), except that Company may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Regeneron's consent. Unless otherwise restricted by any Existing License or New License, Regeneron will have the right to sublicense any of its rights under the first sentence of Section 4.2 only with the prior written consent of Company, such consent not to be unreasonably withheld or delayed, except that Regeneron may sublicense any of its rights hereunder to an Affiliate for purposes of meeting its obligations under this Agreement without Company's consent. Each Party shall remain responsible and liable for the compliance by its Affiliates and Sublicensees with applicable terms and conditions set forth in this Agreement. Any such sublicense agreement will require the Sublicensee of a Party to comply with the obligations of such Party as contained herein, including, without limitation, the confidentiality and non-use obligations set forth in Article 16, and will include, with respect to a Sublicensee of Company, an obligation of the Sublicensee to account for and report its sales of Licensed Products to Company on the same basis as if such sales were Net Sales by Company. For the avoidance of doubt, Regeneron shall be entitled to receive its share of the Territory Profit Split based on Net Sales of Licensed Products sold by Sublicensees under this Agreement. In the event of a breach by a Sublicensee of any sublicense agreement which has or is reasonably likely to have a materially adverse effect on Regeneron or any of its Affiliates or any Regeneron Intellectual Property, then Regeneron may cause Company or its Affiliate to exercise, and the Company or its Affiliate will promptly exercise, any termination rights it may have under the sublicense with the Sublicensee. Any sublicense agreement will provide for the termination of the sublicense or the conversion of the sublicense to a license directly between the Sublicensee and Regeneron, at the option of Regeneron, upon termination of this Agreement, Furthermore, any such sublicense shall prohibit any further sublicense or assignment. Company will forward to Regeneron a complete copy of each fully executed sublicense agreement (and any amendment(s) thereto) within ten (10) days of the execution of such agreement.
- 4.4 No Implied License. Except as expressly provided in this Article 4 or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's Patent Rights, Know-How, or Party Information either expressly or by implication, estoppel or otherwise.
- 4.5 <u>Retained Rights</u>. With respect to the licenses granted under this Article 4, Regeneron reserves for itself and its Affiliates and Third Party licensees under the Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions, (a) the right to make, have made, distribute, import, export and use Regeneron Products in the Field in the Territory exclusively for Development purposes, and (b) the right to Manufacture and, if agreed to by Company or set forth in any Plans, the right to Commercialize Licensed Products for use in the Field in the Territory in accordance with this Agreement. For the avoidance of doubt, Regeneron retains all rights in Regeneron

Intellectual Property, Regeneron's interest in the Joint Inventions and Regeneron Products not expressly licensed hereunder, including, without limitation the right (i) to exploit Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions to make, have made, use, sell, offer to sell, have sold, import or export Products for use outside the Field; (ii) to exploit Regeneron Intellectual Property and Regeneron's interest in the Joint Inventions to make, have made, use, sell, offer to sell, have sold, and import and export Products for use in the Field in the Excluded Territory and (iii) to exploit Regeneron Intellectual Property and Regeneron's interest in Joint Inventions for purposes unrelated to the Licensed Products in the Field.

ARTICLE V DEVELOPMENT ACTIVITIES

- 5.1 <u>Development of Licensed Products</u>. Subject to the terms of this Agreement, the Parties shall undertake Development activities with respect to Licensed Products in the Field pursuant to the Development Plans under the general direction and oversight of the JDC. Each Party shall use Commercially Reasonable Efforts to Develop Licensed Products in the Field, carry out the Development activities assigned to it in Development Plans in a timely manner and conduct all such activities in compliance with applicable Laws, including, without limitation, Good Practices. Regeneron may conduct separate Development activities to support Regeneron Products in the Excluded Territory, and Company may conduct separate Development activities to support Company Products in the Excluded Territory, in each case, subject to the conditions and requirements set forth herein, including, without limitation, Section 2.6(b).
- 5.2 <u>Development Plans</u>. The JDC shall prepare and update Development Plans for Licensed Products in the Field under this Agreement for approval by the JSC. Except for the first Global Development Plan incorporating the Initial Development Plan referred to below in this Section 5.2, an updated Global Development

Plan (and, if applicable, Territory Development Plan) will be presented by the JDC for approval by the JSC, and approved by the JSC, at least two (2) months prior to the end of each Contract Year. Each Development Plan will set forth the plan for Development of each Product in the Field over at least three (3) Contract Years and will include (a) strategies and timelines for Developing and obtaining Approvals for the Licensed Products in the Field in the Territory and, subject to Section 2.7, the Excluded Territory, and (b) the allocation of responsibilities for Development activities between the Parties, and/or Third Party service providers to the extent provided by the applicable Development Plan. Each Development Plan will be reviewed and informally updated by the JDC not less frequently than every six (6) months for the ensuing three (3) year period. The activities agreed to by the Parties (together with the associated estimated budget) as set forth on Schedule 5 shall constitute the initial plan for the Development of Licensed Products in the Field under this Agreement (the "Initial Development Plan"). No later than sixty (60) days after the Effective Date, the JDC will meet to finalize the first Global Development Plan (which, as provided above, shall incorporate, or be substantially consistent with, the Initial Development Plan). Until the first Global Development Plan is approved by the JSC, the Parties will Develop the Licensed Products in the Field under this Agreement in accordance with the Initial Development Plan, unless otherwise agreed to by the JSC. Unless otherwise agreed to by the JDC, each update to the Development Plan(s) shall include the activities and timelines described in or referred to in the Initial Development Plan until the activities described therein are completed in a timely manner.

5.3 Development Budgets. The Territory Development Plan shall include the Territory Development Budget and the Global Development Plan shall include the Global Development Budget (each individually, a "Development Budget" and both collectively, the "Development Budgets") and the Development Budgets shall be prepared, updated, reviewed and approved as part of the preparation, update and approval of the Development Plans in accordance with this Agreement. Amendments and updates to any Development Budgets shall not be effective without the approval of the JSC. In the event that, during any Contract Year (the "First Year"), any Development activity expressly provided for in the approved Development Budget to be completed during such First Year is not completed during such First Year (to the extent incomplete, an "Incomplete Activity") and the full expense budgeted for such activity for such First Year is not incurred (to the extent not incurred, a "Non-Incurred Amount"), then such Incomplete Activity shall be completed during Contract Years following such First Year (the "Succeeding Year(s)") and the Non-Incurred Amount shall be included in the Development Budget for such Succeeding Year(s) has not yet been approved by the JSC, then the Non-Incurred Amount shall be included in the proposed Development Budget for such Succeeding Year(s) without otherwise limiting any other Development activities or any amounts related thereto, unrelated to the Incomplete Activity, which, pursuant to the Development Plan, would have been performed during such Succeeding Year(s) has been approved by the JSC, then the Development Budget for such Succeeding Year (s) shall be revised automatically to include the Non-Incurred Amount.

- 5.4 <u>Development Reports</u>. Within forty-five (45) days after the end of each Quarter, Regeneron and Company shall each provide to the other Party a written report (in electronic form) summarizing the material activities undertaken by such Party during such Quarter in connection with each Development Plan, together with a statement of Development Costs incurred by such Party during such Quarter, which statement shall detail those amounts to be included in the Consolidated Payment Report for such Quarter and shall be in such form, format and of such level of detail as approved by the JFC. At the next JDC meeting held following such forty-five (45) day period, the JDC will approve the final Development Costs which will be used in the calculation of the Global Development Balance.
- 5.5 Review of Clinical Trial Protocols. The JDC will establish procedures for the expeditious review of clinical trial protocols for the Licensed Products submitted to the JDC by either Party pursuant to Section 2.6(b), including, without limitation, pre-approval authorizations for Non-Approval Trials meeting established criteria. In no event will such procedures require more than ten (10) Business Days for the JDC to accept or reject a proposed protocol and/or clinical trial design for a clinical study to be conducted solely for purposes of obtaining an Approval in the Excluded Territory.

ARTICLE VI COMMERCIALIZATION

- 6.1 <u>Commercialization of Products in the Field in the Territory.</u> Subject to the terms of this Agreement, the Parties shall undertake Commercialization activities with respect to Licensed Products in the Field in the Territory under the direction and oversight of the JCC and in accordance with the Territory Commercialization Plan and the Country Commercialization Plans. Except as set forth in this Agreement, Company shall bear all costs and expenses to Commercialize the Licensed Products in the Field in the Territory.
- 6.2 Territory Commercialization Plan. The Territory Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. The initial Territory Commercialization Plan will be prepared by Company, with Regeneron's participation and input with respect to the portions of such Plan directly applicable to the Major Market Countries, and submitted to the JCC for review and approval. Once approved by the JCC, the Territory Commercialization Plan will be presented to the JSC for review and approval at least [*********] before the Anticipated First Commercial Sale in the Territory. The Territory Commercialization Plan for each subsequent Contract Year shall be updated by the JCC and approved by the JSC at least two (2) months prior to the end of the then current Contract Year. Each Territory Commercialization Plan shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

- (a) the overall strategy for Commercializing Licensed Products in the Field in the Territory, including Licensed Product target product profiles, branding, positioning, promotional materials and core messages;
 - (b) subject to applicable Law, Licensed Product pricing guidelines in the Field in the Territory;
 - (c) the Territory Commercialization Budget;
 - (d) anticipated launch dates for applicable countries in the Territory;
- (e) any global Commercialization activities that are designed to benefit the Licensed Product in the Field in both the Territory and the Excluded Territory (including, without limitation, such activities that relate to global branding, global market research, Licensed Product websites and certain publication strategies);
 - (f) market and sales forecasts for the Licensed Products in the Field in the Territory in a form to be agreed between the Parties;
- (g) strategies for the detailing and promotion of Licensed Products in the Field in the Territory, including recommended sales force sizes in the countries in the Territory;
 - (h) anticipated major advertising, public relations and patient advocacy programs for Licensed Products in the Field in the Territory;
- (j) post-marketing clinical trials to support Commercialization of Licensed Products in the Field in the Territory which [****************************, including any such clinical trials sponsored by Third Parties using Licensed Product supplied by the Parties ("Non-Approval Trials");
 - (k) proposed use of Third Party sales representatives, Sublicensees and/or distributors in any country in the Territory;
- (l) target incentive product weighting and performance goals for sales representatives detailing the Licensed Products in the Field in the Territory; and
 - (m) all other Marketing Guidelines.
- 6.3 <u>Country Commercialization Plans</u>. Each Country Commercialization Plan and all updates and amendments thereto will be consistent with the principles of the Collaboration Purpose. The initial Country Commercialization Plan for each Major Market Country will be prepared by Company, with Regeneron's participation and input, and approved by the JCC at least [*********] before the Anticipated First Commercial Sale in the applicable Major Market Country. The Country

Commercialization Plan for each subsequent Contract Year shall be updated and approved by the JCC at least two (2) months prior to the end of the then current Contract Year. Each Country Commercialization Plan shall include (with sufficient detail, relative to time remaining to Anticipated First Commercial Sale, to enable the JCC and JSC to conduct a meaningful review of such Plan) information and formatting as will be agreed upon by the JCC, including:

- (a) the overall strategy for Commercializing Licensed Products in the Field in the Major Market Country, including Licensed Product branding, positioning, promotional materials, core messages, pricing strategies and competitive analyses;
 - (b) the Country Commercialization Budget;
 - (c) anticipated launch dates for the Licensed Product in the Field in the Major Market Country;
- (d) market and sales forecasts for the Licensed Products in the Field in the Major Market Country in a form to be agreed between the Parties;
- (e) strategies for the detailing and promotion of Licensed Products in the Field in the Major Market Country, including sales force and medical affairs field force sizes, the number and type of Licensed Product details to be performed by Company sales representatives and target opinion leaders in the Major Market Country;
 - (f) FTE requirements and Shared Promotion Expenses to fulfill the requirements of the Country Commercialization Plan;
- (g) advertising, patient advocacy programs, professional symposia, public relations, marketing, sales and promotion efforts for Licensed Products in the Field in the Major Market Country;
- - 6.4 Commercialization Activities; Sharing of Commercial Information.
- (a) Company (through its Affiliates where appropriate) shall use Commercially Reasonable Efforts to Commercialize Licensed Products in the Field in the Territory in accordance with the Territory Commercialization Plan and the Country Commercialization Plans. Without limiting the foregoing, Company will, as necessary, build, train and apply a field force in the Territory necessary to

Commercialize the Licensed Products in the Field in the Territory in accordance with the Territory Commercialization Plan and Country Commercialization Plans.

- (b) Company will use reasonable efforts to provide Regeneron with full access to Company information directly relating to the Commercialization of the Licensed Products in the Field in the Territory, including, without limitation, information relating to anticipated launch dates, the development of sales targets by customer segment and territory, key market metrics, market research, sales forecasting and modeling, sales, prescription and patient data, reimbursement and pricing matters, and field force plans, goals, incentives and training.
- (c) Each Party shall, on a periodic and reasonably current basis, keep the other Party informed regarding major market developments, acceptance of the Licensed Products in the Field, Licensed Product quality complaints and similar information from the Territory or the Excluded Territory, as the case may be.
- (d) No Party may initiate or support any Non-Approval Trial for a Licensed Product in the Field in the Territory without the prior approval of the JDC.
- 6.6 Sales and Product Distribution in the Territory; Other Responsibilities. Company (or its Affiliate) shall invoice and book, and appropriately record, all sales of the Licensed Products in the Field in the Territory. Company (or its Affiliate) also shall be responsible for (a) the distribution of Licensed Products in the Field in the Territory and for paying all governmental rebates which are due and owing with respect to the Licensed Products in the Field in the Territory, (b) handling all returns of Licensed Product sold under this Agreement and (c) handling all aspects of ordering, processing, invoicing, collection, distribution and receivables with respect to Licensed Products in the Field in the Territory. If Licensed Product sold in the Field in the Territory is returned to Regeneron, it shall promptly be shipped to a facility designated by Company. If Regeneron Product sold in the Excluded Territory is returned to Company, it shall promptly be shipped to a facility designated by Regeneron. If Regeneron receives an order for Licensed Product in the Field in the Territory (or Company receives an order for Regeneron Product in the Field in the Excluded Territory), the Party erroneously receiving the order shall refer such orders to the other Party.
- 6.7 <u>Commercialization Efforts</u>. Company's sales representatives in the Territory shall provide the FTE effort and promote and detail the Licensed Products in the Field in accordance with the approved Country Commercialization Plan (if applicable), Territory Commercialization Plan and all applicable Laws. Company shall, at its own expense, comply with the training plan contained in any Country Commercialization Plan.

Beginning in the Quarter of the First Commercial Sale in each Major Market Country, Company will provide Regeneron on a quarterly basis with reports of the activity within its field force in each such Major Market Country, which will include reasonable data from reports created by Company for its internal management purposes. Company (through its local Affiliates where appropriate) shall maintain records relating to its sales representative FTEs for the Licensed Products in the Field in the countries in a manner sufficient to permit the determination of Sales Force Cost and Medical Affairs Cost and the incentive compensation requirements set forth in the Marketing Guidelines.

6.8 Contract Sales Force. Company shall not use the services of a sales representative employed by a Third Party without Regeneron's prior written consent. Company will be responsible for (a) all costs associated with retaining any such contract sales force in excess of the expected Sales Force Cost if Company provided its own field force and for such Third Party's compliance with this Agreement, (b) ensuring such contract sales force's compliance with all applicable Laws and (c) ensuring that sales representatives in such contract sales force have minimum skill levels customary for sales representatives in the Field at major pharmaceutical companies in such country.

6.9 Promotional Materials.

- (a) Company will be responsible, consistent with the Marketing Guidelines, the Territory Commercialization Plan and the Country Commercialization Plans (as applicable), for the creation, preparation, production and reproduction of all Promotional Materials and for filing, as appropriate, all Promotional Materials with all Regulatory Authorities in the Territory. Upon request, Regeneron will have the right to review and comment on all major Promotional Materials for use in any country in the Territory prior to their distribution by Company for use in the Territory. (b) Company shall use its own corporate name and/or logo on Promotional Materials and Licensed Product labels in connection with Commercialization of Licensed Products in the Territory, unless otherwise mutually agreed by the Parties.
 - (b) The Parties shall jointly own all rights to all Promotional Materials, including all copyrights thereto, in the Major Market Countries.
- 6.10 <u>Promotional Claims/Compliance</u>. Neither Company nor any of its Affiliates shall make any medical or promotional claims for any Licensed Product in the Field other than as permitted by applicable Laws. When distributing information related to any Licensed Product or its use in the Field in the Territory (including information contained in scientific articles, reference publications and publicly available healthcare economic information), Company and its Affiliates shall comply with all applicable Laws and any guidelines established by the pharmaceutical industry in the applicable country.
- 6.11 <u>Restriction on Bundling in the Territory</u>. If Company or its Affiliates or Sublicensees sell a Licensed Product in the Field in the Territory to a customer who also purchases other products or services from any such entity, Company agrees not to, and to require its Affiliates and Sublicensees not to, bundle or include any Licensed

Product as part of any multiple product offering or discount or price the Licensed Products in a manner that (a) is reasonably likely to disadvantage a Licensed Product in order to benefit sales or prices of other products offered for sale by a Party or its Affiliates to such customer or (b) is inconsistent with the Collaboration Purpose.

- 6.12 <u>Inventory Management</u>. Company shall use Commercially Reasonable Efforts to manage Licensed Product inventory on hand at wholesalers and Sublicensees so as to maintain levels of inventory appropriate for expected demand and to avoid taking action that would result in unusual levels of inventory fluctuation.
- 6.13 Medical and Consumer Inquiries. Company shall be responsible for responding to medical questions or inquiries from members of the medical and paramedical professions and consumers regarding Licensed Products in the Field in the Territory. The Parties will work together to formulate responses to the major inquiries, which shall be used, if possible, by Company in the Territory and Regeneron in the Excluded Territory. If Regeneron receives questions about Licensed Products in the Field in a country in the Territory, it shall refer such questions to Company, and Company shall be responsible for responding thereto. If Company receives a question about Regeneron Products in the Field in a country in the Excluded Territory (or about any Regeneron Product outside the Field), it shall refer such questions to Regeneron, and Regeneron shall be responsible for responding thereto.
- 6.14 <u>Market Exclusivity Extensions</u>. Each Party shall use Commercially Reasonable Efforts to maintain, and, to the extent available, legally extend, the period of time during which, in any country in the Territory, (a) a Party(ies) has the exclusive legal right, whether by means of a Patent Right or through other rights granted by a Governmental Authority in such country, to Commercialize a Licensed Product in the Field in such country and (b) no generic equivalent of a Product in the Field may be marketed in such country.
- 6.15 <u>Post Marketing Clinical Trials</u>. Subject to the provision of this Agreement, the Parties shall comply with any clinical trial obligations with respect to a Marketing Approval with respect to any Licensed Product use in the Field in any country in the Territory, imposed by applicable Law, pursuant to the Approvals or required by a Regulatory Authority.

Products as to which, as of the date notice of such termination is received by Regeneron, Regeneron has ownership of, or a license to. A Party shall not be considered in breach of this Section 6.16 solely by reason of the acquisition by such Party of a Person (i) if such Party includes the offending Product(s) in the licenses granted to the other Party pursuant to this Agreement or (ii) if prior to the closing of such acquisition, the acquiring Party commits in writing to the other Party that, promptly following the closing of such acquisition, it will divest itself of the offending rights and/or activity, and the acquiring Party uses Commercially Reasonable Efforts to pursue such divestiture, and in the event that such divestiture is not completed within six (6) months of the closing of such acquisition, the acquiring Party ceases all Development, Manufacturing and/or Commercialization, as applicable, of the offending Product(s) in the Field or includes the offending Products(s) in the licenses granted to the other Party pursuant to this Agreement.

6.18 Exports from the Territory to the Excluded Territory.

- (a) Company shall supply the [******************************* with Licensed Products in quantities that are appropriate to the size of such market (not including cross-border sales).

- (f) Notwithstanding anything to the contrary contained herein, nothing contained in this Section 6.18 shall require any Party to take actions inconsistent with applicable Law.

ARTICLE VII CLINICAL AND REGULATORY AFFAIRS

7.1 Ownership of Approvals and Registration Filings.

- (a) Regeneron shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, (i) with respect to the Development of Regeneron Products in the Field in the Excluded Territory under the Global Development Plan and (ii) with respect to any site license for its manufacturing facilities anywhere in the world, and shall have the rights and obligations set forth in this Article 7 with respect thereto.
- (b) During the Term, Company shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, (i) with respect to the Licensed Products in the Field in each country in the Territory and (ii) with respect to any site license for its manufacturing facilities anywhere in the world, and shall have the rights and obligations set forth in this Article 7 with respect thereto. Company shall be the Lead Regulatory Party, and shall own all Approvals and Registration Filings, for any Company Products in the Field in the Excluded Territory with respect to the Development of Company Products under a Global Development Plan.
- (c) The Lead Regulatory Party shall, as reasonably necessary to permit a Party to perform obligations under this Agreement, license, transfer, provide a letter of reference with respect to or take other action necessary to make available the relevant Registration Filings and Approvals to and for the benefit of the other Party.

7.2 Regulatory Coordination.

(a) The Lead Regulatory Party shall oversee, monitor and coordinate all regulatory actions, communications and filings with and submissions (including supplements and amendments thereto) to each applicable Regulatory Authority with respect to the Licensed Product in the Field in each jurisdiction as to

which it is the Lead Regulatory Party; provided that it shall adhere to the obligations in this Article 7. Without limiting the foregoing, the Lead Regulatory Party will be responsible for, and will use Commercially Reasonable Efforts in applying for, obtaining and maintaining the applicable Approval or other Registration Filing for the Licensed Products in the Field for which it has responsibility as the Lead Regulatory Party. To the extent applicable, the Lead Regulatory Party shall perform all such activities in accordance with the Plans and all applicable Laws.

- (b) The Parties shall establish procedures, through the JDC or the JCC, to ensure that the Parties exchange on a timely basis all necessary information to enable the other Party and its licensees, as applicable, (i) to comply with its regulatory obligations in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field, including, without limitation, filing updates or supplements with Regulatory Authorities, pharmacovigilance filings, manufacturing supplements and investigator notifications to Regulatory Authorities, (ii) to comply with Laws in connection with the Development, Manufacture and/or Commercialization of the Licensed Products in the Field anywhere in the world, including the Excluded Territory, and (iii) to comply with Laws with respect to the development, manufacture and/or commercialization of Products outside the Field. The Parties shall provide to each other prompt written notice of any Approval of a Licensed Product in the Field anywhere in the world. The Parties shall work together cooperatively through the JDC in the preparation of regulatory strategies and with respect to all material regulatory actions, communications and Regulatory Filings for Licensed Products in the Field in the Territory, and, subject to Section 2.7, with respect to the same in the Excluded Territory to the extent that such strategies, actions, and/or communications would reasonably be expected to materially adversely affect, or have a material impact on, the Development or Commercialization of Licensed Products in the Field in the Territory.
- (c) Subject to Sections 2.7 and 7.2(f), the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party as promptly as practicable with written notice and copies of any material (i) draft filings with, (ii) submissions to and (iii) correspondence (including Approvals) with, Regulatory Authorities that directly pertain to the Development and/or Commercialization of a Licensed Product in the Field under the Plans, and shall use reasonable efforts to afford the other Party's representatives an opportunity to actively participate in the drafting and review of such material filings and submissions (including, without limitation, all annual and periodic safety reports for Licensed Products in the Field). Moreover, the Lead Regulatory Party shall consider in good faith requests from the other Party to have up to two (2) representatives from the other Party attend (but not participate) in all material, pre-scheduled meetings, telephone conferences and/or discussions with the Regulatory Authorities in the Territory or, to the extent such material meetings, telephone conferences and/or discussions pertain to the activities under the Global Development Plan, the Excluded Territory. Without limiting the foregoing, the Lead Regulatory Party shall use Commercially Reasonable Efforts to provide the other Party on a timely basis with all material information, data and materials reasonably necessary for the other Party to participate in the preparation of the material filings and submissions referred to in this paragraph (c), said items to be provided to the other Party in a timely manner. The

Parties will discuss in good faith any disputes on the contents of filings or submissions referred to in this paragraph (c) to the Regulatory Authorities and disputes shall be submitted to the JDC for timely resolution.

- (d) For the avoidance of doubt, nothing in this Section 7.2 entitles Company to attend meetings with Regulatory Authorities in the Excluded Territory or review Registration Filings in connection with the Development of Regeneron Products in the Excluded Territory, except as they relate to the performance of the Global Development Plan. Subject to its obligations hereunder, Regeneron, in its sole discretion, shall have the exclusive right (i) to seek and obtain all Registration Filings and Approvals with respect to the Commercialization of Regeneron Products in the Excluded Territory, (ii) to decide the final content of, and to prepare and submit, any Registration Filings for Marketing Approval for a Regeneron Product in the Excluded Territory and (iii) to make any submissions or conduct any meetings or discussions with Regulatory Authorities in the Excluded Territory concerning Marketing Approval for a Regeneron Product.
- (e) For the avoidance of doubt, nothing in this Section 7.2 entitles Regeneron to attend meetings with Regulatory Authorities in the Excluded Territory or review Registration Filings in connection with the Development of Company Products in the Excluded Territory, except as they relate to the performance of the Global Development Plan. Subject to its obligations hereunder, Company, in its sole discretion, shall have the exclusive right (i) to seek and obtain all Registration Filings and Approvals with respect to the Commercialization of Company Products in the Excluded Territory, (ii) to decide the final content of, and to prepare and submit any, Registration Filings for Marketing Approval for a Company Product in the Excluded Territory and (iii) to make any submissions or conduct any meetings or discussions with Regulatory Authorities in the Excluded Territory concerning Marketing Approval for a Company Product.

7.3 Regulatory Coordination with Third Parties. Regeneron shall use Commercially Reasonable Efforts under the Aventis Agreement (a) to allow Company and its Affiliates to reference the filings, registrations, licenses and authorizations from or with any Regulatory Authority in connection with Regeneron's and Aventis' development, manufacture and commercialization of Products outside the Field to support the Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory under this Agreement and (b) to coordinate the exchange of information (including, without limitation, information pertaining to pharmacovigilance, development, manufacture and commercialization) related to Licensed Products inside and outside the Field between Regeneron, Company and Aventis (or any other Third Party licensee of Regeneron engaged in the development, manufacture and/or commercialization of Licensed Products outside the Field) in order to ensure compliance with applicable Laws. It is agreed that (i) Regeneron and its Affiliates and licensees of Regeneron Products outside the Field (including, without limitation, Aventis) or outside the Territory shall have the right to reference the Registration Filings and/or Approvals of the Parties for the

Regeneron Products to support their development, manufacture and commercialization of Regeneron Products outside the Field or outside the Territory and (ii) Company and its Affiliates and licensees of Company Products outside the Field or outside the Territory shall have the right to reference the Registration Filings and/or Approvals of the Parties for the Company Products to support the development, manufacture and commercialization of Company Products outside the Field or outside the Territory. Company and Regeneron shall work in good faith to coordinate the exchange of information (including, without limitation, pharmacovigilance information) related to Products inside and outside the Field (and inside and outside the Territory) between Regeneron, Company and Aventis (or any other Third Party licensee of a Party engaged in the development, manufacture and/or commercialization of Products outside the Field or outside the Territory) in order to ensure compliance with applicable Laws. As between the Parties, Regeneron shall have the exclusive right to communicate with Regulatory Authorities with respect to Regeneron Products outside the Field and, subject to Section 2.7, in the Excluded Territory, and Company will have the exclusive right to communicate with Regulatory Authorities with respect to Company Products outside the Field and, subject to Section 2.7, in the Excluded Territory.

- 7.4 <u>Regulatory Events</u>. Each Party shall keep the other Party informed, commencing within forty-eight (48) hours after notification (or other time period specified below), of any action by, or notification or other information which it receives (directly or indirectly) from, any Regulatory Authority, Third Party or other Governmental Authority in the Territory or Excluded Territory, which:
 - (a) raises any material concerns regarding the safety or efficacy of any Licensed Product in the Field;
- (b) indicates or suggests a potential investigation or formal inquiry by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of a Licensed Product in the Field under the Plans; provided, however, that each Party shall inform the other Party of the foregoing no later than twenty-four (24) hours after receipt of a notification referred to in this clause (b); or
 - (c) is reasonably likely to lead to a recall or market withdrawal of any Licensed Product in the Field in the Territory.

Information that shall be disclosed pursuant to this Section 7.4 shall include, but not be limited to:

- (i) Governmental Authority inspections of Manufacturing, Development, distribution or other facilities;
- (ii) inquiries by Regulatory Authorities or other Governmental Authorities concerning clinical investigation activities (including inquiries of investigators, clinical research organizations and other related parties) or pharmacovigilance activities, in each case, to the

extent involving matters described in clauses (a), (b) or (c) of this Section 7.4;

- (iii) receipt of a warning letter issued by a Regulatory Authority;
- (iv) an initiation of any Regulatory Authority or other Governmental Authority investigation, detention, seizure or injunction; and
- (v) receipt of product complaints concerning actual or suspected Licensed Product tampering, contamination, or mix-up (e.g., wrong ingredients).
- 7.5 Pharmacovigilance and Product Complaints. While the Lead Regulatory Party shall be responsible for managing pharmacovigilance and product complaints for its territory and for formulating and implementing any related strategies, both Parties will cooperate with each other in order to fulfill all regulatory requirements concerning drug safety surveillance and product complaint reporting in all countries in which the Licensed Products (both in the Field and out of the Field) are being developed, manufactured, or commercialized in the Territory or in the Excluded Territory. Without limitation to the foregoing, the Parties shall within ninety (90) days of the Effective Date execute a Pharmacovigilance Agreement setting forth the specific procedures to be used by the Parties to coordinate the investigation and exchange of reports of adverse drug experiences and Licensed Product complaints to ensure timely communication to Regulatory Authorities and compliance with Laws.
- 7.6 Regulatory Inspection or Audit. If a Regulatory Authority desires to conduct an inspection or audit of a Party with regard to a Licensed Product in the Field, each Party agrees to cooperate with the other and the Regulatory Authority during such inspection or audit, including by allowing, to the extent practicable, a representative of the other Party to be present during the applicable portions of such inspection or audit to the extent it relates to the Development, Manufacture or Commercialization of a Licensed Product for use in the Field under this Agreement. Following receipt of the inspection or audit observations of the Regulatory Authority (a copy of which the receiving Party will promptly provide to the other Party), the Party in receipt of the observations will prepare any appropriate responses; provided that the other Party, to the extent practicable, shall have the right to review and comment on such responses to the extent they cover or may be reasonably expected to adversely impact the Licensed Products in the Field in the Territory, and the Party that received the observations shall consider in good faith the comments made by such other Party. In the event the Parties disagree concerning the form or content of a response, the Party that received the observations will decide the appropriate form and content of the response. Without limiting the foregoing, each Party (and its Third Party subcontractors) shall notify the other Party within forty-eight (48) hours of receipt of a notification from a Regulatory Authority of the intention of such Regulatory Authority to audit or inspect facilities used or proposed to be used for the Manufacture of Licensed Products for use in the Field under this Agreement; provided that such notification shall be given no later than twenty-four (24) hours prior to any such Regulatory Authority audit or inspection.

7.7 Recalls and Other Corrective Actions. Decisions with respect to any recall, market withdrawal or other corrective action related to any Licensed Product in the Field in the Territory shall be made only upon mutual agreement of the Parties, which agreement shall not be unreasonably withheld or delayed; provided, however, that nothing herein shall prohibit either Party from initiating or conducting any recall or other corrective action mandated by a Governmental Authority or Law. The Party that determines that a recall or market withdrawal of a Licensed Product in the Field in the Territory may be required shall, within twenty-four (24) hours, notify the other Party and, without limitation of and subject to the proviso in the immediately preceding sentence, the Parties shall decide whether such a recall or market withdrawal is required. The Parties shall cooperate with respect to any actions taken or public statements made in connection with any such recall or market withdrawal. Expenses associated with such recalls will be treated as Other Shared Expenses.

ARTICLE VIII MANUFACTURING AND SUPPLY

- 8.2 <u>Finished Product Supply in the Field in the Territory</u>. The Parties, through the JSC, will identify which Party or Third Party will perform the filling, packaging, labeling and testing of the Formulated Bulk Product to supply Finished Product for Clinical Supply Requirements and Commercial Supply Requirements for use in the Field under this Agreement. The Finished Product Manufactured by or on behalf of a Party will be billed at the Manufacturing Cost to the other Party as a Development Cost or Commercial Supply Cost, as the case may be, in accordance with Schedule 1.

assurance and Good Practices and provide for terms for forecasting, ordering, delivery, payment and supply consistent with the terms of this Agreement.

- 8.5 Manufacturing Shortfall. Each Party is required to provide prompt written notice to the other Party if it reasonably determines that it will not be able to supply the agreed upon demand forecast for the Licensed Products set forth in the Manufacturing Plan. Upon such notification, the matter will be referred to the JSC to determine what, if any (and identify and establish, as quickly as possible, if applicable) alternative supply source of Licensed Product should be utilized. In case of Finished Product or Formulated Bulk Product shortages, available supplies will be allocated as between the Parties on a pro rata basis based on their forecasted requirements for Licensed Product in the Field in the Territory and the Excluded Territory over the relevant period; provided that priority shall be given to meeting supply requirements for countries in which Licensed Products are in the launch phase and that, if the shortage is due solely to a breach by Regeneron, Company's (and, if applicable, Regeneron's) reasonable requirements under the Plans will be filled first in advance of filling requirements for the Excluded Territory.
- 8.6 Manufacturing Compliance. Each Party will use diligent efforts to Manufacture the Formulated Bulk Product and Finished Product supplied under this Article 8 or, as applicable, to ensure that the same is Manufactured by Third Parties in conformity with Good Practices and applicable Laws. Each Party will timely notify and seek the approval of the other Party, which approval shall not be unreasonably withheld or delayed, for any Manufacturing changes for the Formulated Bulk Product or Finished Product that are reasonably likely to have an adverse impact on (a) the quality of the Licensed Products supplied under this Agreement or (b) the regulatory status of the Licensed Products in the Territory, including requirements to support or maintain any Approvals. Each Party shall have the right to conduct inspections and audits of the other Party's facilities involved in the Manufacture of Licensed Products in the Field pursuant to

this Agreement at reasonable times and on reasonable prior notice on terms to be agreed upon by the Parties. Moreover, each Party will use diligent efforts to negotiate agreements that would allow the other Party to audit the facilities of Third Party contractors (including Aventis, if applicable) involved in the Manufacture of Licensed Products for use in the Field under this Agreement.

ARTICLE IX PERIODIC REPORTS; PAYMENTS

9.1 Upfront Payment and Milestone Payments.

- (a) Within five (5) Business Days of the Effective Date, Company will pay to Regeneron the non-refundable, non-creditable amount of US \$75,000,000 (which shall not be reduced by any withholding or similar taxes).
- (b) In addition to the other payments contemplated herein, Company shall be obligated to pay the non-refundable, non-creditable milestone payments listed in Schedule 3 to Regeneron upon the occurrence of the applicable milestone event. Company shall have five (5) Business Days from the receipt of an invoice from Regeneron related to the achievement of any such milestone to pay the corresponding amount to Regeneron, which, in each case, shall not be reduced by any withholding or similar taxes.

9.2 Development Costs.

Development Plan in accordance with the terms of this Agreement by or on behalf of Company, Regeneron and their respective Affiliates.

- (b) Commencing on the Effective Date and continuing during the Term, Company shall be responsible for paying one hundred percent (100%) of the total Development Costs incurred under the Territory Development Plan in accordance with the terms of this Agreement by or on behalf of Company, Regeneron and their respective Affiliates.
- - 9.3 Periodic Reports. Company and Regeneron shall each prepare and deliver to the other Party the periodic reports specified below:
 - (a) Each Party shall deliver electronically the reports required to be delivered by it pursuant to Section 5.4;
- (b) Within twenty (20) days following the end of each month, Company shall deliver electronically to Regeneron a monthly detailed Net Sales report with monthly and year-to-date sales for each Licensed Product in the Field in the Territory by country in United States Dollars;
- (c) Within forty-five (45) days following the end of each Quarter, Company shall deliver electronically to Regeneron a written report setting forth,

on a country-by-country basis in the Territory for such Quarter (i) the Net Sales of each Licensed Product in local currency and in United States Dollars, (ii) Licensed Product quantities sold in the Field by dosage form and unit size and (iii) gross Licensed Product sales in the Field and an accounting of the deductions from gross sales permitted by the definition of Net Sales;

- (d) Within forty-five (45) days following the end of each Quarter, each Party that has incurred any Other Shared Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Other Shared Expenses incurred by such Party in such Quarter, including whether any such expenses are also included in the reports delivered pursuant to clause (e) below;
- (e) Within forty-five (45) days after the end of each Quarter commencing after the First Commercial Sale in a country in the Territory (or such earlier agreed upon calendar Quarter, if appropriate), Company shall provide to Regeneron, in electronic form, a Country Commercialization Report for each country in the Territory.
- (f) Within forty-five (45) days following the end of each Quarter commencing after the First Commercial Sale in the Territory (or such earlier agreed upon calendar Quarter, if appropriate), each Party that has incurred any Shared Promotion Expenses in that Quarter shall deliver electronically to the other Party a written report setting forth in reasonable detail the Shared Promotion Expenses incurred by such Party in such Quarter;
- (g) Within forty-five (45) days following the end of each Quarter, each Party (if applicable) shall deliver electronically to the other Party a written report setting forth Commercial Supply Costs incurred by such Party for such Quarter, and
- (h) Within sixty (60) days following the end of each Quarter, Company shall deliver electronically to Regeneron a Consolidated Payment Report in respect of such Quarter, combining the information reported by each Party pursuant to this Article 9 and showing its calculations in accordance with Schedule 2 of the amount of any payments to be made by the Parties hereunder for such Quarterly period as contemplated by Section 9.4 and, if applicable, providing for the netting of such payments.

All reports referred to in this Section 9.3 shall be in such form, format and level of detail as may be approved by the JFC. Unless otherwise agreed by the JCC, the financial data in the reports will include calculations in local currency and United States Dollars.

9.4 <u>Funds Flow.</u> The Parties shall make Quarterly True-Up payments as set forth in Schedule 2. If Company is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Payment Report, it shall, subject to Section 9.10, make such payment to Regeneron within ten (10) days after its delivery to Regeneron of such Consolidated Payment Report. If Regeneron is the Party owing the Quarterly True-Up based on the calculations in the Consolidated Payment Report, it shall, subject to Section

- 9.10, make such payment to Company within ten (10) days after its receipt of such Consolidated Payment Report from Company. Notwithstanding the foregoing, no later than fifty-five (55) days after the end of each Quarter, Company shall pay Regeneron fifty percent (50%) of the amount of royalties or other amounts payable under any Existing License or New License (to the extent attributable to the Manufacture, Development and/or Commercialization of Licensed Products under the Plans for the Territory) to which Regeneron is a party on account of the Commercialization of Licensed Products in the Field in the Territory and provide such supporting documentation required by such Existing License and/or New License, as the case may be.
- 9.5 <u>Invoices and Documentation</u>. The JFC shall approve the form of any necessary documentation relating to any payments hereunder so as to afford the Parties appropriate accounting treatment in relation to any of the transactions or payments contemplated hereunder.
- 9.6 <u>Payment Method and Currency</u>. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the Party to which such payments are due. All sums due under this Agreement shall be payable in United States Dollars. In those cases where the amount due in United States Dollars is calculated based upon one or more currencies other than United States Dollars, such amounts shall be converted to United States Dollars at the average rate of exchange for the Quarter to which such payment relates, as reported in *The Bloomberg Professional*, a service of Bloomberg LP, or in the event *The Bloomberg Professional* does not have data available for the Quarter, then in *The Wall Street Journal* and by a method of conversion consistent with Company's customary and usual procedures used for currency conversion in its financial statements.
- 9.7 <u>Late Payments</u>. The Parties agree that, unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, amounts due by one Party to the other shall be payable to a bank account, details of which are to be communicated by the receiving Party. Unless otherwise mutually agreed by the Parties or otherwise provided in this Agreement, all payments under this Agreement shall earn interest, to the extent permitted by applicable Law, from the date due until paid at a rate equal to the thirty (30) day London Inter-Bank Offering Rate (LIBOR) U.S. Dollars, as quoted in The *Wall Street Journal* (Eastern Edition) effective for the date on which the payment was due, plus [***********] (such sum being referred to as the "Default Interest Rate").
- 9.8 <u>Taxes</u>. Except with respect to the payments provided for in Section 9.1, any withholding or other taxes that either Party or its Affiliates are required by Law to withhold or pay on behalf of the other Party, with respect to any payments to such other Party hereunder, shall be deducted from such payments and paid to the appropriate tax authority contemporaneously with the remittance to the other Party; provided, however, that the withholding Party shall promptly furnish to the other Party proper evidence of the taxes so paid. Each Party shall cooperate with the other and furnish to the other Party appropriate documents to secure application of the most favorable rate of withholding tax under applicable Law (or exemption from such withholding tax payments, as applicable). Without limiting the foregoing, Company agrees to make all lawful and reasonable efforts

to minimize any such taxes, assessments and fees and will claim on Regeneron's behalf the benefit of any available Treaty on the Avoidance of Double Taxation that applies to any payments hereunder.

- 9.9 <u>Adjustments to FTE Rates</u>. Notwithstanding anything herein to the contrary, upon the request of either Party (such request to occur not more than once every three (3) years for any country), the Parties shall meet to review the accuracy of an applicable FTE rate in any country (e.g., Sales Force FTE Rate, Medical Affairs FTE Rate, Development FTE Rate, etc.). The Parties agree to share reasonable supporting documents and materials in connection with an assessment of the applicable FTE rate and to determine in good faith whether to adjust the rate(s) in any country.
- 9.10 <u>Resolution of Payment Disputes</u>. In the event there is a dispute relating to any of the payment obligations or reports under this Article 9, the Party with the dispute shall have its representative on the JFC provide the other Party's representative on the JFC with written notice setting forth in reasonable detail the nature and factual basis for such good faith dispute and the Parties, through the JFC, will seek to resolve the dispute as promptly as possible, but no later than ten (10) days after such written notice is received. In the event that no resolution is reached by the JFC, the matter shall be referred to the JSC in accordance with Section 3.10(a). Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder, provided that all amounts that are not in dispute shall be paid in accordance with the provisions of this Agreement.

ARTICLE X DISPUTE RESOLUTION

- 10.1 <u>Resolution of Disputes</u>. The Parties recognize that disputes as to certain matters may from time to time arise which relate to either Party's rights and obligations hereunder. It is the objective of the Parties to comply with the procedures set forth in this Agreement to use all reasonable efforts to facilitate the resolution of such disputes in an expedient manner by mutual agreement.
- 10.2 Governance Disputes. Disputes, controversies and claims related to matters intended to be decided within the governance provisions of this Agreement set forth in Article 3 ("Governance Disputes") shall be resolved pursuant to Article 3 and, to the extent such matters constitute Technical Development Matters or a dispute referred to in Section 14.2(b), Section 10.4 (subject to, and without limitation of, the proviso in Section 3.10(a)(iii)), except to the extent any such dispute, controversy or claim constitutes a Legal Dispute, in which event the provisions of Section 10.3 shall apply. For the purposes of this Agreement, the term "Technical Development Matter" shall mean (a) any matter involving the Development of a Licensed Product in the Field, including the determination of clinical trial design and any Development or regulatory dispute referred to the Executive Officers pursuant to Section 3.10(a)(iii) and (b) any dispute concerning a Party's refusal to approve a clinical trial proposed pursuant to Section 2.6(b).
- 10.3 <u>Legal Disputes</u> . The Parties agree that, subject to Sections 10.5 and 16.2, they shall use all reasonable efforts, through their participation in the JSC in the first instance, to resolve any Legal Dispute arising after the Effective Date by good faith negotiation and discussion. In the event that the JSC is unable to resolve any such Legal Dispute within five (5) Business Days of receipt by a Party of notice of such Legal Dispute, either Party may submit the Legal Dispute to the Executive Officers for resolution. In the event the Executive Officers are unable to resolve any such Legal Dispute within the time period set forth in Section 3.10(b), the Parties shall be free to pursue any rights and remedies available to them at law, in equity or otherwise, subject, however, to Section 20.1 and Section 20.15.

10.4 Expert Panel

(a) In the event of a dispute between the Parties concerning a Technical Development Matter or a dispute referred to in Section 14.2(b) that cannot be resolved by the Executive Officers pursuant to Section 3.10(b) (other than a Legal Dispute or any dispute concerning any proposed amendment to the Initial Development Plan), either Party may by written notice to the other Party require the specific issue in dispute to be submitted to a panel of experts ("Expert Panel") in accordance with this Section 10.4. Such notice shall contain a statement of the issue forming the basis of the dispute, the position of the moving Party as to the proper resolution of that issue and the basis for such position. For disputes referred to the Expert Panel arising under Section 3.10(a)(iii), the Expert Panel in resolving the dispute shall balance the relative benefits and harm to each Party from the matter in dispute in connection with the applicable

Licensed Product in the Territory and Excluded Territory. Within fifteen (15) days after receipt of such notice, the responding Party shall submit to the moving Party a statement of its conception of the specific issue in question, its position as to the proper resolution of that issue and the basis for such position.

- (b) Within fifteen (15) days of the responding Party's response, each Party shall appoint to the Expert Panel an individual who (i) has expertise in the pharmaceutical or biotechnology industry and the specific matters at issue (or, in the case of a dispute regarding an audit as referred to in Section 14.2(b), expertise in accounting and auditing with respect to the development and commercialization of pharmaceutical products), (ii) is not a current or former director, employee or consultant of such Party or any of its Affiliates, or otherwise has not received compensation or other payments from such Party (or its Affiliates) for the past five (5) years and (iii) has no known personal financial interest or benefit in the outcome or resolution of the dispute, and the appointing Party shall give the other Party written notice of such appointment; provided that for such appointment to be effective and for such individual to serve on the Expert Panel, such individual must deliver to the other Party a certificate confirming that such individual satisfies the criteria set forth in clauses (i) through (iii) above, disclosing any potential conflict or bias and certifying that, as a member of the Expert Panel, such individual is able to render an independent decision.
- (c) Within fifteen (15) days of the appointment of the second expert, the two-appointed experts shall agree on an additional expert who meets the same criteria as described above, and shall appoint such expert as chair of the Expert Panel. If the Party-appointed experts fail to timely agree on a third expert, then upon the written request of either Party, each Party-appointed expert shall, within ten (10) days of such request, nominate one expert candidate and the CPR Institute for Dispute Resolution shall, within ten (10) days of receiving the names of the Parties' respective nominees, select one of those experts to serve as the chair of the Expert Panel. Each expert shall agree, prior to his or her appointment, to render a decision as soon as practicable after the appointment of the full Expert Panel.
- (d) Within seven (7) days of the appointment of the third expert, the Expert Panel shall hold a preliminary meeting or teleconference with the Parties or their representatives and shall designate a time and place for a hearing of the Parties on the dispute and the procedures to be utilized at the hearing. The Parties may agree in writing to waive the hearing and have the Expert Panel reach a decision on the basis of written submissions alone. The Expert Panel may order the Parties to produce any documents or information which are relevant to the dispute. All such documents or information shall be provided to the other Party and the Expert Panel as expeditiously as possible but no later than one (1) week prior to the hearing (if any), along with the names of all witnesses who will testify at the hearing and a brief summary of their testimony. The hearing shall be held in New York, NY, unless otherwise agreed by the Parties, and shall take place as soon as possible but no more than forty-five (45) days after the appointment of the third expert, unless the Parties otherwise agree in writing or the Expert Panel agrees to extend such time period for good cause shown. The hearing shall last no more than one (1) day, unless otherwise agreed by the Parties or the Expert Panel

agrees to extend such time period for good cause shown. After the conclusion of all testimony (or if no hearing is held after all submissions have been received from the Parties), at a time designated by the Expert Panel no later than seven (7) days after the close of the hearing or the receipt of all submissions, each Party shall simultaneously submit to the Expert Panel and exchange with the other Party its final proposed resolution.

- (e) In rendering the final decision (which shall be rendered no later than fifteen (15) days after receipt by the Expert Panel of the Parties' respective proposed resolutions), the Expert Panel shall be limited to choosing a resolution proposed by a Party without modification; provided, however, that in no event shall the Expert Panel render a decision that is inconsistent with the Collaboration Purpose and the Parties' intentions as set forth in this Agreement. The agreement of two (2) of the three (3) experts shall be sufficient to render a decision and the Parties shall abide by such decision.
- (f) The decision of the Expert Panel shall be final and binding on the Parties and may be entered and enforced in any court having jurisdiction. Each Party shall bear the cost of its appointee to the Expert Panel and the Parties shall share equally the costs of the third expert.
- 10.5 <u>No Waiver</u>. Nothing in this Article 10 or elsewhere in this Agreement shall prohibit either Party from seeking and obtaining immediate injunctive or other equitable relief if such Party reasonably believes that it will suffer irreparable harm from the actions or inaction of the other.

ARTICLE XI TRADEMARKS AND CORPORATE LOGOS

- 11.1 Corporate Names. Each Party and its Affiliates shall retain all right, title and interest in and to their respective corporate names and logos.
- 11.2 Selection of Product Trademarks. For each Licensed Product, the JCC shall select one Product Trademark for use in the Field throughout the Territory and in the Excluded Territory, if applicable pursuant to Section 3.4(b)(i), unless such Product Trademark is prohibited by law in any country in the Territory. Each Licensed Product in the Field shall be promoted and sold in the Territory, and if applicable pursuant to Section 3.4(b) (i) in the Excluded Territory, under the applicable Product Trademark(s), trade dress and packaging approved by the JCC.
- 11.3 Ownership of Product Trademarks. Unless otherwise mutually agreed between the Parties, and subject to Sections 11.4 and 11.5, Company (or its local Affiliates, as appropriate) shall own and retain all right, title and interest in and to Product Trademark(s), together with all associated domain names and all goodwill related thereto in all countries in the Territory. It is understood and agreed that Regeneron shall own and retain all right, title and interest in the Product Trademark(s) for Regeneron Products,

together with all associated domain names and all goodwill related thereto in the Excluded Territory.

- 11.4 <u>Prosecution and Maintenance of Product Trademark(s)</u>. Company will use Commercially Reasonable Efforts to prosecute and maintain the Product Trademark(s) in all countries in the Territory. Notwithstanding the foregoing, in the event Company elects not to prosecute or maintain any Product Trademark(s) in any country in the Territory, Regeneron shall have the right to do so on behalf of Company for use with Licensed Products, subject to consultation and cooperation with Company.
- 11.5 <u>License to the Product Trademark(s)</u>. Company hereby grants to Regeneron a co-exclusive license to use the Product Trademark(s) for the Licensed Products solely for the purposes of Regeneron's Development, Manufacturing, and, if agreed to by Company or set forth in any Plans, Commercialization activities pursuant to this Agreement and subject to the terms and conditions of this Agreement. Company shall utilize the Product Trademark(s) only on approved Promotional Materials or other approved product-related materials for the Licensed Products in the Field in the Territory for the purposes contemplated herein, and all use by Company or its Affiliates or Sublicensees of the Product Trademark(s) shall be in accordance with (a) rules established by the JCC and (b) quality standards established by the JCC which are reasonably necessary in order to preserve the validity and enforceability of the Product Trademark(s). Each Party agrees that at no time during the Term will it or any of its Affiliates attempt to use or register any trademarks, trade dress, service marks, trade names or domain names confusingly similar to the Product Trademark(s) or take any other action which damages or dilutes the rights to, or goodwill associated with, the Product Trademark(s). Upon request by either Party, the other Party shall (or shall cause its Affiliates, as appropriate, to) execute such documents as may reasonably be required for the purpose of recording with any Governmental Authority the license, or a recordable version thereof, referred to above in this Section 11.5.
- 11.6 <u>Use of Corporate Names</u>. Company (through its Affiliates, as appropriate) shall use Commercially Reasonable Efforts to include Regeneron's name with equal prominence on materials exclusively related to each Licensed Product in the Field (including, without limitation, package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with such Licensed Product) in the Major Market Countries, unless to do so would be prohibited under applicable Laws; provided, however, in the case of multi-product materials that refer to a Licensed Product in the Field in the Major Market Countries as well as other pharmaceutical products, the prominence of Regeneron's name shall be commensurate with the relative prominence of the Licensed Product in such materials. Each Party grants to the other Party (and its Affiliates) the right, free of charge, to use its name and logo on package inserts, packaging, trade packaging, samples and all Promotional Materials used or distributed in connection with the applicable Licensed Product in the Field in the Territory during the Term and for a maximum period of three (3) years thereafter with respect to Promotional Materials, package inserts, packaging, labeling, trade packaging and samples solely to the extent necessary to exhaust the existing inventory of Licensed Product and Promotional Materials containing such name or logo. During the Term, each Party shall submit samples of each

such package inserts, packaging, trade packaging, etc. to such other Party for its prior approval, which approval shall not be unreasonably withheld or delayed, at least thirty (30) days before dissemination of such materials. Failure of the receiving Party to object within such thirty (30) day period shall constitute approval of the submitting Party's package inserts, packaging, trade packaging, etc.

ARTICLE XII NEWLY CREATED INVENTIONS

12.1 Ownership of Newly Created Intellectual Property.

- (a) Each Party (and each Party's respective Affiliates) shall exclusively own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created in connection with the Collaboration solely by such Party, its Affiliates, employees, agents and consultants ("Sole Inventions"). Sole Inventions made solely by Company, its Affiliates, employees, agents and consultants are referred to herein as "Company Sole Inventions." Sole Inventions made solely by Regeneron, its Affiliates, employees, agents and consultants are referred to herein as "Regeneron Sole Inventions." The Parties agree that nothing in this Agreement, and no use by a Party of the other Party's Intellectual Property pursuant to this Agreement, shall vest in a Party any right, title or interest in or to the other Party's Intellectual Property, other than the license rights expressly granted hereunder.
- (b) The Parties shall jointly own all intellectual property (including, without limitation, Know-How, Patents and Patent Applications and copyrights) discovered, invented, authored or otherwise created under the Collaboration during the Term that is invented or authored jointly by an individual or individuals having an obligation to assign such intellectual property to Company or its Affiliate (or for which ownership vests in Company or its Affiliate by operation of law), on the one hand, and an individual or individuals having an obligation to assign such intellectual property to Regeneron or its Affiliate (or for which ownership vests in Regeneron or its Affiliate by operation of law), on the other hand, on the basis of each Party (or its Affiliate) having an undivided interest in the whole ("Joint Inventions").
- (c) Notwithstanding the foregoing in Section 12.1(b), (i) for purposes of determining whether a patentable invention is a Company Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of inventorship shall be resolved in accordance with United States patent laws, (ii) for purposes of determining whether a copyrighted work is a Company Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of copyright authorship shall be resolved in accordance with United States copyright laws and (iii) for purposes of determining whether Know-How (other than copyrighted work and Patent Applications) is a Company Sole Invention, a Regeneron Sole Invention or a Joint Invention, questions of authorship or inventorship shall be resolved in accordance with the laws of the State of New York, United States.

- (d) To the extent that any right, title or interest in or to any intellectual property discovered, invented, authored or otherwise created under the Collaboration during the Term vests in a Party or its Affiliate, by operation of Law or otherwise, in a manner contrary to the agreed upon ownership as set forth in this Agreement, such Party (or its Affiliate) shall, and hereby does, irrevocably assign to the other Party any and all such right, title and interest in and to such intellectual property to the other Party without the need for any further action by any Party.
- (e) The Parties hereby agree that each Party's use of the Joint Inventions is governed by the terms and conditions of this Agreement shall be governed as follows: each Party's interest in the Joint Inventions may be sublicensed to Third Parties, and any ownership rights therein transferred, in whole or in part, by each Party without consent of the other Party (unless otherwise prohibited by this Agreement); provided that (i) each of the Parties acknowledges that it receives no rights to any Intellectual Property of the other Party underlying or necessary for the use of any Joint Invention, except as may be expressly set forth in Article 4, (ii) each Party agrees not to transfer any of its ownership interest in any of the Joint Inventions without securing the transferee's written agreement to be bound by the terms of this Section 12.1(e) and (iii) nothing in this Article 12 shall relieve a Party or its Affiliates of their obligations under Article 16 with respect to confidential Party Information provided by the other Party or such other Party's Affiliates. Neither Party hereto shall have the duty to account to the other Party for any revenues or profits obtained from any transfer of its interest in, or its use, sublicense or other exploitation of, the Joint Inventions outside the scope of the Collaboration. Each of the Parties (or its Affiliate), as joint owner of the Joint Inventions, agrees to cooperate with any enforcement actions brought by the other joint owner(s) against any Third Parties, and further agrees not to grant any licenses to any such Third Parties against which such enforcement actions are brought during the time of such dispute, without the prior written consent of the other joint owner(s), such consent not to be unreasonably withheld. The provisions governing Joint Inventions set forth in this Section 12.1(e) shall survive the expiration or termination of this Agreement.

12.2 Prosecution and Maintenance of Patent Rights.

(a) Regeneron shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Regeneron Patent Rights in the Territory and shall confer with and keep Company reasonably informed regarding the status of such activities. In addition, Regeneron shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents in the Territory included in the Regeneron Patent Rights: (i) Regeneron shall use Commercially Reasonable Efforts to provide to Company for review and comment a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Regeneron and consider in good faith any comment from Company; (ii) Regeneron shall provide Company promptly with copies of all material communications received from or filed in patent offices in the Territory with respect to such filings; (iii) Regeneron shall consult with Company promptly

following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications and (iv) Regeneron shall consult with Company a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Regeneron desires to abandon any Patent included in the Regeneron Patent Rights in the Territory, Regeneron shall provide reasonable prior written notice to Company of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Regeneron Patent with the applicable patent office) and, subject to any rights granted to Aventis under the Aventis Agreement, Company shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Regeneron's name, unless, with respect to any such Patent Applications that are unpublished, Regeneron notifies Company that Regeneron would prefer to maintain the subject matter of such Patent Application as a trade secret.

(b) Company shall use Commercially Reasonable Efforts to prepare, file, prosecute and maintain Patents and Patent Applications (as applicable) included in the Company Patent Rights in the Territory and shall confer with and keep Regeneron reasonably informed regarding the status of such activities. In addition, Company shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents in the Territory included in the Company Patent Rights: (i) Company shall use Commercially Reasonable Efforts to provide to Regeneron for review and comment a copy of a substantially completed draft of any priority Patent Application in the Territory at least thirty (30) days prior to the filing of any such priority Patent Application by Company and consider in good faith any comment from Regeneron; (ii) Company shall provide Regeneron promptly with copies of all material communications received from or filed in patent offices with respect to such filings; (iii) Company shall consult with Regeneron promptly following the filing of the priority Patent Applications in the Territory to mutually determine in which countries in the Territory it shall file convention Patent Applications and (iv) Company shall consult with Regeneron a reasonable time prior to taking or failing to take action that would materially affect the scope or validity of rights under any Patent Applications or Patents in the Field (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country). In the event that Company desires to abandon any Patent included in the Company Patent Rights in the Territory, Company shall provide reasonable prior written notice to Regeneron of such intention to abandon (which notice shall, in any event, be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Company Patent with the applicable patent office) and Regeneron shall have the right, but not the obligation, to assume responsibility for the prosecution and maintenance thereof in Company's name, unless, with respect to any such Patent Applications that are unpublished. Company notifies Regeneron that

Company would prefer to maintain the subject matter of such Patent Application as a trade secret.

(c) With respect to any Joint Patent Rights, the Parties shall consult with each other regarding the filing, prosecution and maintenance of any Patents and Patent Applications, and responsibility for such activities shall be the obligation of the Controlling Party. The Controlling Party shall undertake such filings, prosecutions and maintenance in the names of both Parties as co-owners. The Controlling Party shall have the following obligations with respect to the filing, prosecution and maintenance of Patent Applications and Patents under any such Joint Patent Rights: (i) the Controlling Party shall use Commercially Reasonable Efforts to provide the non-Controlling Party with notice and a copy of a substantially completed draft of any priority Patent Application at least thirty (30) days prior to the filing of any such priority Patent Application by the Controlling Party and consider in good faith any comment; (ii) the Controlling Party shall notify the non-Controlling Party prior to the filing of a Patent Application by the Controlling Party; (iii) the Controlling Party shall consult with the non-Controlling Party promptly following the filing of the priority Patent Application to mutually determine in which countries it shall file convention Patent Applications; (iv) the Controlling Party shall provide the non-Controlling Party promptly with copies of all communications received from or filed in patent offices with respect to such filings; and (v) the Controlling Party shall provide the non-Controlling Party a reasonable time prior to taking or failing to take action that would affect the scope or validity of rights under any Patent Applications or Patents, but in no event less than sixty (60) days prior to the next deadline for any action that may be taken with the applicable patent office, (including but not limited to substantially narrowing or canceling any claim without reserving the right to file a continuing or divisional Patent Application, abandoning any Patent or not filing or perfecting the filing of any Patent Application in any country), with notice of such proposed action or inaction so that the non-Controlling Party has a reasonable opportunity to review and make comments, and take such actions as may be appropriate in the circumstances. In the event that the Controlling Party materially breaches the foregoing obligations and such breach is not cured within thirty (30) days of a written notice from the non-Controlling Party to the Controlling Party describing such breach, or in the event that the Controlling Party fails to undertake the filing of a Patent Application within the earlier of (i) ninety (90) days of a written request by the non-Controlling Party to do so, and (ii) sixty (60) days prior to the anticipated filing date, the non-Controlling Party may assume the Controlling Party's responsibility for filing, prosecution and maintenance of any such Joint Patent Right, and will thereafter be deemed the Controlling Party for purposes hereof. Notwithstanding the foregoing, the Controlling Party may withdraw from or abandon any Patent or Patent Application relating to any Joint Patent Rights on thirty (30) days' prior notice to the other Party (provided that such notice shall be given no later than sixty (60) days prior to the next deadline for any action that may be taken with respect to such Patent or Patent Application with the applicable patent office), providing the non-Controlling Party a free-of-charge option to assume the prosecution or maintenance thereof.

(d) Each Party agrees to cooperate with the other with respect to the preparation, filing, prosecution and maintenance of Patents and Patent Applications

pursuant to this Section 12.2, including, without limitation, the execution of all such documents and instruments and the performance of such acts (and causing its relevant employees to execute such documents and instruments and to perform such acts) as may be reasonably necessary in order to permit the other Party to continue any preparation, filing, prosecution or maintenance of Joint Patent Rights that such Party has elected not to pursue as provided for in Section 12.2(c). The JCC, with the approval of the JSC, will determine which of the Company Patent Rights, Regeneron Patent Rights and Joint Patent Rights for which to seek an extension of term and the applicable Party will file for said patent term extension.

(e) All Out-of-Pocket Costs incurred in the filing, prosecution and maintenance of any Company Patent Rights, Regeneron Patent Rights and Joint Patent Rights in the Territory for use in the Field, and any extensions thereof, shall be shared by the Parties as part of Other Shared Expenses.

12.3 Interference, Opposition and Reissue.

- (a) Each Party will notify the other within ten (10) days of receipt by such Party of information concerning the request for, or filing or declaration of, any interference, opposition or reexamination relating to Regeneron Patent Rights, Company Patent Rights or Joint Patent Rights in the Territory. The Parties will thereafter consult and cooperate fully to determine a course of action with respect to any such proceeding. Decisions on whether to initiate or how to respond to such a proceeding, as applicable, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Company, (ii) with respect to Company Patent Rights, by Company in consultation with Regeneron and (iii) with respect to Joint Patent Rights, jointly by the Parties. Regeneron may have certain obligations under Section 12.3 of the Aventis Agreement with respect to any such proceeding described in this Section 12.3(a) and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.
- (b) All Out-of-Pocket Costs incurred in connection with any interference, opposition, reissue or reexamination proceeding relating to the Regeneron Patent Rights, Company Patent Rights and/or Joint Patent Rights in the Territory for use in the Field shall be shared by the Parties as part of Other Shared Expenses.

ARTICLE XIII INTELLECTUAL PROPERTY LITIGATION

13.1 Third Party Infringement Suits.

(a) In the event that either Party or any of its Affiliates becomes aware of an actual or suspected infringement of a Company Patent Right, a Regeneron Patent Right, a Joint Patent Right, Product Trademark or any other intellectual property

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right jointly owned or licensed under this Agreement, by a Third Party's activities in the Field in the Territory, the Party that became aware of the infringement shall promptly notify the other Party in writing of this claim or assertion and shall provide such other Party with all available evidence supporting such known or suspected infringement or unauthorized use. As soon as reasonably practicable after the receipt of such notice, the Parties shall cause the JSC to meet and consider the appropriate course of action with respect to such infringement. The Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning prosecution and/or settlement of any such claim. Regeneron may have certain obligations under Article 13 of the Aventis Agreement with respect to any such actual or suspected infringement described in this Section 13.1 and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.

- (b) With respect to any infringement by virtue of a Third Party's activities in the Field in the Territory, the Parties will consult and cooperate fully to determine a course of action. Final decisions on whether to initiate a proceeding, and the course of action in such proceeding, including settlement negotiations and terms, will be made (i) with respect to Regeneron Patent Rights, by Regeneron in consultation with Company, (ii) with respect to Company Patent Rights, by Company in consultation with Regeneron, and (iii) with respect to Joint Patent Rights, jointly by the Parties. Any disagreement between the Parties concerning the enforcement of Joint Patent Rights shall be referred to the Executive Officers for resolution. The Party initiating the litigations shall be referred to as the "Lead Litigation Party". The non-Lead Litigation Party will provide reasonable assistance to the Lead Litigation Party in prosecuting any suit, and if required by Law, will join in the suit. Although the Lead Litigation Party has the right to select counsel of its own choice, it shall first consult with the other Party and consider in good faith the recommendations of the other Party. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory shall be shared equally by the Parties, subject to any obligations under any New License or Existing License.
- (c) All Out-of-Pocket Costs incurred in connection with any litigation under Section 13.1(b) related to activities in the Field in the Territory shall be shared by the Parties as part of Other Shared Expenses.
- (d) For the avoidance of doubt, neither Party will enter into any settlement of any suit referenced in this Section 13.1 that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent.
- 13.2 <u>Patent Marking</u>. Each Party shall comply with the patent marking statutes in each country in which a Licensed Product in the Field is made, offered for sale, sold or imported by such Party, its Affiliates and/or Sublicensees.

13.3 Third Party Infringement Claims; New Licenses.

- (a) If either Party or its Affiliates shall learn of an allegation that the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory under this Agreement infringes or otherwise violates the intellectual property rights of any Third Party in the Territory, then such Party shall promptly notify the other Party in writing of this allegation. As soon as reasonably practicable after the receipt of such notice and at all times thereafter, the Parties shall meet and consider the appropriate course of action with respect to such allegation of infringement. In any such instance, each Party shall have the right to defend any action naming it; however, the Parties shall at all times cooperate, share all material notices and filings in a timely manner, provide all reasonable assistance to each other and use Commercially Reasonable Efforts to mutually agree upon an appropriate course of action, including, as appropriate, the preparation of material court filings and any discussions concerning a potential defense and/or settlement of any such claim. The rights and obligations in this Section 13.3 shall apply even if only one Party defends any claimed infringement action commenced by a Third Party in the Territory claiming that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes or otherwise violates any intellectual property rights of any Third Party. Regeneron may have certain obligations under Article 13 of the Aventis Agreement with respect to any allegation described in this Section 13.3 and, notwithstanding anything to the contrary herein, Regeneron shall have the right to comply with its obligations and exercise its rights thereunder.
- (b) Except as otherwise set forth in this Agreement, all Out-of-Pocket Costs (except for the expenses of the non-controlling Party's counsel, if only one Party defends a claim) incurred in connection with any litigation referred to in this Section 13.3 shall be shared by the Parties as Other Shared Expenses.
- (c) For the avoidance of doubt, neither Party will enter into any settlement of any suit involving Licensed Products that materially affects the other Party's rights or obligations with respect to the applicable Licensed Product in the Field in the Territory without the other Party's prior written consent. Furthermore, no Party shall enter into any Third Party intellectual property license requiring the payment of royalties or other amounts based on the Development, Manufacture or Commercialization of Licensed Products in the Field in the Territory under this Agreement without the other Party's prior written consent.
- (d) License fees, royalties and other payments under Existing Licenses and New Licenses to the extent attributable to, and based on, the Manufacture of Commercial Supply Requirements or the Commercialization of Licensed Products in the Field in the Territory shall be shared by the Parties as Other Shared Expenses.

ARTICLE XIV
BOOKS, RECORDS AND INSPECTIONS; AUDITS AND ADJUSTMENTS

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14.1 <u>Books and Records</u>. Each Party shall, and shall cause each of its respective Affiliates to, keep proper books of record and account in which full, true and correct entries (in conformity with GAAP or IAS/IFRS) shall be made for the purpose of determining the amounts payable or owed pursuant to this Agreement. Each Party shall, and shall cause each of its respective Affiliates to, permit auditors, as provided in Section 14.2, to visit and inspect, during regular business hours and under the guidance of officers of the Party being inspected, and to examine the books of record and account of such Party or such Affiliate to the extent relating to this Agreement and discuss the affairs, finances and accounts of such Party or such Affiliate to the extent relating to this Agreement with, and be advised as to the same by, its and their officers and independent accountants.

14.2 Audits and Adjustments.

- (a) Each Party shall have the right (at its costs), upon no less than thirty (30) days advance written notice and at such reasonable times and intervals and to such reasonable extent as the investigating Party shall request, not more than once during any Contract Year, to have the books and records of the other Party and its Affiliates to the extent relating to this Agreement for the preceding two (2) years audited by an independent "Big Four" (or equivalent) accounting firm of its choosing under reasonable appropriate confidentiality provisions, for the sole purpose of verifying the accuracy of all financial, accounting and numerical information and calculations provided, and payments made, under this Agreement; provided that no period may be subjected to audit more than one (1) time unless a material discrepancy is found in any such audit of such period, in which case additional audits of such period may be conducted until no material discrepancies are found.
- (b) The results of any such audit shall be delivered in writing to each Party and shall be final and binding upon the Parties, unless disputed by a Party within ninety (90) days. Unless otherwise mutually agreed by the Parties, any disputes regarding the results of any such audit shall be subject to dispute resolution in accordance with Article 10. If the audited Party or its Affiliates have underpaid or over billed an amount due under this Agreement resulting in a cumulative discrepancy during any year of more than ten percent (10%), the audited Party shall also reimburse the other Party for the costs of such audit (with the cost of the audit to be paid by the auditing party in all other cases). Such accountants shall not reveal to the Party seeking verification the details of its review, except for such information as is required to be disclosed under this Agreement, and shall be subject to the confidentiality provisions contained in Article 16.
- (c) If any examination or audit of the records described above discloses an under- or over-payment of amounts due hereunder, then unless the result of the audit is to be contested pursuant to Section 14.2(b) above, the Party owing any money hereunder shall pay the same (plus interest thereon at the Default Interest Rate from the date of such underpayment through the date of payment of the amount required to be paid pursuant to this Section 14.2(c)) to the Party entitled thereto within thirty (30) days after receipt of the written results of such audit pursuant to this Section.

14.3 <u>GAAP/IAS/IFRS</u>. Except as otherwise provided herein, all costs and expenses and other financial determinations with respect to this Agreement shall be determined in accordance with GAAP or IAS/IFRS as generally and consistently applied.

ARTICLE XV REPRESENTATIONS AND WARRANTIES

- 15.1 <u>Due Organization</u>, Valid Existence and Due Authorization. Each Party hereto represents and warrants to the other Party, as of the Effective Date, as follows: (a) it is duly organized and validly existing under the Laws of its jurisdiction of incorporation; (b) it has full corporate power and authority and has taken all corporate action necessary to enter into and perform this Agreement; (c) the execution and performance by it of its obligations hereunder will not constitute a breach of, or conflict with, its organizational documents nor any other agreement by which it is bound or any requirement of applicable Laws or regulations; (d) this Agreement is its legal, valid and binding obligation, enforceable in accordance with the terms and conditions hereof (subject to applicable Laws of bankruptcy and moratorium); (e) such Party is not prohibited by the terms of any agreement to which it is a party from granting, the licenses granted to the other under Article 4 hereof; and (f) no broker, finder or investment banker is entitled to any brokerage, finder's or other fee in connection with this Agreement or the transactions contemplated hereby based on arrangements made by it or on its behalf. Company additionally represents and warrants to Regeneron that it has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement.
- 15.2 Knowledge of Pending or Threatened Litigation. Each Party represents and warrants to the other Party that, as of the Effective Date, there is no claim, announced investigation, suit, action or proceeding pending or, to such Party's knowledge, threatened, against such Party before or by any Governmental Authority or arbitrator that, individually or in the aggregate, could reasonably be expected to (a) materially impair the ability of such Party to perform any of its obligations under this Agreement or (b) prevent or materially delay or alter the consummation of any or all of the transactions contemplated hereby. During the Term, each Party shall promptly notify the other Party in writing upon learning of any of the foregoing.
- 15.3 <u>Additional Regeneron Representations and Warranties</u>. Regeneron additionally represents and warrants to Company that, as of the Effective Date:
- (a) Regeneron has the right and authority to grant the rights and licenses granted pursuant to the terms and conditions of this Agreement and Regeneron has not granted any rights that remain in effect which conflict with the rights and licenses granted herein;
- (b) Except as set forth in Schedule 6, Regeneron is the sole owner of the Regeneron Patent Rights existing at the Effective Date, to Regeneron's knowledge, its title is free and clear of all liens, security interests and other encumbrances

(other than unilateral creditor filings, as to which this representation and warranty is made only to Regeneron's knowledge), and, except for the joint owner identified in Schedule 6 (and with respect to the Existing Licenses, the Third Party licensors referred to in Schedule 4), no Third Party has any right, title or interest in the Territory in the Field with respect to the Regeneron Patent Rights existing at the Effective Date;

- (c) It has no knowledge that the making, using or selling of the VEGF Trap in the Field in the Territory would infringe any valid claims of the Patents of any Third Party in the Territory, nor does it have knowledge that any Third Party is infringing or misappropriating any of the Regeneron Intellectual Property;
- (d) There are no judgments or settlements against or owed by Regeneron with respect to the Regeneron Intellectual Property owned by Regeneron;
- (e) There are no claims, announced investigations, actions or other proceedings pending before or, to Regeneron's knowledge, threatened by any Regulatory Authority or other government agency with respect to the VEGF Trap, any Regeneron facility or, to Regeneron's knowledge, any other facility where the VEGF Trap is Manufactured, and Regeneron has not received written notice threatening any such claim, investigation, action or other proceeding;
- (f) To the knowledge of Regeneron, the Development and Manufacture of VEGF Trap in the Field has been conducted by Regeneron and its Affiliates and its subcontractors in compliance in all material respects with applicable Laws, rules and regulations, and none of Regeneron or, to the knowledge of Regeneron, any of its Affiliates or subcontractors have received any notice in writing, or otherwise has knowledge of any facts, which have, or reasonably should have, led Regeneron to believe that any of the Registration Filings relating to the VEGF Trap in the Field are not currently in good standing with the FDA;
- (g) To Regeneron's knowledge, neither Regeneron, nor any officer, employee or agent of Regeneron, has made an untrue statement of a material fact to any Regulatory Authority with respect to the VEGF Trap in the Field (whether in any submission to such Regulatory Authority or otherwise), or knowingly failed to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the VEGF Trap in the Field:
- (h) To Regeneron's knowledge, Regeneron and its employees, agents, clinical institutions and clinical investigators have materially complied with all FDA statutory and regulatory requirements with respect to VEGF Trap in the Field;
- (i) Each Existing License is, to Regeneron's knowledge, in full force and effect as of the Effective Date. Regeneron has, to the extent contractually permitted, provided to Company, or allowed Company access to review, a true and complete copy of each Existing License. Regeneron will devote Commercially Reasonable Efforts to maintain the Existing Licenses in full force and effect and to perform its obligations thereunder and to keep Company informed of any material

development pertaining thereto that would reasonably be expected to have a material adverse effect on Company's rights under this Agreement. Regeneron shall not, without the prior written approval of Company, (i) amend any provision of an Existing License that would reasonably be expected to have a material adverse effect on Company's rights under this Agreement or (ii) make any election or exercise any right or option to terminate in whole or in part any Existing License to the extent such election or exercise would reasonably be expected to have a material adverse effect on Company's rights under this Agreement; and

(j) Regeneron has made available to Company, to the extent material, (i) written preclinical and clinical study results and protocols for the VEGF Trap in the Field, (ii) written communications to and from FDA with respect to the VEGF Trap in the Field, including but not limited to Registration Filings with the FDA and FDA minutes of meetings and telephone conferences, (iii) written FDA requests for data and studies with respect to the VEGF Trap in the Field and (iv) written reports of adverse drug experiences and other IND safety reports with respect to the VEGF Trap in the Field.

In reference to Section 15.3(c) above, the Parties acknowledge that they are aware of patents and pending patent applications owned by Genentech, Inc. that claim certain chimeric VEGF receptor compositions. Although Regeneron does not believe that the VEGF Trap infringes any valid claim in these patents or patent applications (if they were to issue), Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover the VEGF Trap. An adverse determination by a court in any such potential patent litigation would likely require the Parties to seek a license, which may not be available, or result in the Parties' inability to Develop, Manufacture or Commercialize the VEGF Trap in the Field in the Territory or in a damage award.

15.4 <u>Disclaimer of Wartanties</u>. EXCEPT AS OTHERWISE SPECIFICALLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, CONCERNING THE SUCCESS OR POTENTIAL SUCCESS OF THE DEVELOPMENT, COMMERCIALIZATION, MARKETING OR SALE OF ANY LICENSED PRODUCT IN THE FIELD. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

15.5 <u>Mutual Covenants</u>. Each Party hereby covenants to the other Party as of the Effective Date as follows: (a) It will not during the Term grant any right or license to any Third Party in the Territory which would conflict with the rights granted to the other Party under this Agreement, and will not take any action that would materially conflict with or adversely affect its obligations to the other Party under this Agreement; (b) Neither Party will use the Patent Rights or Know-How of the other Party outside the scope of the licenses and rights granted to it under this Agreement; and (c) In the course of the Development or Commercialization of a Licensed Product in the Field under this

Agreement, it will not knowingly use and will not have knowingly used an employee or consultant who is or has been debarred by a Regulatory Authority or, to the best of such Party's knowledge, is or has been the subject of debarment proceedings by a Regulatory Authority.

ARTICLE XVI CONFIDENTIALITY

16.1 Confidential Information.

(a) Each of Company and Regeneron acknowledges (subject to the further provisions of this Article 16 and the provisions of Article 19) that all Party Information provided to it (or its Affiliate) or otherwise made available to it by the other Party or its respective Affiliates pursuant to this Agreement (or, in the case of Company, Party Information provided to it under the confidentiality agreement between the Parties dated July 6, 2006) is confidential and proprietary to such other Party. Furthermore, each of Company and Regeneron acknowledges (subject to the further provisions of this Article 16) that all New Information is confidential and proprietary to both Parties. Subject to the further provisions of this Article 16, each of Company and Regeneron agrees to (i) maintain such Party Information of the other Party (or its Affiliates) and all New Information in confidence during the Term and for a period of ten (10) years thereafter and (ii) use such Party Information of the other Party (or its Affiliate) and New Information solely for the purpose of exercising its rights and performing its obligations hereunder. Each of Company and Regeneron covenants that neither it nor any of its respective Affiliates shall disclose any such Party Information of the other Party (or its Affiliate) or New Information to any Third Party except (A) to its employees, agents or any other Person under its authorization; provided such employees, agents or Persons are subject in writing to substantially the same confidentiality obligations as the Parties, (B) as approved by both Parties hereunder or (C) as set forth elsewhere in this Agreement.

(b) Notwithstanding anything provided above, the restrictions provided in this Article 16 shall not apply to information that was or is (and such information shall not be considered confidential or proprietary under this Agreement) (i) already in the public domain as of the Effective Date or becomes publicly known through no act, omission or fault of the receiving Party or its Affiliate or any Person to whom the receiving Party or its Affiliate provided such information; (ii) already in the possession of the receiving Party or its Affiliate at the time of disclosure by the disclosing Party, other than under an obligation of confidentiality; (iii) disclosed to the receiving Party or its Affiliate on an unrestricted basis from a Third Party not under an obligation of confidentiality to the other Party or any Affiliate of such other Party with respect to such information; (iv) similar in nature to the purported Party Information or New Information but has been independently created, as evidenced by written or electronic documentation, without any aid, application or use of the Party Information or New Information; (v) necessary to file, prosecute or defend Patents and Patent Applications for which the Party has the right to assume filing, prosecution, defense or maintenance

pursuant to this Agreement; or (vi) required by a Governmental Authority, applicable Law (including the rules and regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded), or court order to be disclosed, provided that the receiving Party uses reasonable efforts to give the disclosing Party advance notice of such required disclosure in sufficient time to enable the disclosing Party to seek confidential treatment for such information or to request that the receiving Party seek confidential treatment for such information, if applicable, and provided, further, that the receiving Party provides all reasonable cooperation to assist the disclosing Party to protect such information and limits the disclosure to that information which is required by Governmental Authority, applicable Law (including the rules or regulations of any stock exchange or trading market on which the disclosing Party's (or its parent entity's) securities are traded) or court order to be disclosed. Moreover, either Party may use Party Information and New Information to enforce the terms of this Agreement if it gives reasonable advance notice to the other Party to permit the other Party a sufficient opportunity to take any measures to ensure confidential treatment of such information and the disclosing Party shall provide reasonable cooperation to protect the confidentiality of such information.

- (c) Notwithstanding anything provided above or elsewhere in this Agreement, Regeneron and its Affiliates shall have the right to use and disclose any New Information directly related to the Regeneron Products (including the Manufacture or use thereof) (i) to Aventis or any other Third Party licensee or contractor of Regeneron engaged in, and for use in connection with, the development, manufacture and/or commercialization of Regeneron Products outside the Field under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years, (ii) in connection with Regeneron's Development, Manufacture and/or Commercialization of Regeneron Products outside the Field, (iii) to any Third Party licensee or contractor of Regeneron engaged in the Development, Manufacture and/or Commercialization of Regeneron Products in the Excluded Territory under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years, and (iv) to Governmental Authorities or Regulatory Authorities as required by Law.
- (d) Notwithstanding anything provided above or elsewhere in this Agreement, Company and its Affiliates shall have the right to use and disclose any New Information directly related to Company Products (including the Manufacture or use thereof) (i) to any Third Party licensee or contractor of Company or any of its Affiliates' engaged in and for use in connection with the development, manufacture and/or commercialization of Company Products outside the Field under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a term of at least five (5) years, (ii) in connection with Company's or any of its Affiliates' Development, Manufacture, and/or Commercialization of Company Products outside the Field, (iii) to any Third Party licensee or contractor of Company engaged in the Development, Manufacture and/or Commercialization of Company Products in the Excluded Territory under substantially the same confidentiality obligations as are set forth herein, except that the confidentiality obligations shall have a

term of at least five (5) years and (iv) to Governmental Authorities or Regulatory Authorities as required by Law.

- 16.2 <u>Injunctive Relief</u>. Each Party acknowledges that damages resulting from breach of this Article 16 would not be an adequate remedy and that, notwithstanding the provisions of Article 10, in the event of any such disclosure or any indication of an intent to disclose such information, a Party owning such Party Information (or each Party with respect to New Information) shall be entitled to seek, by way of private litigation, injunctive relief or other equitable relief, in addition to any and all remedies available at law or in equity, including the recovery of damages and reasonable attorneys' fees, and in any such action for equitable relief in a court of competent jurisdiction, the Parties will not assert as a defense that there is an adequate remedy at law.
- 16.3 <u>Publication of New Information</u>. During the Term, if either Company or Regeneron (the "<u>Publishing Party</u>") desires to disclose any New Information in scientific journals, publications or scientific presentations, the Publishing Party shall provide the other Party an advance copy of any proposed publication or summary of a proposed oral presentation relating to the New Information prior to submission for publication or disclosure. Such other Party shall have a reasonable opportunity to recommend any changes it reasonably believes are necessary to prevent any specific, material adverse effect to it or the Licensed Product as a result of the publication or disclosure (such recommendation of changes to include a description of the specific material adverse effect) to which the Publishing Party shall give due consideration. Disputes concerning publication shall be resolved by the JDC (other than Legal Disputes).
- 16.4 Other Publications. The Parties will mutually agree upon the contents of a joint press release with respect to the execution of this Agreement which shall be issued simultaneously by both Parties on the Effective Date. During the Term, Company and Regeneron agree not to (and to ensure that their respective Affiliates do not) issue any other press releases or public announcements concerning this Agreement or any other activities contemplated hereunder without the prior written consent of the other Party (which shall not be unreasonably withheld or delayed), except as required by a Governmental Authority or applicable Law (including the rules and regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded); provided that the Party intending to disclose such information shall use reasonable efforts to provide the other Party advance notice of such required disclosure, an opportunity to review and comment on such proposed disclosure (which comments shall be considered in good faith by the disclosing Party) and all reasonable cooperation to assist the other Party to protect such information and shall limit the disclosure to that information which is required to be disclosed. Notwithstanding the foregoing, without prior submission to or approval of the other Party, either Party may issue press releases or public announcements which incorporate information concerning this Agreement or any activities contemplated hereunder which information was included in a press release or public disclosure which was previously disclosed under the terms of this Agreement or which contains only non-material factual information regarding the Collaboration (e.g., that the Collaboration is ongoing in accordance with the terms of this Agreement). Except as required by a Governmental Authority or applicable Law (including the rules and

regulations of any stock exchange or trading market on which a Party's (or its parent entity's) securities are traded), or in connection with the enforcement of this Agreement, neither Party (or their respective Affiliates) shall disclose to any Third Party, under any circumstances, any financial terms of this Agreement that have not been previously disclosed publicly pursuant to this Article 16 without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; except for disclosures to Third Parties that are bound by obligations of confidentiality and nonuse substantially equivalent in scope to those included herein with a term of at least five (5) years. The Parties, through the Committees, shall establish mechanisms and procedures to ensure that there are coordinated timely corporate communications relating to the Licensed Products in the Field. Company acknowledges that Regeneron as a publicly traded company is legally obligated to make timely disclosures of all material events relating to Licensed Products. The Parties acknowledge that either or both Parties may be obligated to file a copy of this Agreement with the United States Securities and Exchange Commission or its equivalent in the Territory. Each Party will be entitled to make such filing but shall use reasonable efforts to obtain confidential treatment of confidential, including trade secret, information in accordance with applicable Law. The filing Party will provide the non-filing Party with an advance copy of the Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and will reasonably consider the non-filing Party's timely comments thereon.

ARTICLE XVII INDEMNITY

17.1 Indemnity and Insurance.

(a) Company will defend, indemnify and hold harmless Regeneron, its Affiliates and their respective officers, directors, employees, licensees and agents ("Regeneron Indemnitees") from and against all claims, demands, liabilities, damages, penalties, fines, costs and expenses, including reasonable attorneys' and expert fees and costs, and costs or amounts paid to settle (collectively, "Damages"), arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Regeneron Indemnitee that is due to or based upon:

(i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law by or of Company, its Affiliates or their respective directors, officers, employees, agents or Sublicensees, including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee; or

- (ii) material breach by Company of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.
- (b) Regeneron will defend, indemnify and hold harmless Company, its Affiliates and their respective officers, directors, employees, Sublicensees and agents ("Company Indemnitees") from and against all Damages arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against a Company Indemnitee that is due to or based upon:
 - (i) the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of law by or of Regeneron, its Affiliates or their respective directors, officers, employees, licensees or agents including, without limitation, in connection with the Development, Manufacture or Commercialization of any Licensed Product in the Field, except to the extent that Damages arise out of, and are allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts, or omissions or violations of Law committed by Company or any other Company Indemnitee; or
 - (ii) material breach by Regeneron of the terms of, or the inaccuracy of any representation or warranty made by it in, this Agreement.
- (c) Subject to the last sentence of Section 19.6, in the event of any Third Party claim alleging that the Development, Manufacture and/or Commercialization of any Licensed Product in the Field under this Agreement infringes a Patent Right of a Third Party for which neither Party is entitled to indemnification hereunder, each Party shall indemnify the other Party for fifty percent (50%) of all Damages therefrom and during the Term such Damages shall be treated as Other Shared Expenses.
- (d) Company agrees to indemnify the Regeneron Indemnitees from and against all Damages arising from product liability or other Third Party contractual claims arising from Company's or its Affiliates' or Sublicensees' Commercialization of Licensed Products in the Field in the Territory, except that Regeneron shall indemnify Company under Section 17.1(b) for all such claims resulting from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee. Regeneron agrees to indemnify the Company Indemnitees from and against all Damages arising from product liability or other Third Party contractual claims arising from Regeneron's or its Affiliates' or Sublicensees' commercialization of Regeneron Products in the Field in the Excluded Territory, except that Company shall indemnify Regeneron under Section 17.1(a) for all such claims resulting from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Company or any other Company Indemnitee. Company agrees to indemnify the Regeneron Indemnitees from and against all Damages arising from product liability or other Third Party contractual claims arising from Company's or its Affiliates' or Sublicensees'

commercialization of Company Products in the Field in the Excluded Territory, except that Regeneron shall indemnify Company under Section 17.1 (b) for all such claims resulting from, and to the extent allocable to, the gross negligence, recklessness, bad faith, intentional wrongful acts or omissions or violations of Law committed by Regeneron or any other Regeneron Indemnitee. Damages from product liability or other Third Party claims arising from the Development of any Licensed Product in the Field under this Agreement for which neither Party is entitled to indemnification under this Section 17.1 shall be treated as Development Costs.

- (e) Immediately upon First Commercial Sale in the Territory, during the Term and for a period of five (5) years after the expiration of this Agreement or the earlier termination thereof, each Party shall use Commercially Reasonable Efforts to obtain and/or maintain (either directly or as a named insured on a Third Party insurance policy or policies), at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amounts, respectively, which are reasonable and customary for comparable products in the pharmaceutical industry for companies of comparable size and activities at the respective place of business of each Party; provided that Regeneron shall not be required to obtain or maintain such insurance in an amount greater than [*********] per incident and in the aggregate. Such product liability insurance or self-insured arrangements shall insure against personal injury, physical injury or property damage arising out of, for Regeneron, Manufacture of Licensed Products (if applicable) and sale, distribution or marketing of Regeneron Products in the Excluded Territory, and for Company, the sale, distribution or marketing of Licensed Products in the Territory.
- (f) Notwithstanding anything to the contrary in this Section 17.1, neither Party shall be responsible to indemnify the other Party (or the Regeneron Indemnitees or Company Indemnitees, as the case may be) from Third Party claims resulting from, and to the extent allocable to, the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed by Third Parties contracted to Manufacture any part of the Clinical Supply Requirements or Commercial Supply Requirements pursuant to Article 8; provided, however, that nothing in this Section 17.1(f) limits either Party's indemnification obligations to the extent any Third Party claims arise from the negligence, recklessness, bad faith, intentional wrongful acts or omissions, or violations of Law committed directly by the Party that is responsible for contracting with such Third Party Manufacturer(s) pursuant to Article 8.
- 17.2 <u>Indemnity Procedure</u>. The Party entitled to indemnification under this Article 17 (an "<u>Indemnified Party</u>") shall notify the Party potentially responsible for such indemnification (the "<u>Indemnifying Party</u>") within five (5) Business Days of becoming aware of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; provided, however, that the failure to give such notice shall not relieve the Indemnifying Party of its indemnity obligation hereunder except to the extent that such failure materially prejudices its rights hereunder. For the avoidance of doubt, the indemnification procedures in this Section 17.2 shall not apply to claims for which each Party indemnifies the other Party for fifty percent (50%) of all Damages, under the terms of Section 17.1(c).

- (a) If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending such claim, the Indemnifying Party shall have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings, which proceedings shall be prosecuted diligently by the Indemnifying Party to a final conclusion or settled at the discretion of the Indemnifying Party; provided, however, that the Indemnifying Party may not enter into any compromise or settlement unless (i) such compromise or settlement includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim, and (ii) such compromise or settlement does not (A) include any admission of legal wrongdoing by the Indemnified Party, (B) require any payment by the Indemnified Party that is not indemnified hereunder or (C) result in the imposition of any equitable relief against the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party shall have the right, at the expense of the Indemnifying Party, upon ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not unreasonably withheld or delayed); provided that the Indemnified Party shall keep the Indemnifying Party apprised of all material developments with respect to such claim and promptly provide the Indemnified Party with copies of all correspondence and documents exchanged by the Indemnified Party and the opposing party(ies) to such litigation. The Indemnified Party may not compromise or settle such litigation without the prior written
- (b) The Indemnified Party may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 17.2 and shall bear its own costs and expenses with respect to such participation; provided, however, that the Indemnifying Party shall bear such costs and expenses if counsel for the Indemnifying Party shall have reasonably determined that such counsel may not properly represent both the Indemnifying and the Indemnified Party.
- (c) The amount of any Damages for which indemnification is provided under this Article 17 will be reduced by the insurance proceeds received, and any other amount recovered if any, by the Indemnified Party in respect of any such Damages.
- (d) If an Indemnified Party receives an indemnification payment pursuant to this Article 17 and subsequently receives insurance proceeds from its insurer with respect to the Damages in respect of which such indemnification payment(s) was made, the Indemnified Party will promptly pay to the Indemnifying Party an amount equal to the difference (if any) between (i) the sum of such insurance proceeds or other amounts received, and the indemnification payment(s) received from the Indemnifying Party pursuant to this Article 17 and (ii) the amount necessary to fully

and completely indemnify and hold harmless the Indemnified Party from and against such Damages. However, in no event will such refund ever exceed the Indemnifying Party's indemnification payment(s) to the Indemnified Party under this Article 17.

ARTICLE XVIII FORCE MAJEURE

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of terrorism, acts of war (whether war be declared or not), insurrections, strikes, riots, civil commotions or acts of God ("Force Majeure"). Such excuse from liability and responsibility shall be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the affected Party has not caused such event(s) to occur. The affected Party will notify the other Party of such Force Majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such Force Majeure circumstances.

ARTICLE XIX TERM AND TERMINATION

19.1 Term/Expiration of Term.

- (a) The "Term" of this Agreement shall commence on the Effective Date and, unless this Agreement is earlier terminated as provided hereafter, shall end at such time as neither Party, nor either Party's Affiliates or Sublicensees, is Developing or Commercializing any Licensed Product in the Field in the Territory under this Agreement and such cessation of Development and Commercialization activities is acknowledged by both Parties in writing to be permanent; provided, that if at any time during the Term Company loses the exclusive legal right to Commercialize Licensed Product in the Field in any Major Market Country, whether due to expiration of Regeneron Patent Rights or expiration of any statutory marketing exclusivity period for Licensed Product in such Major Market Country, the Parties shall meet to discuss and attempt to enter into an amendment to this Agreement for the purpose of simplifying the governance structure hereunder.
- (b) Upon expiration of the Term, except as set forth in this Agreement, all licenses and rights with respect to Products shall automatically terminate and revert to the granting Party.

forth above (the "Termination Notice Period") and the terms of Schedule 7 shall apply. Except as set forth in this Section 19.2, Section 19.8 (last paragraph), or Schedule 7, during the Termination Notice Period, the Parties shall continue to Develop, Manufacture and Commercialize Licensed Products in the Field in accordance with Plans. During the Termination Notice Period, to the extent set forth or requested in one or more written notices from Regeneron to Company hereunder and in any event upon the expiration of the applicable Termination Notice Period, whether or not any such notice is given by Regeneron, (a) the licenses and rights granted to Company hereunder shall automatically terminate as of a date specified in such notice(s) (and in any event not later than the expiration of the applicable Termination Notice Period) and (b) Company will promptly take the actions required by Schedule 7 and Regeneron will reasonably cooperate with Company (for avoidance of doubt, such cooperation shall not require Regeneron to pay any amounts or incur any liabilities or obligations not otherwise required hereunder to be paid or incurred by Regeneron) to facilitate Regeneron's (or its nominee's) expeditious assumption during the Termination Notice Period and thereafter, with as little disruption as reasonably possible, of the continued Development, Manufacture and Commercialization of Licensed Products in the Field in the Territory. In addition, during the Termination Notice Period,[**********************,] and (ii) neither Party will, without the prior written consent of the other Party's representatives on the applicable Committee, propose or implement any amendment or change to any Plan. Notwithstanding the foregoing, the Committee(s) will have an obligation under this Agreement and the Collaboration Purpose to propose and adopt in a timely manner an interim Plan for any Plan that expires during the Termination Notice Period. The most recent approved Plan(s) shall be extended pending approval of the new interim Plan(s

19.3 Termination For Material Breach. Upon and subject to the terms and conditions of this Section 19.3, this Agreement shall be terminable by a Party in its entirety if the other Party commits a material breach of this Agreement. Such notice of termination shall set forth in reasonable detail the facts underlying or constituting the alleged breach (and specifically referencing the provisions of this Agreement alleged to have been breached), and the termination which is the subject of such notice shall be effective ninety (90) days after the date such notice is given unless the breaching Party shall have cured such breach within such ninety (90) day period (or, if such material breach, by its nature, is a curable breach but such breach is not curable within such ninety (90) day period, such longer period not to exceed one hundred eighty (180) days so long as the breaching party is using Commercially Reasonable Efforts to cure such breach, in which event if such breach has not been cured, such termination shall be effective on the earlier of the expiration of such one hundred eighty (180) day period or such time as the breaching party ceases to use Commercially Reasonable Efforts to cure such breach). Notwithstanding the foregoing, in the case of breach of a payment obligation hereunder, the ninety (90) day period referred to in the immediately preceding sentence shall instead be thirty (30) days (and the immediately preceding parenthetical clause in the immediately preceding sentence shall not apply). For purposes of this Section 19.3, the term "material breach" shall mean a breach by a Party that substantially undermines the benefits reasonably expected to be realized by the non-breaching Party from the Collaboration, taken as a whole.

19.4 <u>Termination for Insolvency</u>. Either Party shall have the right to terminate this Agreement in its entirety, by and effective immediately, upon written notice to the other Party, if, at any time, (a) the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of its assets, (b) if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed or stayed within ninety (90) days after the filing thereof or (c) if the other Party shall make a general assignment for the benefit of creditors. In the event that this Agreement is terminated or rejected by a Party or its receiver or trustee under applicable bankruptcy Laws due to such Party's bankruptcy, then all rights and licenses granted under or pursuant to this Agreement by such Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code and any similar Laws in any other country in the Territory, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, including, without limitation, any patents or patent applications in any country of a party covered by the license grants under this Agreement, are part of the "intellectual property" as defined under Section 101(52) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country.

19.5 <u>Termination for Breach of Standstill</u>. Notwithstanding anything to the contrary herein, Regeneron will have the unilateral right to terminate this Agreement in its entirety, effective immediately, upon written notice to Company, if Section 20.16 of this Agreement shall have been breached. For the avoidance of doubt, Company will not be deemed to have breached Section 20.16, and Regeneron shall not have the right to terminate this Agreement, as a result of an inadvertent breach of Section 20.16 arising from (a) discussion with any Third Parties that are initiated by such Third Parties, are not publicly disclosed and do not result in any actions referred to in paragraphs (a) through (g) of Section 20.16 or (b) any informal discussions covering general corporate or other business matters the purpose of which is not to effectuate or lead to any of the actions referred to in paragraphs (a) through (g) of Section 20.16.

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19.7 Effect of Termination.

(a) Except as set forth in Section 19.7(b) below, upon termination of this Agreement prior to expiration of the Term (and during the applicable Termination Notice Period or 6-Month Notice Period), the provisions of Schedule 7 shall apply, and except to the extent required by Company to fulfill its obligations pursuant to Schedule 7, (i) all licenses and rights granted by Regeneron to Company hereunder shall automatically terminate, and revert to Regeneron, (ii) all licenses and rights granted by Company to Regeneron hereunder with respect to Company Products shall automatically terminate, and revert to Company, and (iii) the licenses from Company and its Affiliates

to Regeneron referred to in Schedule 7 shall come into full force and effect. In addition, upon termination of this Agreement prior to expiration of the Term (and during the applicable Termination Notice Period or 6-Month Notice Period), the following paragraphs of Schedule 8 shall apply with respect to any Company Products: (i) paragraph 1 of Schedule 8, (ii) paragraph 3 of Schedule 8 and (iii) paragraph 4 of Schedule 8. If Regeneron terminates this Agreement pursuant to Section 19.3, 19.4 or 19.5, then Company shall pay to Regeneron, in addition to any other amount payable by Company to Regeneron under this Agreement, under Law, or pursuant to any contractual remedies available to Regeneron, an amount equal to (i) fifty percent (50%) of the Development Costs incurred by Regeneron under the Global Development Plan but excluding the Aggregate Regeneron Payment Amount, and (ii) one hundred percent (100%) of the Development Costs incurred by Regeneron under the Territory Development Plan, during the period commencing on the effective date of such termination of this Agreement pursuant to any of such Sections and ending on the twelve (12) month anniversary of such date.

(b) Upon termination of this Agreement by Company pursuant to Section 19.3 or 19.4, the provisions of Schedule 8 shall apply with respect to any Company Product and, except to the extent required by Regeneron to fulfill its obligations pursuant to Schedule 8, (i) all licenses and rights granted by Company to Regeneron hereunder with respect to Company Products shall automatically terminate, and revert to Company, (ii) all licenses and rights granted by Regeneron to Company hereunder with respect to Regeneron Products shall automatically terminate and revert to Regeneron and (iii) the licenses from Regeneron and its Affiliates to Company referred to in Schedule 8 shall come into full force and effect for the Company Products. In addition, upon termination of this Agreement by Company pursuant to Section 19.3 or 19.4, the following paragraphs of Schedule 7 shall apply with respect to any Regeneron Products: (i) paragraph 1 of Schedule 7, (ii) paragraph 3 of Schedule 7 and (iii) paragraph 4 of Schedule 7.

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19.8 <u>Survival of Obligations</u>. Except as otherwise provided in this Article 19, Schedule 7 or Schedule 8, upon expiration or termination of this Agreement, the rights and obligations of the Parties hereunder shall terminate, and this Agreement shall cease to be of further force or effect, provided that notwithstanding any expiration or termination of this Agreement:

(a) neither Company nor Regeneron shall be relieved of any obligations (including payment obligations) of such Party arising prior to such expiration or termination, including, without limitation, the payment of any non-cancelable costs and expenses incurred as part of a Plan (even if such costs and expenses arise following termination or expiration, as the case may be), except that Regeneron's obligations with respect to the Global Development Balance Payments provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero;

- (b) subject to the provisions of this Article 19, including Schedule 7 and Schedule 8 to the extent applicable, the obligations of the Parties with respect to the protection and nondisclosure of Party Information and New Information in accordance with Article 16, as well as other provisions (including, without limitation, Sections 6.16, 7.5, 9.7, 9.8, 9.10 and 10.3, and Articles 12 (with respect to Joint Inventions), 16, 17, 19 and 20) which by their nature are intended to survive any such expiration or termination, shall survive and continue to be enforceable; and
- (c) such expiration or termination and this Article 19 shall be without prejudice to any rights or remedies a party may have for breach of this Agreement.

Notwithstanding the foregoing or any other term or provision of this Agreement, (i) if Company terminates this Agreement under Section 19.2 or Section 19.6 and, during the Termination Notice Period or 6-Month Notice Period, as the case may be, Regeneron enters into a license agreement for a Licensed Product in the Field in the Territory substantially similar in scope as, and providing for the assumption and performance by the counterparty thereto of the obligations of Company under, this Agreement, Company's continuing obligations under the Plans pursuant to Section 19.2 or Section 19.6, as applicable, shall expire, and (ii) upon termination of this Agreement for any reason other than a material breach by Regeneron and consequent termination by Company under Section 19.3, except as set forth in Section 19.7(c), Regeneron's obligations with respect to Global Development Balance Payments to Company provided for in Schedule 2 shall automatically terminate and the Global Development Balance shall equal zero.

ARTICLE XX MISCELLANEOUS

- 20.1 <u>Governing Law; Submission to Jurisdiction</u>. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, without regard to conflict of laws principles. Except as set forth in Article 10, the Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.
- 20.2 <u>Waiver</u>. Waiver by a Party of a breach hereunder by the other Party shall not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder shall preclude the later exercise of any such right, power or privilege by such Party. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.
- 20.3 <u>Notices</u>. All notices, instructions and other communications hereunder or in connection herewith shall be in writing, shall be sent to the address of the relevant Party set forth on Schedule 9 attached hereto and shall be (a) delivered personally,

- (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable nationwide overnight courier service or (d) sent by facsimile transmission, with a confirmation copy to be sent by registered or certified mail, return receipt requested, postage prepaid. Any such notice, instruction or communication shall be deemed to have been delivered upon receipt if delivered by hand, three (3) Business Days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) Business Day after it is sent via a reputable nationwide overnight courier service or when transmitted with electronic confirmation of receipt, if transmitted by facsimile (if such transmission is made during regular business hours of the recipient on a Business Day; or otherwise, on the next Business Day following such transmission). Either Party may change its address by giving notice to the other Party in the manner provided above.
- 20.4 Entire Agreement. This Agreement contains the complete understanding of the Parties with respect to the subject matter hereof and thereof and supersedes all prior understandings and writings relating to the subject matter hereof and thereof.
- 20.5 <u>Amendments</u>. No provision in this Agreement shall be supplemented, deleted or amended except in a writing executed by an authorized representative of each of Company and Regeneron.
 - 20.6 <u>Headings</u>. Headings in this Agreement are for convenience of reference only and shall not be considered in construing this Agreement.
- 20.7 Severability. If, under applicable Laws, any provision hereof is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement in any jurisdiction ("Modified Clause"), then, it is mutually agreed that this Agreement shall endure and that the Modified Clause shall be enforced in such jurisdiction to the maximum extent permitted under applicable Laws in such jurisdiction; provided that the Parties shall consult and use all reasonable efforts to agree upon, and hereby consent to, any valid and enforceable modification of this Agreement as may be necessary to avoid any unjust enrichment of either Party and to match the intent of this Agreement as closely as possible, including the economic benefits and rights contemplated herein.
- 20.8 <u>Registration and Filing of the Agreement</u>. To the extent that a Party concludes in good faith that it is or may be required to file or register this Agreement or a notification thereof with any Governmental Authority in accordance with applicable Laws, such Party may do so subject to the provisions of Section 16.4. The other Party shall promptly cooperate in such filing or notification and shall promptly execute all documents reasonably required in connection therewith. The Parties shall promptly inform each other as to the activities or inquiries of any such Governmental Authority relating to this Agreement, and shall promptly cooperate to respond to any request for further information therefrom.
- 20.9 <u>Assignment</u>. Except as otherwise expressly provided herein, neither this Agreement nor any of the rights or obligations hereunder may be assigned by either

Company or Regeneron without (a) the prior written consent of Regeneron in the case of any assignment by Company or (b) the prior written consent of Company in the case of an assignment by Regeneron, except in each case (i) to an Affiliate of the assigning Party that has and will continue to have the resources and financial wherewithal to fully meet its obligations under this Agreement, provided that the assigning Party shall remain primarily liable hereunder notwithstanding any such assignment, or (ii) to any other party who acquires all or substantially all of the business of the assigning Party by merger, sale of assets or otherwise, so long as such Affiliate or other party agrees in writing to be bound by the terms of this Agreement. The assigning Party shall remain primarily liable hereunder notwithstanding any such assignment. Any attempted assignment in violation hereof shall be void.

20.10 <u>Successors and Assigns</u>. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, and shall also inure to the benefit of the Regeneron Indemnitees and Company Indemnitees to the extent provided in the last sentence of Section 20.13.

20.11 Affiliates. Each Party may, and to the extent it is in the best interests of the Licensed Products in the Field in the Territory shall, perform its obligations hereunder through one or more of its Affiliates. Without limiting the foregoing, each Party shall take reasonable efforts to ensure that each of its Affiliates engaged in the development or commercialization of ophthalmic products or technologies and which have know-how or technologies that are materially useful for the Development or Commercialization of Licensed Products, engage in the Development or Commercialization of Licensed Products or otherwise license their Know-How under this Agreement. Each Party absolutely, unconditionally and irrevocably guarantees to the other Party prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act or omission) which such Party is prohibited hereunder from committing directly. If an Affiliate of a Party will engage in the Development, Manufacture or Commercialization of a Licensed Product or will otherwise license its Know-How under this Agreement, then such Party shall enter into a separate agreement with such Affiliate pursuant to which the obligations of such Party hereunder shall be binding on such Affiliate and which shall provide that the other Party is a third-party beneficiary of such agreement entitled to enforce such agreement and this Agreement against such Affiliate.

20.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument.

20.13 <u>Third-Party Beneficiaries</u>. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of any Party hereto. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any Party hereto. Notwithstanding the

foregoing, Article 17 is intended to benefit, in addition to the Parties, the other Regeneron Indemnitees and Company Indemnitees as if they were parties hereto, but this Agreement is enforceable only by the Parties.

20.14 Relationship of the Parties. Each Party shall bear its own costs incurred in the performance of its obligations hereunder without charge or expense to the other Party except as provided for in this Agreement. Neither Company nor Regeneron shall have any responsibility for the hiring, termination or compensation of the other Party's employees or for any employee compensation or benefits of the other Party's employees. No employee or representative of a Party shall have any authority to bind or obligate the other Party to this Agreement for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other Party without said Party's approval. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, Regeneron's legal relationship under this Agreement to Company, and Company's legal relationship under this Agreement to Regeneron, shall be that of an independent contractor. Nothing in this Agreement shall be construed to establish a relationship of partners or joint ventures between the Parties or any of their respective Affiliates.

20.15 Limitation of Damages. IN NO EVENT SHALL REGENERON OR COMPANY BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARDLESS OF THE THEORY OF LIABILITY (INCLUDING CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE) AND REGARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 20.15 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLIGATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD-PARTY CLAIMS .

20.16 <u>Standstill Agreement</u>. During the period commencing on the Effective Date and expiring on the date which is five (5) years after the end of the Term, neither Company nor any of its Affiliates (for purposes of this Section 20.16, Company, together with such Affiliates, being referred to as the "<u>Investor</u>") shall:

(a) directly or indirectly, acquire beneficial ownership of Shares of Then Outstanding Capital Stock or any securities convertible into or exchangeable for Shares of Then Outstanding Capital Stock, or make a tender, exchange or other offer to acquire Shares of Then Outstanding Capital Stock, if after giving effect to such acquisition (and assuming the conversion of all convertible securities), the Investor would beneficially own (as defined in Rule 13d-3 under the Securities Exchange Act of 1934, as amended) twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock; provided, however, that notwithstanding the provisions of this Section 20.16, if the number of shares constituting Shares of Then Outstanding Capital Stock is reduced or if the aggregate ownership of the Investor is increased as a result of a recapitalization of Regeneron, Investor shall not be required to dispose of any of its holdings of Shares of Then Outstanding Capital Stock even though such action resulted

in Investor's ownership totaling twenty percent (20%) or more of the Shares of Then Outstanding Capital Stock;

- (b) directly or indirectly, propose or nominate for election to the Board of Directors of Regeneron any Person whose nomination has not been approved by a majority of the Board of Directors of Regeneron, or vote or cause to be voted in favor of such Person for election to the Board of Directors of Regeneron any Shares of Then Outstanding Capital Stock;
- (c) directly or indirectly, accept or support a tender, exchange or other offer or proposal by any other Person or group (an "Offeror") the consummation of which would result in a Change of Control of Regeneron (an "Acquisition Proposal");
- (d) directly or indirectly, solicit proxies or consents or become a participant in a solicitation (as such terms are defined in Regulation 14A under the Securities Exchange Act) in opposition to the recommendation of a majority of the Board of Directors of Regeneron with respect to any matter, or seek to advise or influence any Person, with respect to voting of any Shares of Then Outstanding Capital Stock of Regeneron or any of its Affiliates;
- (e) deposit any Shares of Then Outstanding Capital Stock in a voting trust or subject any Shares of Then Outstanding Capital Stock to any arrangement or agreement with respect to the voting of such Shares of Then Outstanding Capital Stock;
 - (f) act in concert with any Third Party to take any action in clauses (a) through (e) above;
- (g) request or propose that Regeneron or any of Regeneron's officers or its Board of Directors amend, waive, or consider the amendment or waiver of any provisions set forth in this Section 20.16; or
- (h) enter into discussions, negotiations, arrangements or agreements with any Person relating to the foregoing actions referred to in clauses (a) through (g) above;

provided that the mere voting of any Shares of Then Outstanding Capital Stock held by the Company shall not constitute a violation of any of clauses (a) through (f) above.

20.18 Non-Solicitation. During the Term and for a period of two (2) years thereafter, neither Party shall solicit or otherwise induce or attempt to induce any employee of the other Party directly involved in the Development, Manufacture or Commercialization of any Licensed Product to leave the employment of the other Party and accept employment with the first Party. Notwithstanding the foregoing, this prohibition on solicitation does not apply to actions taken by a Party solely as a result of an employee's affirmative response to a general recruitment effort carried through a public solicitation or general solicitation.

20.19 No Strict Construction. This Agreement has been prepared jointly and will not be construed against either Party.

IN WITNESS WHEREOF, Company and Regeneron have caused this Agreement to be executed by their duly authorized representatives as of the day and year first above written.

BAYER HEALTHCARE LLC

/s/ Jeffrey M. Greenman Name: Jeffrey M. Greenman

Title: General Counsel and Secretary

REGENERON PHARMACEUTICALS, INC.

By /s/ Murray A. Goldberg

Name: Murray A. Goldberg
Title: Senior Vice President, Finance & Administration

and Chief Financial Officer

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Manufacturing Cost

"Manufacturing Cost" as used in this Agreement shall be determined as provided in this Schedule 1.

A. General Principles

- 1. Regeneron shall supply Formulated Bulk Product for Clinical Supply Requirements and Commercial Supply Requirements at Fully Burdened Manufacturing Cost, calculated as described in Section B below.
- 2. To the extent that a Manufacturing Plan includes the use of Formulated Bulk Product or Finished Product that was Manufactured by Regeneron prior to the Effective Date, Regeneron shall supply such Formulated Bulk Product or Finished Product at its actual average Fully Burdened Manufacturing Cost, calculated as described in Section B below, plus Cost of Finishing, as described in Section C below.

3.[3.	[**********************	1
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4. If a Manufacturing Plan calls for Regeneron to reserve its facility to Manufacture Formulated Bulk Product, including, without limitation,
purifying/processing the bulk drug substance, and the Parties subsequently amend the Manufacturing Plan such that the facility is not used as
originally set forth therein, then Regeneron shall be reimbursed for what otherwise would have been its Fully Burdened Manufacturing Cost as if
such facility had been used for Manufacturing as originally required in the Manufacturing Plan, except for such variable costs as are actually
avoided or mitigated; provided, however, that Regeneron shall not be reimbursed hereunder if such amendment of the Manufacturing Plan has
been agreed upon at least twelve (12) months prior to its effective date.

Quarterly True-Up

At the end of each Quarter, the Parties will calculate the net payment one Party shall be required to make to the other Party (the "Quarterly True-Up") equal to (a) the Territory Profit Split for such Quarter (as set forth in Part II), plus (b) the Regeneron Reimbursement Amount for such Quarter (as set forth in Part II), plus or minus (c) the Global True-Up (as set forth in Part III), minus (d) the Global Development Balance Payment (commencing in the Quarter of the First Commercial Sale in a Major Market Country) (as set forth in Part IV). In the event that the Quarterly True-Up is an amount shall be payable by Company to Regeneron in accordance with the terms set forth in Article 9. In the event that the Quarterly True-Up is an amount less than zero, the absolute value of such amount shall be payable by Regeneron to Company in accordance with the terms set forth in Article 9. An example of the Quarterly True-Up is shown in Part V.

I. TERRITORY PROFIT SPLIT

The "<u>Territory Profit Split</u>" shall mean fifty percent (50%) of Territory Profits in a Quarter. "<u>Territory Profits</u>" shall mean aggregate Net Sales in the Territory in the Quarter less the sum of aggregate COGS and aggregate Shared Promotion Expenses incurred by both Parties in the Territory in the Quarter.

An example of a calculation of the Territory Profit Split in a Quarter would be:

Net Sales in the Territory	Aggregate	Company 1000	Regeneron	Territory Profit Split
COGS	(50)	(50)	0	
Shared Promotion Expenses	(350)	(300)	(50)	
Territory Profits	600			300

II. REGENERON REIMBURSEMENT AMOUNT

The "Regeneron Reimbursement Amount" for a Quarter shall mean (a) Shared Promotion Expenses incurred by Regeneron in the Quarter (if any), plus (b) Commercial Supply Costs incurred by Regeneron in the Quarter (if any), plus (c) Development Costs incurred by Regeneron under the Territory Development Plan in the Quarter (if any).

An example of a calculation of the Regeneron Reimbursement Amount in a Quarter would be:

Regeneron Shared Promotion Expenses	50
Regeneron Commercial Supply Costs	10
Regeneron Development Costs under Territory Development	Plan 5
Regeneron Reimbursement Amount	65

III. GLOBAL TRUE-UP

The "Global True-Up" for a Quarter shall mean (a) fifty percent (50%) of the sum of (i) aggregate Development Costs incurred by both Parties under the Global Development Plan in the Quarter and (ii) aggregate Other Shared Expenses incurred by both Parties in the Quarter, minus (b) one hundred percent (100%) of the sum of (i) Development Costs incurred by Company under the Global Development Plan in the Quarter and (ii) Other Shared Expenses incurred by Company during the Quarter. If the Global True-Up is a positive number, it shall be added in the calculation of the Quarterly True-Up and, if it is a negative number, the absolute value of such amount shall be subtracted in the calculation of the Quarterly True-Up.

An example of a calculation of the Global True-Up in a Quarter would be:

				Global
	Aggregate	Company	Regeneron	True-Up
Development Costs under Global Development Plan	80	30	50	
Other Shared Expenses	40	35	5	
Total	120	65	55	(5)
2				

IV. GLOBAL DEVELOPMENT BALANCE PAYMENT

The "Global Development Balance" for a Quarter shall mean (a) twenty-five percent (25%) of the aggregate amount of Development Cobb by both Parties under the Global Development Plan from January 1, 2007 through the close of such Quarter [(************************************	urred by
The "Global Development Balance Payment" shall mean, [************************************	
An example of a calculation of the Global Development Balance Payment in a Quarter would be:	
Territory Profit Split	300
Global Development Balance [************************************	200 [****]
Global Development Balance Payment	[***]
2	

V. EXAMPLE OF QUARTERLY TRUE-UP

An example of a calculation of the Quarterly True-up in a Quarter would be:

Territory Profit Split	300
Regeneron Reimbursement Amount	65
Global True-Up	(5.)
Global Development Balance Payment	[****]
Quarterly True-up	[***]

In this example, Company would pay Regeneron [***] in accordance with the terms set forth in Article 9.

A more detailed illustration of the calculations under this Schedule 2 will be prepared by the JFC promptly after the Effective Date.

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Milestone Payments

I. DEVELOPMENT MILESTONES

Milestone	Payment	Milestone Event
1.	US \$20,000,000	For each Regeneron Product, upon administration of the Regeneron Product to the first
2.	[*******	[***********
3.	[*********	
4.	[*******	[***********

II. SALES MILESTONES

In addition to all other amounts payable under this Agreement, Company shall make the following additional non-refundable, non-creditable milestone payments to Regeneron based on the aggregate Net Sales in any twelve (12) consecutive month time period ("Twelve Month Period"):

Milestone Payment	Milestone Event
1. [***********	First Twelve Month Period in which
	aggregate Net Sales in such period equal
	or exceed US \$200,000,000
2. [***********]	First Twelve Month Period in which
	aggregate Net Sales in such period equal or exceed [*********]
	or exceed [*********]

Milestone	Payment	Milestone Event
3.	[*********	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]
4.	[**********	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*********]
5.	[***********	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*********]
6.	[*********	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]
7	[********	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]
8.	[***********	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [*********]
9.	[********	First Twelve Month Period in which aggregate Net Sales in such period equal or exceed [**********]

For purposes of further clarification, each separate milestone in this Section II of Schedule 3 may be achieved only once and the milestone numbers are included for reference purposes only.

For purposes of this Schedule 3, Net Sales will be converted to United States Dollars using the currency conversion procedure described in Section 9.6.

Regeneron Patent Rights

[***********

Termination Arrangements

- 1. Company shall promptly collect and return, and cause its Affiliates and Sublicensees to collect and return, to Regeneron or, at Regeneron's request, destroy, all documents containing New Information or Party Information of Regeneron and its Affiliates, and shall immediately cease, and cause its Affiliates and Sublicensees to cease, all further use of any New Information and Party Information of Regeneron and its Affiliates. In addition, at Regeneron's request, Company shall collect and transfer to Regeneron any remaining inventory of Regeneron Product Promotional Materials, Regeneron Product sales training materials, Regeneron Product samples, and Regeneron Product inventory. Notwithstanding the foregoing, Company may retain copies of any New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.
- 2. Regeneron and its Affiliates shall have a worldwide, fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Company Excluded Territory Intellectual Property existing at the effective date of termination to Develop, Manufacture and Commercialize Regeneron Products in the Field.
- 3. Company shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Regeneron to enable Regeneron (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture, and Commercialization of the Regeneron Products in the Field. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:
- (a) Company shall transfer and assign to Regeneron (or its nominee) all Marketing Approvals, Pricing Approvals, and other regulatory filings (including Registration Filings) made or obtained by Company or its Affiliates or any of its Sublicensees to the extent specifically relating to Regeneron Products.
- (b) Company shall assign and transfer to Regeneron (or its nominee) Company's entire right, title and interest in and to all Product Trademarks and Promotional Materials relating to Regeneron Products; provided that nothing herein is intended to convey any rights in or to Company's corporate name and logos or any trade names except for the limited rights set forth herein.
- (c) Company shall provide to Regeneron (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Regeneron Products in the Field in the Territory) of all information (including any New Information) in its possession or

under its control to the extent directly relating to any Regeneron Products in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Company, or such other format as may be reasonably requested by Regeneron.

- (d) Company shall use Commercially Reasonable Efforts to assign to Regeneron any applicable sublicenses to the extent related to any Regeneron Product and/or contracts relating to significant services to be performed by Third Parties to the extent related to Development, Manufacture or Commercialization of any Regeneron Product in the Field in the Territory, as reasonably requested by Regeneron and subject to the German Employee Invention Act.
- (e) Without limitation of Company's other obligations under this Schedule 7, to the extent Company or its Affiliate is Manufacturing (in whole or in part) Regeneron Products for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Company (or its Affiliate) will perform such Manufacturing responsibilities and supply Regeneron with Clinical Supply Requirements and/or Commercial Supply Requirements of Regeneron Products, and Regeneron shall purchase such Regeneron Products, at the same price, and on such other terms and conditions on which Company was supplying, or in the absence of termination would have been required to supply, such Regeneron Products, through the second anniversary of the effective date of termination of this Agreement or such shorter period if Regeneron notifies Company that Regeneron is able to Manufacture or have Manufactured Regeneron Products on comparable financial terms.
- 4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture, and Commercialization of the Regeneron Products in the Field hereunder to Regeneron (or its sublicensee or Third Party designee) as soon as is reasonably possible.
- 5. For the avoidance of doubt, Regeneron shall not be required to provide Company any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 7; provided, however, that Regeneron shall be solely responsible for paying any royalties, fees or other consideration that Company may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Regeneron of such licenses or other rights.

Termination Arrangements

- 1. Regeneron shall promptly collect and return, and cause its Affiliates and sublicensees to collect and return, to Company or, at Company's request, destroy, all documents containing New Information or Party Information of Company and its Affiliates, and shall immediately cease, and cause its Affiliates and sublicensees to cease, all further use of any New Information related to the Development, Manufacture and Commercialization of Company Products and any Party Information of Company and its Affiliates. In addition, at Company's request, Regeneron shall collect and transfer to Company any remaining inventory of Company Product Promotional Materials, Company Product sales training materials, Company Product samples and Company Product inventory. Notwithstanding the foregoing, Regeneron may retain copies of any New Information to the extent required by Law, as well as retain one (1) copy of such information solely for legal archive purposes.
- 2. Company and its Affiliates shall have a worldwide, fully paid-up, royalty-free, non-exclusive right and license, with the right to sublicense unless otherwise restricted by any Existing License or New License, under the Regeneron Excluded Territory Intellectual Property existing at the effective date of termination to Develop, Manufacture and Commercialize Company Products in the Field.
- 3. Regeneron shall use Commercially Reasonable Efforts to provide all cooperation and assistance reasonably requested by Company to enable Company (or its nominee) to assume with as little disruption as reasonably possible, the continued Development, Manufacture and Commercialization of the Company Products in the Field. Such cooperation and assistance shall be provided in a prompt and timely manner (having regard to the nature of the cooperation or assistance requested) and shall include, without limitation, the following:
- (a) Regeneron shall transfer and assign to Company (or its nominee) all Marketing Approvals, Pricing Approvals and other regulatory filings (including Registration Filings) made or obtained by Regeneron or its Affiliates or any of its sublicensees to the extent specifically relating to Company Products.
- (b) Regeneron shall assign and transfer to Company (or its nominee) Regeneron's entire right, title and interest in and to all Product Trademarks for Company Products and Promotional Materials relating to Company Products; provided that nothing herein is intended to convey any rights in or to Regeneron's corporate name and logos or any trade names except for the limited rights set forth herein.
- (c) Regeneron shall provide to Company (or its nominee) a copy (or originals to the extent required by any Regulatory Authority in connection with the Development, Manufacture or Commercialization of the Company Products) of all

information (including any New Information) in its possession or under its control to the extent directly relating to any Company Products in the Field, including, without limitation, all information contained in the regulatory and/or safety databases, all in the format then currently maintained by Regeneron, or such other format as may be reasonably requested by Company.

- (d) Regeneron shall use Commercially Reasonable Efforts to assign to Company any applicable sublicenses to the extent related to any Company Product and/or contracts relating to significant services to be performed by Third Parties to the extent related to Development, Manufacture or Commercialization of any Company Product in the Field, as reasonably requested by Company, and subject to the German Employee Invention Act.
- (e) Without limitation of Regeneron's other obligations under this Schedule 8, to the extent Regeneron or its Affiliate is Manufacturing (in whole or in part) Company Products for use in the Field in accordance with a Manufacturing Plan (or is designated to assume such responsibilities), Regeneron (or its Affiliate) will perform such Manufacturing responsibilities and supply Company with Clinical Supply Requirements and/or Commercial Requirements of Company Products, and Company shall purchase such Company Products, at the same price, and on such other terms and conditions on which Regeneron was supplying, or in the absence of termination would have been required to supply, such Company Products, through the second anniversary of the effective date of termination of this Agreement or such shorter period if Company notifies Regeneron that Company is able to Manufacture or have Manufactured Company Products on comparable financial terms.
- 4. Without limitation of the generality of the foregoing, the Parties shall use Commercially Reasonable Efforts to complete the transition of the Development, Manufacture and Commercialization of the Company Products in the Field hereunder to Company (or its Sublicensee or Third Party designee) as soon as is reasonably possible.
- 5. For the avoidance of doubt, Company shall not be required to provide Regeneron any consideration in exchange for the licenses or other rights granted to it pursuant to the provisions of this Schedule 8; provided, however, that Company shall be solely responsible for paying any royalties, fees or other consideration that Regeneron may be obligated to pay to a Third Party in respect of any such transfer or sublicense to Company of such licenses or other rights.

Notices

(a) If to Company:
Bayer HealthCare LLC
511 Benedict Avenue
Tarrytown, New York 10591
U.S.A.

With copy to:

Bayer HealthCare AG 51368 Leverkusen, Germany Attention: General Counsel

And a copy to:

Bayer Pharmaceuticals Corporation 400 Morgan Lane West Haven, Connecticut 06516 U.S.A. Attention: General Counsel

(b) If to Regeneron:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591 U.S.A.

Attention: President Copy: General Counsel

Nine months

Regeneron Pharmaceuticals, Inc. Computation of Ratio of Earnings to Combined Fixed Charges

(Dollars in thousands)

		77	1.15			ended
	2001	2002	ers ended December :	2004	2005	September 30, 2006
Earnings:	2001	2002	2003	2004	2003	2000
Income (loss) from continuing						
operations before income						
(loss) from equity investee	\$(75,178)	\$(124,350)	\$(107,395)	\$ 41,565	\$(95,456)	\$ (72,179)
Fixed charges	3,888	13,685	14,108	14,060	13,687	10,232
Amortization of capitalized interest		— (333)	33	78	78	58
Interest capitalized	<u></u>	(222)	(276)			
Adjusted earnings	\$(71,290)	\$(110,887)	\$ (93,530)	\$ 55,703	\$(81,691)	\$ (61,889)
Fixed charges:						
Interest expense	\$ 2,657	\$ 11,859	\$ 11,932	\$ 12,175	\$ 12,046	\$ 9,033
Interest capitalized	· · · · · · · · · · · · · · · · · · ·	222	276			
Assumed interest component of						
rental charges	1,231	1,604	1,900	1,885	1,641	1,199
	0000002000020020202020000000	******************************	******************************			000000000000000000000000000000000000000
Total fixed charges	\$ 3,888	\$ 13,685	\$ 14,108	\$ 14,060	\$ 13,687	\$ 10,232
Ratio of earnings to fixed charges	(A)	(A)	(A)	3.96	(A)	(A)

⁽A) Due to the registrant's losses for the years ended December 31, 2001, 2002, 2003, and 2005, and for the nine months ended September 30, 2006, the ratio coverage was less than 1:1. To achieve a coverage ration of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

					Nine months ended		
	Years ended December 31,				September 30,		
	2001	2002	2003	2005	2006		
Coverage deficiency	\$75,178	\$124,572	\$107,638	\$95,378	\$72,121		

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Leonard S. Schleifer, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2006 /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Murray A. Goldberg, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2006 /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance &
Administration, Chief Financial Officer,
Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer November 6, 2006

/s/ Murray A. Goldberg

Murray A. Goldberg Chief Financial Officer November 6, 2006

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 5/4/2007

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)						
\square	QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934					
	For the quarterly period ended March 31,	2007				
		OR				
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934					
	For the transition period from					
	Con	ımission File Nu	mber 0-19034			
			IACEUTICALS, INC. specified in its charter)			
	New York		13-3444607			
	(State or other jurisdiction of incorporation or organization)		(I.R.S. Employer Identification No.)			
	777 Old Saw Mill River Road Tarrytown, New York		10591-6707			
	(Address of principal executive offices)		(Zip Code)			
	(Registrant's	(914) 347- telephone numb	7000 er, including area code)			
1934 during			d to be filed by Section 13 or 15(d) of the Securities Exchange Act of strant was required to file such reports), and (2) has been subject to			
		Yes 🗹	No □			
	check mark whether the registrant is a large accel filer and large accelerated filer" in Rule 12b-2 of Large accelerated filer D	the Exchange A				
Indicate by o	check mark whether the registrant is a shell comp	oany (as defined	in Rule 12b-2 of the Exchange Act).			
		Yes □	No ☑			
Indicate the	number of shares outstanding of each of the iss	uer's classes of	common stock as of April 30, 2007:			
	Class of Common Stock		Number of Shares			
	Class A Stock, \$0.001 par value Common Stock, \$0.001 par value		2,270,353 63,688,790			

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PART I. FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AT MARCH 31, 2007 AND DECEMBER 31, 2006 (Unaudited) (In thousands, except share data)

	March 31, 2007	December 31, 2006
ASSETS		
Current assets Cash and cash equivalents Marketable securities Accounts receivable Prepaid expenses and other current assets Total current assets	\$ 156,484 295,910 33,632 3,137 489,163	\$ 237,876 221,400 7,493 3,215 469,984
Restricted cash Marketable securities Property, plant, and equipment, at cost, net of accumulated depreciation and amortization Other assets Total assets	1,600 60,981 47,781 1,906 \$ 601,431	1,600 61,983 49,353 2,170 \$ 585,090
LIABILITIES and STOCKHOLDERS' EQUITY Current liabilities Accounts payable and accrued expenses Deferred revenue, current portion Total current liabilities	\$ 20,081 63,523 83,604	\$ 21,471 23,543 45,014
Deferred revenue Notes payable Total liabilities	121,138 200,000 404,742	123,452 200,000 368,466
Commitments and contingencies		
Stockholders' equity Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and outstanding-none Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,270,353 in 2007 and 2006 Common Stock, \$.001 par value; 160,000,000 shares authorized, shares issued and outstanding - 63,395,134 in 2007 and 63,130,962 in 2006 Additional paid-in capital Accumulated deficit Accumulated other comprehensive loss Total stockholders' equity Total liabilities and stockholders' equity	63 914,317 (717,534) (159) 196,689 \$ 601,431	2 63 904,407 (687,617) (231) 216,624 \$ 585,090

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share data)

	Three months e	nded March 31,
Revenues Contract research and development Contract manufacturing	\$ 13,645	\$ 14,587 3,632
Technology licensing	2,143 15,788	18,219
Expenses		
Research and development Contract manufacturing	41,235	32,084 1,852
General and administrative	<u>8,202</u> <u>49,437</u>	5,946 39,882
Loss from operations	(33,649)	(21,663)
Other income (expense) Investment income	6,743	3,481
Interest expense	(3,011)	(3,011)
Net loss before cumulative effect of a change in accounting principle Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")	(29,917)	(21,193) 8 13
Net loss	\$ (29,917)	\$ (20,380)
Net loss per share amounts, basic and diluted: Net loss before cumulative effect of a change in accounting principle	\$ (0.46)	\$ (0.37)
Cumulative effect of adopting SFAS 123R Net loss	\$ (0.46)	\$ (0.36)
Weighted average shares outstanding, basic and diluted	65,563	56,727

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) For the three months ended March 31, 2007 (In thousands)

					Additional		Accumulated Other	Total	
	Class A	A Stock	Commo	on Stock	Paid-in	Accumulated	Comprehensive	Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	<u>Capital</u>	Deficit	Loss	<u>Equity</u>	Loss
Balance, December 31, 2006	2,270	\$ 2	63,131	\$ 63	\$ 904,407	\$ (687,617)	\$ (231)	\$ 216,624	
Issuance of Common Stock in									
connection with exercise									
of stock options, net of									
shares tendered	000000000000000000000000000000000000000		199		1,958		555555555555555555555555555555555555	1,958	000000000000000000000000000000000000000
Issuance of Common Stock in									
connection with Company									
401(k) Savings Plan			7.5		1 ቅረማ			1 224	
contribution			65		1,367			1,367	
Stock-based compensation					6,585			6,585	
expense Net loss			800000000000000000000000000000000000000		0,363	(29,917)		(29,917)	\$ (29,917)
Change in net unrealized loss						(42,217)		(23,317)	(23,21/)
on marketable securities							72	72	72
:00000000000000000000000000000000000000	2 2 2 2 0	<u>\$</u> 2	62.305	¢ 62	\$ 914,317	\$ (717,534)		\$ 196,689	\$ (29.845)
Balance, March 31, 2007	2,270	⊅ ∠	63,395	<u> </u>	p 914,31/	<u>Φ (/1/,334</u>)	<u>\$ (159)</u>	a 120,082	a (Z2,643)

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Three months er	nded March 31, 2006
Cash flows from operating activities		
Net loss	<u>\$ (29,917)</u>	\$ (20,380)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities		
Depreciation and amortization	2,855	3,798
Non-cash compensation expense	6,585	4,079
Cumulative effect of a change in accounting principle		(813)
Changes in assets and liabilities	(2(120)	25 511
(Increase) decrease in accounts receivable (Increase) decrease in prepaid expenses and other assets	(26,139) (440)	25,511 1,023
Increase in inventory	(440)	(92)
Increase (decrease) in deferred revenue	37 666	(4,779)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	152	(3,069)
Total adjustments	20,679	25,658
Net cash (used in) provided by operating activities	(9,238)	5,278
1 to taken (asset in) provided by operating about thes	(,,250)	
Cash flows from investing activities		
Purchases of marketable securities	(186,177)	(74,541)
Sales or maturities of marketable securities	113,262	64,317
Capital expenditures	(1,197)	(646)
Net cash used in investing activities	(74,112)	(10,870)
Cash flows from financing activities		
Net proceeds from the issuance of Common Stock	1,958	3,416
Net cash provided by financing activities	1,958	3,416
Net decrease in cash and cash equivalents	(81,392)	(2,176)
Cash and cash equivalents at beginning of period	237,876	184,508
Cash and cash equivalents at end of period	<u>§ 156,484</u>	<u>\$ 182,332</u>

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2006 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2006.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. For the three months ended March 31, 2007 and 2006, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months E	anded March 31,
	2007	2006
Net loss (Numerator)	\$(29,917)	\$(20,380)
Weighted-average shares, in thousands (Denominator)	65,563	56,727
Basic and diluted net loss per share	\$ (0.46)	\$ (0.36)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the March 31, 2007 and 2006 diluted per share amounts because their effect would have been antidilutive, include the following:

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended March 31,		
	2007	2006	
Stock Options:			
Weighted average number, in thousands	15,549	14,401	
Weighted average exercise price	\$ 15.65	\$ 14.27	
Restricted Stock:			
Weighted average number, in thousands		54	
Convertible Debt:			
Weighted average number, in thousands	6,611	6,611	
Conversion price	\$ 30.25	\$ 30.25	

3. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2007 and December 31, 2006 are \$580 and \$755, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2006 and December 31, 2005 are \$233 and \$234, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2006 and 2005 are \$1,367 and \$1,884, respectively, of accrued Company 401 (k) Savings Plan contribution expense. In the first quarter of 2007 and 2006, the Company contributed 64,532 and 120,960 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at March 31, 2007 and December 31, 2006 are \$2,054 and \$1,532, respectively, of accrued interest income. Included in marketable securities at March 31, 2006 and December 31, 2005 are \$656 and \$1,228, respectively, of accrued interest income.

4. Accounts Receivable

Accounts receivable as of March 31, 2007 and December 31, 2006 consist of the following:

	March 31,	December 31,
	2007	2006
Receivable from the sanofi-aventis Group	\$ 9,676	\$ 6,900
Receivable from Bayer HealthCare LLC	3,070	
Receivable from Astellas Pharma Inc.	20,000	
Other	886	593
	\$ 33,632	<u>\$ 7,493</u>

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2007 and December 31, 2006 consist of the following:

	March 31,	December 31,
	2007	2006
Accounts payable	\$ 4,805	\$ 4,349
Accrued payroll and related costs	5,332	9,932
Accrued clinical trial expense	2,673	2,606
Accrued expenses, other	2,229	2,292
Interest payable on convertible notes	5,042	2,292
	\$ 20,081	\$ 21,471

6. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three months ended March 31, 2007 and 2006, the components of comprehensive loss are:

	Three months ended March	
	2007	2006
Net loss	\$(29,917)	\$(20,380)
Change in net unrealized gain (loss) on marketable securities	72	99
Total comprehensive loss	<u>\$(29,845</u>)	\$(20,281)

7. License Agreements

AstraZeneca

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that will allow AstraZeneca to utilize the Company's VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable up-front payment to the Company which was deferred and is being recognized as revenue ratably over approximately the first year of the agreement. AstraZeneca also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's VelocImmune technology. In the first quarter of 2007, the Company recognized \$2,143 of revenue in connection with the AstraZeneca license agreement. At March 31, 2007, deferred revenue was \$17,857.

Astellas

On March 30, 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that will allow Astellas to utilize the Company's VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable up-front payment to the Company, which was received in April 2007. Astellas also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's VelocImmune technology. At March 31, 2007, the \$20.0 million up-front payment from Astellas was included in accounts receivable and deferred revenue.

8. Income Taxes

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes*— *an interpretation of FASB Statement No. 109*. The implementation of FIN 48 had no impact on the Company's financial statements as the Company has no unrecognized tax benefits.

The Company is primarily subject to U.S. federal and New York State income tax. Tax years subsequent to 1991 remain open to examination by U.S. federal and state tax authorities.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of January 1 and March 31, 2007, the Company had no accruals for interest or penalties related to income tax matters.

9. Segment Information

Through 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing. Due to the expiration of the Company's manufacturing agreement with Merck & Co., Inc. in October 2006, beginning in 2007, the Company only has a research and development business segment.

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REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to activities conducted under contract research and technology licensing agreements.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006, the Company produced a vaccine intermediate for Merck under the Merck Agreement, which expired in October 2006.

The table below presents information about reported segments for the three months ended March 31, 2007 and 2006.

	Three me	Three months ended March 31, 2007		
	Research &	Reconciling		
	Development	Items	Total	
Revenues	\$ 15,788		\$ 15,788	
Depreciation and amortization	2,594	261	2,855	
Non-cash compensation expense	6,585		6,585	
Interest expense		3,011	3,011	
Net (loss) income	(33,649)	3,732 (1)	(29,917)	
Capital expenditures	1,022	_	1,022	
Total assets	81,413	520,018 (2)	601,431	

	Three months ended March 31, 2006			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 14,587	\$3,632		\$ 18,219
Depreciation and amortization	3,537	(3)	\$ 261	3,798
Non-cash compensation expense	3,984	95	(813)(4)	3,266
Interest expense	_	_	3,011	3,011
Net (loss) income	(23,443)	1,780	1,283 (1)	(20,380)
Capital expenditures	645	_	_	645
Total assets	67,159	4,526	330,404(2)	402,089

⁽¹⁾ Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the three months ended March 31, 2006, also includes the cumulative effect of adopting Statement of Financial Accounting Standards No. ("SFAS") 123R, Share-Based Payment.

⁽²⁾ Includes cash and cash equivalents, marketable securities, restricted cash (where applicable), prepaid expenses and other current assets, and other assets.

⁽³⁾ Depreciation and amortization related to contract manufacturing was capitalized into inventory and included in contract manufacturing expense when the product was shipped.

⁽⁴⁾ Represents the cumulative effect of adopting SFAS 123R.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

10. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

11. Future Impact of Recently Issued Accounting Standards

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company will be required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Management is currently evaluating the potential impact of adopting SFAS 159 on the Company's financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: IL-1 Trap (rilonacept) in various inflammatory indications, the VEGF Trap in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. In October 2006, we entered into a collaboration with Bayer HealthCare LLC for the development of the VEGF Trap-Eye. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the VelocImmune platform which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move our first new antibody product candidate into clinical trials in the fourth quarter of 2007. We plan to introduce two new antibody product candidates into clinical development each year. We continue to invest in the

development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Clinical Programs:

Below is a summary of the clinical status of our clinical candidates as of March 31, 2007:

1. IL-1 Trap — Inflammatory Diseases

The IL-1 Trap (rilonacept) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating the IL-1 Trap in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called Cryopyrin-Associated Periodic Syndromes (CAPS) and other diseases associated with inflammation.

We recently completed the 24-week open-label safety extension phase of the Phase 3 clinical program in CAPS and are completing the trial analysis. We are preparing to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in the second quarter of 2007. The FDA has granted Orphan Drug status and Fast Track designation to the IL-1 Trap for the treatment of CAPS.

In October 2006, we announced positive data from this Phase 3 trial, which was designed to provide two separate demonstrations of efficacy for the IL-1 Trap within a single group of adult patients suffering from CAPS. This Phase 3 trial included two studies (Part A and Part B). Both studies met their primary endpoints (Part A: p < 0.0001 and Part B: p < 0.001). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive the IL-1 Trap had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo (p<0.0001). Following a 9-week interval during which all patients received the IL-1 Trap, a "randomized withdrawal" study (Part B) was performed, in which the patients in Part A were re-randomized to either switch to placebo or continue treatment with the IL-1 Trap in a double-blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on the IL-1 Trap who had no significant change (p<0.001). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on the IL-1 Trap than on placebo. In these studies, the IL-1 Trap appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study.

CAPS is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID). These syndromes are characterized by spontaneous systemic inflammation and are termed autoinflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS are caused by a range of mutations in the gene *CIAS1* (also known as NALP3) which encodes a protein named cryopyrin. Currently, there are no medicines approved for the treatment of CAPS.

We are also evaluating the potential use of the IL-1 Trap in other indications in which IL-1 may play a role. Based on preclinical evidence that IL-1 appears to play a critical role in gout, we initiated a proof of concept study of the IL-1 Trap in gout in the first quarter of 2007. We are also preparing to initiate exploratory proof of concept studies of the IL-1 Trap in other indications.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our IL-1 Trap currently in clinical development.

2. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

The VEGF Trap is being developed in cancer indications in collaboration with sanofi-aventis. Currently, the collaboration is conducting Phase 2 studies, with patient enrollment underway in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the FDA granted Fast Track designation to the VEGF Trap for the treatment of SMA. Sanofi-aventis reported in February

2007 that a registration filing is possible for the VEGF Trap in at least one of these single-agent indications in 2008.

In addition, six new Phase 2 single-agent studies have begun in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) in relapsed/refractory multiple myeloma, metastatic colorectal cancer, recurrent or metastatic cancer of the urothelium, locally advanced or metastatic gynecological soft tissue sarcoma, recurrent malignant gliomas, and metastatic breast cancer. We and sanofiaventis are working to finalize plans with NCI/CTEP for at least four additional trials in different cancer types.

We and sanofi-aventis intend to initiate five Phase 3 trials evaluating the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer types, the first three of which are planned to begin in 2007. The companies plan to initiate these Phase 3 trials in the following indications:

- first-line metastatic hormone resistant prostate cancer in combination with Taxotere® (Aventis),
- first-line metastatic pancreatic cancer in combination with gemcitabine-based regimen,
- first-line gastric cancer in combination with Taxotere® (Aventis),
- second-line non-small cell lung cancer in combination with Taxotere® (Aventis), and
- second-line metastatic colorectal cancer in combination with FOLFIRI (Folinic Acid (leucovorin), 5-fluorouracil, and irinotecan).

Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the planned Phase 3 clinical program. The companies have previously summarized information from two of these safety and tolerability trials. One study is evaluating the VEGF Trap in combination with oxaliplatin, 5-flourouracil, and leucovorin (FOLFOX4) in a Phase 1 trial of patients with advanced solid tumors. Another study is evaluating the VEGF Trap in combination with irinotecan, 5-fluorouracil, and leucovorin (LV5FU2-CPT11) in a Phase 1 trial of patients with advanced solid tumors. Abstracts published in the 2006 ASCO Annual Meeting Proceedings reported that the VEGF Trap could be safely combined with either FOLFOX4 or LV5FU2-CPT11 at the dose levels studied. The companies are also evaluating the VEGF Trap in separate Phase 1b studies in combination with Taxotere® (Aventis), cisplatin, and 5-fluorouracil; with Taxotere® (Aventis) and cisplatin; and with gemcitabine-erlotinib.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting

angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin® (Genentech) is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

Collaboration with the sanofi-aventis Group

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to \$400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another \$40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

3. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 2 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and in a small pilot study in patients with diabetic macular edema (DME).

In the second quarter of 2006, we initiated a 150 patient, 12 week, Phase 2 trial of the VEGF Trap-Eye in wet AMD. The trial is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. In March 2007, we announced positive preliminary data from a pre-planned interim analysis of this study. The VEGF Trap-Eye met its primary endpoint of a statistically significant reduction in retinal thickness after 12 weeks compared with baseline (all groups combined, decrease of 135 microns, p < 0.0001). Mean change from baseline in visual acuity, a key secondary endpoint of

the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.9 letters, p < 0.0001). Moreover, patients in the dose groups that received only a single dose, on average, compared to baseline, demonstrated a decrease in excess retinal thickness (p < 0.0001) and an increase in visual acuity (p = 0.012) at 12 weeks. There were no drug-related serious adverse events, and treatment with the VEGF Trap-Eye was generally well-tolerated. The most common adverse events were those typically associated with intravitreal injections. Detailed data from this interim analysis is scheduled for presentation at an upcoming scientific conference. We also expect to complete three-month data on all 150 patients enrolled in the study by the end of 2007. We are also conducting a Phase 1 safety and tolerability trial of a new formulation of the VEGF Trap-Eye in wet AMD. An initial Phase 3 trial of the VEGF Trap-Eye in wet AMD utilizing the new formulation is planned to begin in the third quarter of 2007, and a second Phase 3 trial is planned once the full data from the Phase 2 trial has been analyzed.

Also in the second quarter of 2006, we initiated a small pilot study of the VEGF Trap in patients with DME. We expect to initiate a Phase 2 trial in DME in the second half of 2007.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis® (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of the VEGF Trap-Eye. Under the agreement we and Bayer HealthCare will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic eye diseases, and other diseases and disorders. The companies will share equally in profits from any future sales of the VEGF Trap-Eye outside the United States. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retained exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare and can earn up to \$110.0 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market

countries outside the United States. We can also earn up to \$135.0 million in sales milestones if total annual sales of the VEGF Trap outside the United States achieve certain specified levels starting at \$200.0 million.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2007, we had a cumulative loss of \$717.5 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and IL-1 Trap; advance new product candidates into clinical development from our existing research programs utilizing our new technology for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events for 2007 and plans over the next 12 months are as follows:

Clinical Program	2007 Events to Date	2007-8 Plans			
VEGF Trap – Oncology	NCI/CTEP initiated six Phase 2 studies of the VEGF Trap as a single agent	 Sanofi-aventis to initiate at least three of five Phase 3 studies of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer indications 			
		NCI/CTEP to initiate at least four new exploratory efficacy/safety studies			
VEGF Trap-Eye (intravitreal injection)	• Reported positive interim results of Phase 2 trial in wet AMD	• Initiate first Phase 3 trial in wet AMD of the VEGF Trap-Eye compared with Lucentis® (Genentech)			
		• Report final results of Phase 2 trial in wet AMD			
		• Initiate second Phase 3 trial in wet AMD			
		• Report results of the Phase 1 trial in DME			
		• Initiate Phase 2 trial in DME			
		Explore additional eye disease indications			
IL-1 Trap (rilonacept)	• Completed the 24 week open-label safety extension phase of the Phase 3 trial in CAPS	• Submit BLA to the FDA for CAPS			
		• Initiate proof-of-concept studies evaluating the IL-1 Trap in gout and report initial data			
		• Evaluate the IL-1 Trap in other disease indications in which IL-1 may play an important role			
VelocImmune		Initiate first trial for antibody product candidate			

License Agreements

AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that will allow AstraZeneca to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable up-front payment to us. AstraZeneca also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our VelocImmune technology.

Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that will allow Astellas to utilize our VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable up-front payment to us, which was received in April 2007. Astellas also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our VelocImmune technology.

Results of Operations

Three Months Ended March 31, 2007 and 2006

Net Income (Loss):

Regeneron reported a net loss of \$29.9 million, or \$0.46 per share (basic and diluted), for the first quarter of 2007 compared to a net loss of \$20.4 million, or \$0.36 per share (basic and diluted), for the first quarter of 2006.

Revenues:

Revenues for the three months ended March 31, 2007 and 2006 consist of the following:

			Increase
(In millions)	2007	2006	(Decrease)
Contract research & development revenue			
The sanofi-aventis Group	\$ 11.8	\$ 13.9	\$ (2.1)
Other	1,9	0.7	12
Total contract research & development revenue	13.7	14.6	(0.9)
Contract manufacturing revenue		3.6	(3.6)
Technology licensing revenue	2.1		2.1
Total revenue	\$ 15.8	<u>\$ 18.2</u>	<u>\$ (2.4</u>)

We recognize revenue from sanofi-aventis, in connection with the companies' VEGF Trap collaboration, in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and FASB Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable up-front license payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

Sanofi-aventis Contract Research & Development Revenue	Three months er	nded March 31,
(In millions)	2007	2006
Regeneron expense reimbursement	\$ 9,6	\$ 10.8
Recognition of deferred revenue related to up-front payments	2.2	3.1
Total	<u>\$ 11.8</u>	<u>\$ 13.9</u>

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses decreased in the first quarter of 2007 from the same period in 2006, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments decreased in the first quarter of 2007 from the same period in 2006, due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of March 31, 2007, \$67.7 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

As described above, in October 2006 we entered into a VEGF Trap-Eye collaboration with Bayer HealthCare. In 2007, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$50.0 million will be shared equally; Regeneron is solely responsible for the next \$40.0 million; over \$90.0 million will be shared equally. Bayer HealthCare reimbursements of shared development expenses incurred by us are recorded as deferred revenue. We will recognize revenue from Bayer HealthCare, in connection with the companies' collaboration, in accordance with SAB 104 and EITF 00-21. When we and Bayer HealthCare have formalized our projected global development plans for the VEGF Trap-Eye, as well as the projected responsibilities of each of the companies under those development plans, we will begin recognizing contract research and development revenue related to payments from Bayer HealthCare. As a result, no contract research and development revenue has been earned from Bayer HealthCare through March 31, 2007 even though Bayer HealthCare will reimburse us for \$3.1 million of first quarter 2007 shared VEGF Trap-Eye expenses. As of March 31, 2007, deferred revenue from Bayer HealthCare, which will be recognized in future periods, totaled \$78.1 million, consisting of the \$75.0 million up-front payment received in October 2006 and reimbursement of \$3.1 million of shared VEGF Trap-Eye expenses related to the first quarter of 2007.

Other contract research and development revenue includes \$0.7 million recognized in connection with our five-year grant from the National Institutes of Health (NIH).

Contract manufacturing revenue for the first three months of 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the first three months of 2006 was \$0.4 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca which allows AstraZeneca to utilize Regeneron's VelocImmune technology in its internal research

programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable up-front payment to us which was deferred and will be recognized as revenue ratably over approximately the first year of the agreement. In the first quarter of 2007, we recognized \$2.1 million of technology licensing revenue related to the AstraZeneca agreement.

Expenses:

Total operating expenses increased to \$49.4 million in the first quarter of 2007 from \$39.9 million in the same period of 2006. Operating expenses in the first quarter of 2007 and 2006 include a total of \$6.6 million and \$3.9 million, respectively, of non-cash compensation expense related to employee stock option awards (Stock Option Expense), as detailed below:

(In millions)	For the three months ended March 31, 2007		
	Expenses before		
	inclusion of Stock	Stock Option	Expenses as Reported
Expenses	Option Expense	<u>Expense</u>	Reported
Research and development	\$ 37.4	\$ 3.8	\$ 41.2
General and administrative	5.4	2.8	8.2
Total operating expenses	<u>\$ 42.8</u>	<u>\$ 6.6</u>	\$ 49.4

(In millions)	For the three months ended March 31, 2006		
	Expenses before		
	inclusion of Stock	Stock Option	Expenses as
Expenses	Option Expense	Expense	Expenses as Reported
Research and development	\$ 30.1	S 2.0	S 32.1
Contract manufacturing	1.8	0.1	1.9
General and administrative	4.1	1.8	5.9
Total operating expenses	\$ 36.0	\$ 3.9	\$ 39.9

The increase in total Stock Option Expense in the first quarter of 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

Research and Development Expenses:

Research and development expenses increased to \$41.2 million in the first quarter of 2007 from \$32.1 million in the same period of 2006. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2007 and 2006:

(In millions) Three months ended March		rch 31,	
			Increase
Research and development expenses	2007	2006	(Decrease)
Payroll and benefits (1)	S 13.7	\$ 10.0	\$ 3.7
Clinical trial expenses	5.3	3.4	1.9
Clinical manufacturing costs (2)	10.5	9,3	1.2
Research and preclinical development costs	6.0	3.5	2.5
Occupancy and other operating costs	5.7	<u>5.9</u>	(0.2)
Total research and development	\$ 41.2	<u>\$ 32.1</u>	<u>\$ 9.1</u>

- (1) Includes \$3.1 million and \$1.6 million of Stock Option Expense for the three months ended March 31, 2007 and 2006, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.7 million and \$0.4 million of Stock Option Expense for the three months ended March 31, 2007 and 2006, respectively.

Payroll and benefits increased primarily due to higher Stock Option Expense, as described above, and higher compensation expense due, in part, to annual salary increases effective January 1, 2007. Clinical trial expenses increased due to higher VEGF Trap-Eye costs primarily related to our Phase 1 and 2 studies in wet AMD and higher IL-1 Trap costs. Clinical manufacturing costs increased due to higher costs related to manufacturing preclinical and clinical supplies of our first antibody drug candidate, which were partly offset by lower costs related to manufacturing VEGF Trap clinical supplies. Research and preclinical development costs increased primarily due to higher preclinical development costs related to our VEGF Trap and human monoclonal antibody programs.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased in the first quarter of 2007 compared to the same period of 2006 due to the expiration of our manufacturing agreement with Merck in October 2006.

General and Administrative Expenses:

General and administrative expenses increased to \$8.2 million in the first quarter of 2007 from \$5.9 million in the same period of 2006 primarily due to higher Stock Option Expense, as described above, higher compensation expense due, in part, to annual salary increases effective January 1, 2007, higher recruitment and related costs associated with expanding our headcount in 2007, and marketing research and related expenses incurred in 2007 in connection with our IL-1 Trap and VEGF Trap programs.

Other Income and Expense:

Investment income increased to \$6.7 million in the first quarter of 2007 from \$3.5 million in the same period of 2006 resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). Interest expense was \$3.0 million in the first quarter of 2007 and 2006. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, revenue earned under our past and

present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Bayer HealthCare, and Merck, and investment income.

Three Months Ended March 31, 2007 and 2006

At March 31, 2007, we had \$515.0 million in cash, cash equivalents, restricted cash, and marketable securities compared with \$522.9 million at December 31, 2006. In February 2007, we received a \$20.0 million non-refundable up-front payment in connection with our new non-exclusive license agreement with AstraZeneca.

Cash (Used in) Provided by Operations:

Net cash used in operations was \$9.2 million in the first quarter of 2007, compared to net cash provided by operations of \$5.3 million in the first quarter of 2006. Our net losses of \$29.9 million in the first quarter of 2007 and \$20.4 million in the first quarter of 2006 included \$6.6 million and \$4.1 million, respectively, of non-cash stock-based employee compensation costs, of which \$6.6 million and \$3.9 million, respectively, represented Stock Option Expense and, in the first quarter of 2006, \$0.2 million represented non-cash compensation expense from Restricted Stock awards. At March 31, 2007, accounts receivable balances increased by \$26.1 million, compared to end-of-year 2006, primarily due to a \$20.0 million non-refundable up-front payment which was receivable from Astellas in connection with our new non-exclusive license agreement (see "License Agreements" above). Also, our deferred revenue balances at March 31, 2007 increased by \$37.7 million, compared to end-of-year 2006, primarily due to the \$20.0 million up-front payments received or receivable from AstraZeneca and Astellas, as described above. These payments will be recognized as revenue ratably over approximately the first year of the respective agreements. At March 31, 2006, accounts receivable balances decreased by \$25.5 million, compared to end-of-year 2005, primarily due to the January 2006 receipt of a \$25.0 million up-front payment from sanofiaventis, which was receivable at December 31, 2005, in connection with an amendment to our collaboration agreement to include Japan. Also, our deferred revenue balances at March 31, 2006 decreased by \$4.8 million, compared to end-of-year 2005, due primarily to first quarter 2006 revenue recognition of \$3.1 million of deferred revenue related to up-front payments from sanofi-aventis. The majority of our cash expenditures in both the first quarter of 2007 and 2006 were to fund research and development, primarily related to our clinical programs.

Cash Used in Investing Activities:

Net cash used in investing activities was \$74.1 million in the first quarter of 2007 compared to \$10.9 million in the same period of 2006, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first quarter of 2007, purchases of marketable securities exceeded sales or maturities by \$72.9 million, whereas in the first quarter of 2006, purchases of marketable securities exceeded sales or maturities by \$10.2 million.

Cash Provided by Financing Activities:

Cash provided by financing activities decreased to \$2.0 million in the first quarter of 2007 from \$3.4 million in the same period in 2006 due to a decrease in issuances of Common Stock in connection with exercises of employee stock options.

License Agreements with AstraZeneca and Astellas:

Under these non-exclusive license agreements, AstraZeneca and Astellas each made a \$20.0 million non-refundable, up-front payment to us in February and April 2007, respectively. AstraZeneca and Astellas also will each make up to five additional annual payments of \$20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the first three additional payments or earlier if the technology does not meet minimum performance criteria.

Capital Expenditures:

Our additions to property, plant, and equipment totaled \$1.0 million and \$0.6 million for the first three months of 2007 and 2006, respectively. During the remainder of 2007, we expect to incur approximately \$15 million in capital expenditures primarily to support our manufacturing, development, and research activities.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55%-65% of our expenditures for 2007 will be directed toward the preclinical and clinical development of product candidates, including the IL-1 Trap, VEGF Trap, VEGF Trap-Eye and monoclonal antibodies; approximately 10%-15% of our expenditures for 2007 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2007 will be used for capital expenditures and general corporate purposes.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least early 2010, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. Other than the \$1.6 million letter of credit issued to our landlord in connection with our new operating lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of March 31, 2007, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

During the three months ended March 31, 2007, there were no changes to our critical accounting policies and significant judgments and estimates, as described in our Annual Report on Form 10-K for the year ended December 31, 2006.

Future Impact of Recently Issued Accounting Standards

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. (SFAS) 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We will be required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Our management is currently evaluating the potential impact of adopting SFAS 159 on our financial statements.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure

to interest rate changes. We estimated that a one percent change in interest rates would result in approximately a \$1.8 million and \$0.9 million change in the fair market value of our investment portfolio at March 31, 2007 and 2006, respectively. The increase in the impact of an interest rate change at March 31, 2007, compared to March 31, 2006, is due primarily to increases in our investment portfolio's balance and duration to maturity at the end of March 2007 versus the end of March 2006.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2006 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2007, we had a cumulative loss of \$717.5 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities. Until the expiration in October 2006 of our agreement with Merck, we received contract manufacturing revenue pursuant to that agreement. The expiration of that agreement has resulted in a significant loss of revenue to Regeneron.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least early 2010, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay

principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We intend to study our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and IL-1 Trap, in a wide variety of indications. We intend to study the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and the IL-1 Trap in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too

high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of the IL-1 Trap in different diseases after a Phase 2 trial using lower doses of the IL-1 Trap in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

The data from the Phase 3 clinical program for the IL-1 Trap in CAPS (Cryopyrin Associated Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of the IL-1 Trap.

The efficacy and safety data from the Phase 3 clinical program for the IL-1 Trap in CAPS may be inadequate to support approval for its commercialization in this indication. Moreover, if the safety data from the ongoing clinical trials testing the IL-1 Trap are not satisfactory, we may not proceed with the filing of a biological license application, or BLA, for the IL-1 Trap or we may be forced to delay the filing. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance.

Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for the IL-1 Trap, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize the IL-1 Trap profitably.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the IL-1 Trap in those countries.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These include side effects that we have not yet seen in our trials such as heart attack and stroke. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

It is possible that safety or tolerability concerns may arise as we continue to test the IL-1 Trap in patients with inflammatory diseases and disorders. Like cytokine antagonists such as Kineret® (Amgen Inc.), Enbrel® (Immunex Corporation), and Remicade® (Centocor, Inc.), the IL-1 Trap affects the immune defense system of the body by blocking some of its functions. Therefore, the IL-1 Trap may interfere with the body's ability to fight infections. Treatment with Kineret® (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious infections have been reported in patients taking the IL-1 Trap. One subject with adult Still's diseases in a study of the IL-1 Trap developed an infection in his elbow with mycobacterium intracellulare. The patient was on chronic glucocorticoid treatment for Still's disease. The infection occurred after an intraarticular glucocorticoid injection into the elbow and subsequent local exposure to a suspected source of mycobacteria. One patient with polymayalgia rheumatica in another study developed bronchitis/sinusitis, which resulted in hospitalization. One patient in an open-label study of the IL-1 Trap in CAPS developed sinusitis and streptococcus pneumoniae meningitis and subsequently died. In addition, patients given infusions of the IL-1 Trap have developed hypersensitivity reactions or infusion reactions. These

or other complications or side effects could impede or result in us abandoning the development of the IL-1 Trap.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date — in some cases even after pivotal clinical trials have been completed. Subjects who received IL-1 Trap in clinical trials have developed antibodies. It is possible that as we test the VEGF Trap and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap and VEGF Trap-Eye develop antibodies to these product candidates, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye in a Phase 1 Trial. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap-Eye, and IL-1 Trap, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex

legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our VelocImmune technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap or VEGF Trap-Eye or in a damage award.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or

commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2006, which report is included in this Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

If our collaboration with Bayer HealthCare for the VEGF Trap-Eye is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap-Eye in the time expected, or at all, would be harmed.

We rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, provide assistance with the enrollment and monitoring of clinical trials conducted outside the United States, obtaining regulatory approval outside the United States, and provide sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap-Eye development program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our

collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or

lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin® (Genentech), and their extensive, ongoing clinical development plan for Avastin® (Genentech) in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor for wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, ophthalmologists are using offlabel a third-party reformulated version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute recently has received funding for a Phase 3 trial to compare Lucentis® (Genentech) to Avastin® (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis® (Genentech) and the potential off-label use of Avastin® (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis®

(Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin® (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott Biotechnology Ltd.), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize the IL-1 Trap. This is one of the reasons we discontinued the development of the IL-1 Trap in adult rheumatoid arthritis. In addition, even if the IL-1 Trap is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over the IL-1 Trap, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. These drug candidates could offer competitive advantages over the IL-1 Trap. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize the IL-1 Trap. For example, we may find it difficult to enroll patients in clinical trials for the IL-1 Trap if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing the IL-1 Trap for the treatment of a spectrum of rare diseases associated with mutations in the CIAS1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize the IL-1 Trap in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We intend to file an application with the FDA seeking approval to market the IL-1 Trap for

the treatment of a spectrum of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize the IL-1 Trap. Physicians may not prescribe the IL-1 Trap and CAPS patients may not be able to afford the IL-1 Trap if third party payers do not agree to reimburse the cost of IL-1 Trap therapy and this would adversely affect our ability to commercialize the IL-1 Trap profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including the IL-1 Trap, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may

not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners:
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of April 12, 2007, our seven largest shareholders beneficially owned 44.1% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 12, 2007. As of April 12, 2007, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 4.4% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 12, 2007, holders of Class A Stock held 26.4% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 12, 2007:

- our current executive officers and directors beneficially owned 13.2% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2007, and 30.4% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2007; and
- our seven largest shareholders beneficially owned 44.1% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 12, 2007. In addition, these seven shareholders held 51.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of April 12, 2007.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;

- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

In addition, we have a Change in Control Severance Plan and our chief executive officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

Item 6. Exhibits

(a) Exhibits

Exh	ibit
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Number	Description
10.1*	 Non-Exclusive License and Material Transfer Agreement, dated as of March 30, 2007, by and between Astellas Pharma Inc. and Regeneron Pharmaceuticals, Inc.
12.1	 Statement re: computation of ratio of earnings to combined fixed charges.
31.1	— Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	— Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	— Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

* Portions of this document have been omitted and filed separately with the Commission pursuant to requests for confidential treatment pursuant to Rule 24b-2.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: May 4, 2007 By: /s/ Murray A. Goldberg

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

NON-EXCLUSIVE LICENSE AND MATERIAL TRANSFER AGREEMENT

This Non-Exclusive License and Material Transfer Agreement ("Agreement") is entered into with an effective date as of March 30, 2007 (the "Effective Date"), by and between Astellas Pharma Inc., a Japanese company with a principal place of business located at 2-3-11 Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan ("Company"), and Regeneron Pharmaceuticals, Inc. ("Regeneron"), a New York corporation, with a principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591-6707.

WITNESSETH

WHEREAS, Regeneron has developed antibody technology, including genetically modified mice and related know-how, useful to generate human monoclonal antibodies;

WHEREAS, Regeneron owns certain patents and patent applications covering its human antibody technology;

WHEREAS, Company desires to obtain certain non-exclusive licenses under Regeneron Technology (as defined below), including the right to commercialize Antibodies (as defined below) generated from the Mice (as defined below), on the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, Company and Regeneron agree as follows:

ARTICLE I DEFINITIONS

When used in this Agreement, each of the following terms shall have the meanings set forth in this Article I:

- 1.1 "Adjusted Annual Fee" shall mean twenty million United States dollars (US\$20,000,000) adjusted in accordance with the US CPI to reflect any increase in the US CPI from the month and year of the Transfer Date until the month and year of the most recently reported US CPI available on the fourth anniversary of the Transfer Date.
- 1.2 "Affiliate" shall mean, with respect to a Person, any Person that controls, is controlled by, or is under common control with such Person. For purposes of this Section 1.2, "control" shall refer to (a) in the case of a Person that is a corporate entity, direct or indirect ownership of fifty percent (50%) or more of the stock or shares having the right to vote for the election of a majority of the directors of such Person or (b) in the case of a Person that is an entity, whether or not he, she or it is a corporate entity, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of such Person, whether through the ownership of voting securities, by contract or otherwise.
- 1.3 "<u>Antibody</u>" shall mean any antibody, or any derivative, or fragment thereof, including any fusions comprising any such antibody, derivative or fragment, that has been Derived from Mice and/or Mice Materials pursuant to this Agreement and any composition or formulation that incorporates or includes any such antibody, derivative, fragment or fusion molecule.

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- 1.4 "Antibody Materials" shall mean **************
- 1.5 "Applicable Law" shall mean all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any court, tribunal, arbitrator, agency, commission, official or other instrumentality of (a) any government of any country, (b) a federal, state, province, county, city or other political subdivision thereof or (c) any supranational body.
 - 1.6 "Approved Third Party" shall mean a Third Party approved by Regeneron pursuant to Section 3.6.
 - 1.7 "Breeding Pair" shall mean one (1) male Mouse and one (1) female Mouse.
 - 1.8 "Company Know How" shall have the meaning set forth in Section 7.1(c).
- 1.9 "Company Patent Rights" shall mean all Patent Rights owned or Controlled by Company and/or its Affiliates, in each case, which claim any composition (or portion thereof) or use of the Antibody, Antibody Materials, Subject Products or Company Know-How.
 - 1.10 "Company Technology" shall mean Company Patent Rights and Company Know-How.
- 1.11 "Control" and cognates thereof shall mean the ability by a Person to grant (whether directly or through its Affiliates) the right to access or use, or to grant a licence or a sublicense to, or the right to disclose or transfer Regeneron Technology (including, without limitation, Mice), Company Technology or other intellectual property right, or Confidential Information, as the case may be, without violating the terms of any agreement or other arrangement with, or the rights of, any Third Party.
- 1.12 "<u>Derived</u>" and cognates thereof shall mean obtained, developed, acquired, made, invented, discovered, created, synthesized, designed, or otherwise generated or resulting from. For the avoidance of doubt, an antibody or antibody material shall not be deemed Derived from Mice if Company only uses Company Know-How (other than DNA or amino acid sequence information) to derive antibodies from sources other than Mice or Mice Materials.
 - 1.13 "Diagnostic Subject Product" shall mean each Subject Product approved and sold or offered for sale for diagnostic use.
- 1.14 "Distributor" shall mean a Third Party appointed to distribute, market and sell the Subject Products in a country or region other than the United States, Canada, France, Germany, Italy, Japan, Spain, or the United Kingdom, even if that Third Party is supplied Subject Products in unpackaged bulk form; provided that such Third Party does not make any royalty or other payment to Company or any of its Affiliates or Licensees with respect to the Subject Product or intellectual property rights outside of the amounts included in the calculation of Net Sales (other than a reasonable and customary up-front payment that is comparable to payments made by Company to a Distributor for the distribution of its other products in the applicable country or region).

- 1.15 "Exploit" means to make, have made, import, use, sell, or offer for sale, including to research, develop, register, modify, enhance, improve, manufacture, have manufactured, hold/keep (whether for disposal or otherwise), formulate, optimise, have used, export, transport, distribute, promote, market or have sold or otherwise dispose or offer to dispose of a product or process and "Exploitation" shall be construed accordingly.
- 1.16 "Launch" shall mean the first commercial sale of any Subject Product by Company or its Affiliate or Licensee to a Third Party in a given country.
- 1.17 "<u>Licensee</u>" shall mean any Third Party that licenses, either directly or through a sublicense, a Subject Product from Company or any of its Affiliates. For the avoidance of doubt, the term "Licensee" shall include any Third Party that licenses a Subject Product from a Licensee but shall not include a Distributor.
- - 1.19 "Mice Inventions" shall have the meaning set forth in Section 2.4.
 - 1.20 "Mice Materials" shall mean *********************, but excluding Antibodies and Antibody Materials.
- 1.21 "Net Sales" shall mean the gross amounts invoiced by Company, Company's Affiliates and/or Licensees on sales of Subject Products, less the following items:
 - (a) trade, cash and quantity discounts actually allowed and taken directly with respect to such sales;
 - (b) tariffs, duties, excises and sales taxes imposed upon and paid directly with respect to such sales (reduced by any refunds of such taxes deducted in the calculation of Net Sales for prior periods and, for the avoidance of doubt, no deduction shall be permitted for income or similar taxes);
 - amounts repaid or credited by reason of rejections, defects, recalls or returns or because of chargebacks, trial prescriptions or rebates;
 - (d) invoiced amounts that are written off as uncollectible in accordance with Company's accounting policies, as consistently applied over all products of Company, Company's Affiliates and/or Licensees (reduced by any collections of such amounts deducted in the calculation of Net Sales for prior periods); and

The deductions set forth in clauses (a), (b), (c), (d) and (e) above shall be determined in accordance with generally accepted accounting principles, as consistently applied by Company across all of its

products. The amounts set forth in clause (b) above shall only be deducted from gross invoiced sales to the extent included in gross invoiced sales.

Transfers of Subject Products among Company and Company's Affiliates and Licensees for the purpose of subsequent resale to Third Parties shall not be counted for purposes of calculating Net Sales; with respect to such transfers, the gross amounts invoiced in connection with the subsequent resale of such Subject Products by Company or its Affiliates or Licensees to Third Parties shall be included in the calculation of Net Sales.

For purposes of determining Net Sales, the Subject Product(s) shall be deemed to be sold when invoiced and a "sale" shall not include transfers or dispositions made without financial consideration for charitable, promotional, preclinical, clinical, regulatory or governmental purposes.

As used in this paragraph, "Combination Products" means Subject Products that contain an Antibody as an active ingredient together with one or more other active ingredients. With respect to Combination Products, the Net Sales used for the calculation of the royalties under Section 4.2 will be adjusted by multiplying actual Net Sales of such Combination Product by the fraction A / (A+B), where A is the standard sales price of the Subject Product, containing the same amount of Antibody as its sole active ingredient as does the Combination Product in question, in the given country, and B is the standard sales price of the ready-for-sale form of a product containing, as its sole active ingredient(s) the same amount of the other therapeutically active ingredient(s) that is contained in the Combination Product in question, in the given country. If, on a country-by-country basis, the therapeutically active ingredient(s) in the Combination Product other than the Subject Product are not sold separately in that country, Net Sales shall be adjusted by multiplying actual Net Sales of such Combination Product by the fraction A / C, where C is the standard sales price of the Combination Product in such country. If, on a country-by-country basis, neither the Subject Product nor the other active ingredient(s) of the Combination Product is sold separately in said country, Net Sales shall be determined between the Parties in good faith.

- 1.22 "Party" shall mean Regeneron or Company; "Parties" shall mean Regeneron and Company.
- 1.23 "Patent Rights" shall mean all patents and patent applications (including provisional patent applications and any continuations of any such patent applications, claims in continuations-in-part to the extent such claims are entirely supported by the specifications of any such patent applications, and any divisionals, provisionals or substitute applications with respect to any such patent applications), any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplemental patent certificate) of any such patent, and any confirmation patent, registration patent, patent of addition, or inventor's certificate based on or directed to the same invention as any such patent, and all patents and patent applications anywhere in the world that at any time, directly or indirectly, claim priority from, support a claim of priority of or contain substantially identical disclosure as any of the foregoing.
- 1.24 "Person" shall mean any natural person or any corporation, company, partnership, limited liability company, joint venture, firm or other entity, including without limitation a Party.

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- 1.25 "Progeny" shall mean any mice that are produced or developed by breeding or otherwise reproducing Mice.
- 1.26 "Regeneron Know-How" shall mean the trade secrets, unpatented technical information, specifications, protocols, and procedures described or referred to in Exhibit A and any unpatented Mice Inventions.
- 1.27 "Regeneron Patent Rights" shall mean all Patent Rights owned or Controlled by Regeneron and/or its Affiliates as at the Effective Date and, subject to Section 2.5, during the term of this Agreement, in each case, which claim the Mice, Mice Materials or Mice Inventions or the use of the Mice, Mice Materials or Mice Inventions to make Antibodies in general, including, without limitation, the Patent Rights that are listed in Exhibit B. For the avoidance of doubt, Regeneron Patent Rights shall not include (i) any Patent Rights claiming methods relating to Antibody or Antibody Material generation that are not directly related to the Mice or Mice Materials and (ii) any Patent Rights claiming the use of Mice or Mice Materials to make Antibodies against any specific target.
- 1.28 "Regeneron Technology" shall mean the Regeneron Know-How and Regeneron Patent Rights including with respect to any Mice Invention.
 - 1.29 "Royalty Term" shall have the meaning set forth in Section 4.3.
 - 1.30 "SEC" shall mean the United States Securities and Exchange Commission.
- 1.32 "Subject Product" shall mean any product (including, without limitation, any therapeutic or diagnostic for human or veterinary use) that contains as an ingredient or component an Antibody or Antibody Materials.
 - 1.33 "Therapeutic Subject Products" shall mean all Subject Products except for Diagnostic Subject Products.
 - 1.34 "Third Party" shall mean any Person other than Regeneron, Company, or their respective Affiliates.
- 1.36 "<u>US CPI</u>" shall mean the Consumer Price Index —Urban Wage Earners and Clerical Workers, U.S. City Average, All Items, 1982-1984 = 100, published by the United States Department of Labor, Bureau of Statistics (or its successor equivalent index) or such other index as may be mutually agreed upon by the Parties.
- 1.37 "Valid Claim" shall mean a claim which satisfies both of the conditions set forth in (i) and (ii) below: (i) the relevant claim is either (a) a claim of an issued and unexpired patent

which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through re-issue or disclaimer or otherwise or (b) a claim of a pending patent application which claim was filed in good faith and which has not been pending for more than seven (7) years and that has not been abandoned or finally rejected without the possibility of appeal or refilling, and (ii) the relevant claim would be infringed by a Third Party if such Third Party Exploits a Subject Product.

ARTICLE II LICENSE

- 2.1 <u>License Grant</u>. Subject to the terms of this Agreement, Regeneron on behalf of itself and its Affiliates hereby grants to Company a non-exclusive, worldwide license under the Regeneron Technology:
 - (a) to make Mice at the Site (but not to have Mice made other than by an Approved Third Party) (i) solely by means of breeding Mice with other Mice in accordance with the breeding practices outlined on Exhibit A as supplemented by disclosures made by Regeneron pursuant to Section 3.1 and Section 3.2 and (ii) as specifically set forth in the last sentence of Section 5.4;
 - (b) to use Mice at the Site (but not to have Mice used other than by an Approved Third Party) supplied by Regeneron or made by or for Company in accordance with (a) above to Derive Mice Materials for the purpose of making or having made Antibodies and/or Antibody Materials for internal research purposes, including for use in human clinical trials; and
 - (c) to use Mice Materials at the Site (but not to have Mice Materials used other than by an Approved Third Party) to Derive Antibodies and Antibody Materials.

As of the Effective Date, Regeneron has no Affiliates that Control any Regeneron Technology.

- 2.2 No Sublicense. Company shall not sublicense or otherwise transfer its rights (except as specifically provided in Sections 3.6 and 10.1) granted under Regeneron Technology; provided, however, that Company shall have the right to grant sublicenses under the licenses granted pursuant to Section 2.1 to its Affiliates; provided, further, that Company shall ensure that the terms of each such sublicense are consistent with the terms of this Agreement and that its Affiliates shall not commit any act (including any act of omission) which Company is prohibited from committing directly.
- 2.3 No Implied Licenses. The grant of the license to Company under Regeneron Technology set forth herein shall not constitute a grant of a license to Company under any Patent Rights or know-how other than the Regeneron Technology.
- 2.4 <u>Mice Inventions</u>. Company acknowledges and agrees that (a) the licenses granted to it pursuant to Section 2.1 permit Company (and Affiliates and Approved Third Parties) to use the Mice and Mice Materials solely for the purposes set forth therein, (b) neither Company nor any

of its Affiliates shall use the Mice or Mice Materials other than for the purposes set forth in Section 2.1, (c) Company has no right to use and shall not use the Mice or Mice Materials to discover, develop or otherwise make improvements that directly relate to the Mice or Mice Materials ("Mice Inventions") under such grants except for inventions made in the ordinary course of using the Mice and Mice Materials for the purpose of making (or having made) and using Antibodies and Antibody Materials under the grants in Sections 2.1(a) through (c). For the avoidance of doubt, Regeneron acknowledges that Mice Inventions shall not include Antibodies or Antibody Materials and general methods relating to the generation of antibodies or antibody materials. Without limiting any of Regeneron's rights under this Agreement or otherwise, should Company make any Mice Inventions, Company shall promptly disclose to Regeneron, in writing, any such Mice Inventions and shall, and hereby does, assign, for itself and on behalf of its Affiliates, to Regeneron all right, title, and interest it or they have in Mice Inventions without additional compensation. Company agrees, for itself and on behalf of its Affiliates, to execute any and all further instruments, forms of assignments and other documents, and to take such further actions as Regeneron may request, in order to transfer all of Company's (and/or its Affiliates) rights in the Mice Inventions. Without limiting the foregoing, Regeneron shall have the right to prepare, file and prosecute, in Regeneron's name as assignee, patent applications on all Mice Inventions.

2.5 New Regeneron Patent Rights.

2.6 <u>Prohibited Uses</u>. Notwithstanding Section 2.1, Company agrees, for itself and on behalf of its Affiliates, that it and they shall not Derive Mice, Mice Materials, Antibodies or Antibody Materials for any Third Party as a contractor or service provider of such Third Party.

ARTICLE III MATERIAL TRANSFER; OWNERSHIP OF MICE

- 3.1 <u>Technology Transfer</u>. Subject to Section 3.5, Regeneron shall transfer to Company the materials, including Regeneron Know-How and Mice, set forth on <u>Exhibit A</u>. Subject to Section 8.1, all such Regeneron Know-How and Mice listed in <u>Exhibit A</u> shall be considered Confidential Information. Other than the grant of license in Section 2.1, Regeneron retains all right, title and interest in and to the Regeneron Technology, Mice, and Mice Materials described in <u>Exhibit A</u>. Except as set forth in this Article III, Regeneron shall not have any obligation to provide to Company any trade secrets, know-how, information, specifications, protocols or procedures.

- 3.5 Ownership of Mice and Mice Materials; Assignment. Company agrees, for itself and on behalf of its Affiliates, that Regeneron retains all right, title and interest in the Mice and Mice Materials. Without limiting the foregoing, Company hereby assigns, for itself and on behalf of its Affiliates, to Regeneron any right, title and interest it or they may have in Progeny and Mice Materials. Company agrees, for itself and on behalf of its Affiliates, to execute any and all further instruments, forms of assignments and other documents, and to take such further actions as

Regeneron may reasonably request at Regeneron's cost, in order to transfer all of Company's (and/or its Affiliates) rights, if any, in Mice (including, without limitation, Progeny) and Mice Materials to Regeneron and on such transfer any such rights shall be included in Regeneron Technology and subject to the licenses granted pursuant to Section 2.1. During the term of this Agreement, it is agreed that (i) Company shall have the right to transfer the Mice and Mice Materials to Sites solely for purposes of this Agreement, and (ii) Company, its Affiliates and Approved Third Parties may use Mice (including, without limitation, Progeny) and Mice Materials only in the manner contemplated by Section 2.1.

3.6 Approved Third Party. Company may use Approved Third Party service providers (a) to have Mice made solely by means of breeding Mice with other Mice in accordance with the terms of the license grant in Section 2.1(a); and (b) to have Mice or Mice Materials made or used in accordance with the license grants in Sections 2.1(b) and 2.1(c), in each case, under the following conditions: (i) Regeneron shall within thirty (30) days of receiving written notice from the Company of the identity of the relevant Third Party and such other information as Regeneron may reasonably require to assess such appointment have notified Company in writing whether such Third Party is approved or not (such approval not to be unreasonably withheld or delayed); and (ii) such Third Party service provider shall have entered into a separate writing with Regeneron substantially in the form annexed hereto as Exhibit C. Company shall remain responsible for the performance of its Approved Third Party with the obligations of Company under this Agreement and shall ensure that any such Approved Third Party does not commit any act (including any act of omission) which Company is prohibited from committing directly and commits such acts as Company is obligated to hereunder.

ARTICLE IV PAYMENTS AND RECORDS

- 4.1 <u>Up-Front Fee/Annual Fees</u>. Company shall pay Regeneron a non-refundable amount of twenty million United States dollars (US\$20,000,000) within seven (7) days of the execution of this Agreement. In addition, Company shall pay Regeneron a non-refundable amount of twenty million United States dollars (US\$20,000,000) on each of the first, second, and third anniversaries of the Transfer Date. Company shall pay to Regeneron the Adjusted Annual Fee on each of the fourth and fifth anniversaries of the Transfer Date unless this Agreement shall have been terminated prior to the fourth anniversary of the Transfer Date in accordance with Section 9.2. All payments to be made pursuant to this Section 4.1 shall be made by bank wire transfer in immediately available funds to an account designated by Regeneron.
- 4.3 <u>Royalty Term</u>. The royalties payable under Section 4.2 shall be paid to Regeneron for the period of time, as determined on a Subject Product by Subject Product and country-by-country basis, commencing on the Effective Date and ending on the later of (a)

4.4 Reports. Company shall keep and maintain, and shall cause its Affiliates and Licensees to keep and maintain, records and books of account, in accordance with generally accepted accounting practices, detailing full written accountings of Net Sales of Subject Products subject to royalty obligations to Regeneron, and all other information necessary for the accurate determination of royalty payments (including, without limitation, currency conversion rate methodologies). Company shall deliver to Regeneron each calendar quarter commencing upon the first calendar quarter following the first sale of a Subject Product, a report detailing the information on which the royalty payments were calculated, including a breakdown of Net Sales of each Subject Product on a country-by-country basis, which report shall accompany the royalty due under Section 4.2. Furthermore, for each Subject Product, Company shall notify Regeneron in writing promptly following (a) the date on which Company first initiates a Phase 2 trial (as defined in 21 CFR 312.21(b), as amended from time to time) (or a Phase 3 trial (as defined in 21 CFR 312.21(c), as amended from time to time), if no Phase 2 trial is conducted) of a Subject Product, and (b) each receipt, on a country-by-country basis, by Company (or by any of its Affiliates or Licensees) of regulatory approval to market and sell Subject Products.

4.5 Records and Audits.

- (a) Company shall keep, and shall cause its Affiliates and Licensees to keep, complete and accurate records of the latest three (3) years relating to gross sales, Net Sales, and all information reasonably relevant under Sections 4.2 and 4.3. For the sole purpose of verifying amounts payable to Regeneron, Regeneron shall have the right, no more than once each calendar year, to review such records, through independent certified public accountants proposed by Regeneron and reasonably acceptable to Company (such consent not to be unreasonably withheld or delayed), upon fifteen (15) days' prior written notice. The accounting firm shall disclose to Regeneron and Company only whether the royalty reports are correct and details concerning any discrepancies, but no other information shall be disclosed to Regeneron.
- (b) If any review pursuant to Section 4.5(a) reflects an underpayment to Regeneron, such underpayment shall be promptly remitted to Regeneron, together with interest calculated in the manner provided in Section 4.8. If the underpayment is equal to or greater than five percent (5%) of the amount that was otherwise due for any calendar quarter, Regeneron shall be entitled to have Company pay all of the reasonable costs of

such review otherwise such costs will be paid by Regeneron. If the review reflects an overpayment by Company, then, at Company's option, such overpayment shall either be promptly refunded to Company by Regeneron or creditable against amounts payable by Company in subsequent payment periods.

- 4.6 United States Dollars (or U.S.dollars). All dollar (\$) amounts specified in this Agreement are United States (U.S.) dollar amounts.
- 4.7 <u>Currency Exchange</u>. With respect to sales of Subject Products invoiced in a currency other than U.S. dollars and other amounts received by Company, Company's Affiliates and/or Licensees in a currency other than U.S. dollars, such amounts shall be expressed in their local currency and in their U.S. dollar equivalents calculated using the exchange rate conversion methodology then in consistent use by Company throughout its business in accordance with generally accepted accounting principles and used in its preparation of the financial statements filed with the SEC (or similar regulatory agency in another country if no financial statements are filed with the SEC).
- 4.8 <u>Late Payments</u>. Company shall pay interest to Regeneron on the aggregate amount of any payments that are not paid on or before the date such payments are due under this Agreement at a rate per annum equal to the lesser of (a) ****** above LIBOR; or (b) the highest rate permitted by Applicable Law, calculated on the number of days such payments are received by Regeneron after the date such payments are due. In addition, Company shall reimburse Regeneron for all costs and expenses, including without limitation reasonable attorney fees and legal expenses, incurred in the collection of late payments. For the purposes of this Agreement, LIBOR shall mean the London Interbank Offered Rate as calculated by the British Bankers' Association or, if LIBOR ceases to be available, the base rate of a London bank selected by Regeneron.
- 4.9 No Set Off. Except as set forth in Section 4.10, (a) neither Party shall set off any of its obligations against or otherwise withhold from, any amount payable by it to the other Party hereunder without the other Party's prior written consent and (b) there shall be no deduction or withholding from the amounts payable hereunder.

4.10 <u>Taxes.</u>

(a) <u>General</u>. The royalties and other amounts payable by Company to Regeneron pursuant to this Agreement ("Payments") shall not be reduced on account of any taxes unless required by Applicable Law. Regeneron alone shall be responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be paid by Company) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Company shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Regeneron is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to Company or the appropriate governmental authority (with the assistance of Company to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Company of its

obligation to withhold tax, and Company shall apply the reduced rate of withholding, or dispense with withholding, as the case may be, provided that Company has received evidence, in a form satisfactory to Company, of Regeneron's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least fifteen (15) days prior to the time that the Payments are due. If, in accordance with the foregoing, Company withholds any amount, it shall pay to Regeneron the balance when due, make timely payment to the proper taxing authority of the withheld amount, and send to Regeneron proof of such payment within sixty (60) days following that payment.

- (b) <u>Indirect Taxes</u>. Notwithstanding anything contained in Section 4.10(a), this Section 4.10(b) shall apply with respect to value added taxes, sales taxes, consumption taxes and other similar taxes ("Indirect Taxes"). All Payments are exclusive of Indirect Taxes. If any Indirect Taxes are chargeable in respect of any Payments, Company shall pay such Indirect Taxes at the applicable rate in respect of any such Payments following the receipt, where applicable, of an Indirect Taxes invoice in the appropriate form issued by Regeneron in respect of those Payments, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate.
- (c) <u>Changes Following Assignment</u>. If following an assignment of this Agreement under Section 10.1 the treatment of any Payments or Indirect Taxes for either Party is affected by the assignment, then the Parties shall use their best efforts to promptly negotiate a provision in replacement of the affected sections of this Agreement that is consistent with and achieves as nearly as possible the original treatment of such Payments and Indirect Taxes immediately prior to any such assignment.

ARTICLE V REPRESENTATIONS AND WARRANTIES; COVENANTS

- 5.1 Representations and Warranties of Company. Company represents and warrants as follows:
 - (a) Company is validly incorporated under the laws of Japan;
 - (b) Company has the corporate and legal right, authority and power to enter into this Agreement and to perform its obligations hereunder:
 - (c) Company has taken all necessary action to authorize the execution, delivery and performance of this Agreement;
 - (d) upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Company, enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law); and

- (e) the performance of Company's obligations under this Agreement will not conflict with its charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a party.
- 5.2 Representations and Warranties of Regeneron. Regeneron represents and warrants to Company that, subject to the terms of Schedule 5.2,
 - (a) Regeneron is a corporation duly organized, validly existing and in good standing under the laws of the State of New York, United States of America;
 - (b) Regeneron has the corporate and legal right, authority and power to enter into this Agreement and to perform its obligations hereunder;
 - (c) Regeneron has taken all necessary action to authorize the execution, delivery and performance of this Agreement;
 - (d) upon the execution and delivery of this Agreement, this Agreement shall constitute a valid and binding obligation of Regeneron, enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' and contracting parties' rights generally and except as enforceability may be subject to general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);
 - (e) the performance of Regeneron's obligations under this Agreement will not conflict with its charter documents or result in a breach of any agreements, contracts or other arrangements to which it is a party;
 - (f) Regeneron has the right to grant the licenses granted to Company on the terms set forth herein;
 - (g) as of the Effective Date and with no further duty to update (except pursuant to Section 7.3), (i) there is no pending litigation that alleges that any of Regeneron's activities directly relating to the Regeneron Technology, Mice, or Mice Materials have violated, or would violate, any of the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation); and (ii) to its knowledge, no litigation has been otherwise threatened which alleges that any of its activities directly relating to the Regeneron Technology, Mice, or Mice Materials have violated or would violate, any of the intellectual property rights of any Third Party;
 - (h) Regeneron has disclosed or made available to Company all the Regeneron Technology needed for Company to make and use "VelocImmune 2" Mice pursuant to Section 2.1 (a) and (b) of this Agreement;

- (j) to its knowledge, the issued patents included in the Regeneron Technology existing at the Effective Date are not invalid or unenforceable in whole or part;
- (k) to its knowledge, the development or reproduction of the Mice or the conception, development and reduction to practice of the Regeneron Technology existing as of the Effective Date has not constituted or involved the misappropriation of trade secrets or other rights of any Person; and
 - (1) to its knowledge, the Know-How listed or referred to in Exhibit A is sufficient to establish a colony of Mice.

For purposes hereof, "to its knowledge" shall mean actual knowledge with no duty of inquiry or investigation

- 5.3 <u>Disclaimer of Warranty</u>. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, ALL REGENERON TECHNOLOGY AND MICE ARE PROVIDED TO COMPANY (a) "AS IS" AND WITHOUT ANY WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY, TITLE OR FITNESS FOR A PARTICULAR PURPOSE AND (b) WITHOUT ANY REPRESENTATION OR WARRANTY THAT THE USE OF REGENERON TECHNOLOGY OR MICE WILL NOT INFRINGE ANY THIRD PARTY'S PATENT OR OTHER RIGHT.
 - 5.4 Covenants. Company agrees, for itself and on behalf of its Affiliates, that it and they:
 - (a) will abide by all industry accepted guidelines applicable to the use, handling and disposal of genetically modified animals and comply in all material respects with all Applicable Laws which relate to the use of the Mice and Mice Materials;
 - (b) will use diligent efforts to ensure that the Mice do not come into contact with any mice other than Mice; and in particular will not intentionally or recklessly breed Mice with any mice other than Mice, except as specifically set forth in the last sentence of this Section 5.4;
 - (c) will not make any heritable genetic modifications to the Mice;
 - (d) will not Derive embryonic or other stem cells from the Mice or other Mice Material that could be used to make Mice;
 - (e) will not use Mice or Mice Materials to directly manufacture or produce Subject Products for sale. For the avoidance of doubt, Regeneron acknowledges that Company may (i) isolate cDNA from Mice which code for a given antibody (the "Isolated Mice Sequences"), (ii) modify DNA sequences of cell lines derived from sources other than the Mice and mice to incorporate the Isolated Mice Sequence or modifications

thereof, and (iii) manufacture Subject Products for sale using such modified cell lines or using other Antibody Materials and such use shall not constitute a breach of Section 5.4(e);

(f) will not use Mice Materials to create Mice, mice or any transgenic animals; and

(g) will ensure that all Mice (including Progeny) and Mice Material supplied to it or Derived under this Agreement remain in the possession of Company, its Affiliates or Approved Third Parties.

ARTICLE VI INDEMNIFICATION

6.1 Indemnification by Company. Company agrees to indemnify and hold harmless Regeneron and Regeneron's Affiliates and their respective shareholders, directors, officers, employees and agents ("Regeneron Indemnitees") from and against any liabilities, losses, costs, damages, fees or expenses arising out of any Third Party claim relating to (a) any breach by Company or any of its Affiliates or Approved Third Parties of any of its representations, warranties or obligations pursuant to this Agreement (or, in the case of the Approved Third Party, the letter agreement with Regeneron in the form annexed hereto as Exhibit C), (b) any product liability, personal injury, property damage or other damage resulting from the testing, manufacture, use, offer for sale, sale or importation of Antibodies, Antibody Materials, or Subject Products, or (c) infringement or misappropriation of any patent or other intellectual property rights of any Third Party (other than Third Party patents specifically covering Regeneron Technology, such patents being referred to as "Regeneron Technology Blocking Patents") resulting from the manufacture, use, offer for sale, sale or importation of Antibodies, Antibody Materials, or Subject Products, by Company or Company's Affiliates, Licensees, Distributors, Approved Third Parties or contract manufacturers, provided, however, that Company shall not be obligated to indemnify or hold harmless Regeneron Indemnitees from any such liabilities, losses, costs, damages, fees or expenses to the extent that (i) such liabilities, losses, costs, damages, fees or expenses have resulted from the grossly negligent (or more culpable) act or omission of a Regeneron Indemnitee or (ii) Regeneron has an obligation to indemnify any Company Indemnitee pursuant to Section 6.2 in respect of such liabilities, losses, costs, damages, fees or expenses.

6.2 <u>Indemnification by Regeneron</u>. Regeneron agrees to indemnify and hold harmless Company and Company's Affiliates, Approved Third Parties, Company's contract manufacturers of Subject Products, Distributors, and Licensees, and their respective shareholders, directors, officers, employees and agents ("Company Indemnitees") from and against any liabilities, losses, costs, damages, fees or expenses arising out of any Third Party claim relating to any breach by Regeneron of any of its representations, warranties or obligations pursuant to this Agreement; provided, however, that Regeneron shall not be obligated to indemnify or hold harmless Company Indemnitees from any such liabilities, losses, costs, damages, fees or expenses to the extent that such liabilities, losses, costs, damages, fees or expenses have resulted from the grossly negligent (or more culpable) act or omission of a Company Indemnitee.

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6.3 Claims for Indemnification. A Person entitled to indemnification under this Article VI (an "Indemnified Party") shall give prompt written notification to the Person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third-Party claim as provided in this Section 6.3 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and only to the extent that such Indemnifying Party is actually damaged as a result of such failure to give notice). Within thirty (30) days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense and, without limiting the Indemnifying Party's indemnification obligations, the Indemnifying Party shall reimburse the Indemnified Party for all reasonable and verifiable out-of-pocket costs, including attorney fees, incurred by the Indemnified Party in defending itself within sixty (60) days after receipt of any invoice therefor from the Indemnified Party. The Party not controlling such defense may participate therein at its own expense; provided that, if the Indemnifying Party assumes control of such defense and the Indemnified Party in good faith concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable and verifiable fees and expenses of counsel to the Indemnified Party in connection therewith. The Party controlling such defense shall keep the other Party advised of the status of such action, suit. proceeding or claim and the defense thereof and shall consider recommendations made by the other Party with respect thereto. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, delayed or conditioned. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof without the prior written consent of the Indemnified Party, which shall not be unreasonably withheld, delayed or conditioned.

ARTICLE VII INTELLECTUAL PROPERTY PROTECTION AND RELATED MATTERS

7.1 Ownership of Intellectual Property.

(a) Subject to the license grants to Company under Section 2.1 and the ownership and assignment provisions in Section 2.4 and Section 3.5, as between the Parties, each Party shall own and retain all right, title and interest in and to any and all information, improvements and inventions that are conceived, discovered, developed or otherwise made, as necessary to establish authorship, inventorship or ownership, by or on behalf of such Party (or its Affiliates or its licensees (excluding, in the case of Regeneron, Company, its Affiliates and Licensees) under or in connection with this Agreement, whether or not patented or patentable, and any and all Patent Rights and intellectual property rights with respect thereto. Determination of authorship, inventorship or ownership shall be made in accordance with applicable United States law.

- (b) Except as specifically set forth herein, Regeneron and Regeneron's Affiliates shall retain all right, title and interest in and to all Regeneron Technology.
- (c) Company and Company's Affiliates shall retain all right, title and interest in and to (i) all Antibodies, Antibody Materials and Subject Products and (ii) subject to Section 2.4, Section 3.5, and Article VIII, all results, technical information, inventions, materials and data, and any intellectual property rights therein, or otherwise resulting from Company's or Company's Affiliates use of (A) the Mice, Mice Materials and other Regeneron Technology in accordance with this Agreement, or (B) Antibodies, Antibody Materials and Subject Products ("Company Know-How").

7.2 Prosecution of Patent Rights.

- (b) Company shall have the right and option (but not the obligation) to file and prosecute any patent applications and to maintain any patents within the Company Patent Rights in Company's name, and to control any interferences, reissue proceedings and re-examinations relating thereto.
- 7.3 Infringement. Company shall promptly report in writing to Regeneron during the term of this Agreement any (a) known or suspected infringement of any of the Regeneron Patent Rights, or (b) unauthorized use of any of the Regeneron Know-How of which the Company becomes aware. In the event that either Party or any of its Affiliates shall receive written notice from a Third Party claiming that the Mice, Mice Materials or Regeneron Technology infringes or otherwise violates the intellectual property rights of such Third Party, then such Party shall promptly notify the other Party in writing of this notice of infringement. Regeneron shall promptly report to Company the initiation of any formal legal proceedings during the term of this Agreement claiming the infringement of or unauthorized use of any Regeneron Patent Rights or Regeneron Know-How.
- 7.4 <u>Enforcement</u>. Regeneron shall have the sole right to initiate a suit or take other appropriate action that it believes is reasonably required to protect Regeneron Patent Rights from any known or suspected infringement or to prevent the unauthorised use or disclosure of Regeneron Know-How. Company shall have the sole right to initiate a suit or take other appropriate action that it believes is reasonably required to protect Company Patent Rights from any known or suspected infringement or to prevent the unauthorised use or disclosure of any Company Know-How.

- 7.5 <u>Defense</u>. In the event that a Third Party asserts, as a defense or as a counterclaim in any infringement action under Section 7.4 or in a declaratory judgment action or similar action or claim filed by such Third Party, that Regeneron Patent Rights are invalid or unenforceable, Regeneron shall have the sole right, but not the obligation, through counsel of its choosing, to respond to such defense or defend against such counterclaim, action or claim (as applicable), including the right to settle or otherwise compromise such claim.
- 7.6 <u>Third Party Litigation</u>. Notwithstanding Section 7.4 or Section 7.5, in the event of any actual or threatened suit against Company, or its Affiliates, Licensees, distributors or customers alleging that the use of Regeneron Technology, the Mice, Mice Materials, Antibodies or Antibody Materials or the Exploitation of Subject Products by or on behalf of Company under this Agreement infringes the Patent Rights or other intellectual property rights of any Person (an "Infringement Suit"), Company shall be solely responsible for assuming direction and control of the defense of claims arising therefrom (including the right to settle such claims at its sole discretion), unless Company is seeking indemnification under the terms of Section 6.2.
- 7.7 <u>Co-operation</u>. Each Party shall provide to the other all reasonable assistance requested by the other Party (and at the other Party's reasonable expense) in connection with any action claim or suit under this Article VII, including allowing access to the other Party's files and documents and to such other Party's personnel who may have possession of relevant information.

7.8 Recoveries.

- (a) With respect to any suit or action to protect Regeneron Technology brought or taken by Regeneron, Regeneron shall retain one hundred percent (100%) of any recovery obtained by it as a result of any suit or action to protect Regeneron Technology.

ARTICLE VIII CONFIDENTIALITY

8.1 <u>Definition of Confidential Information</u>. Subject to the last paragraph in this Section 8.1, Confidential Information includes all information, data and know-how disclosed by either Party or its Affiliates (the "Disclosing Party") to the other Party or its Affiliates (the "Receiving Party") hereunder, whether orally or as embodied in tangible materials, including research, inventions, discoveries, writings, drawings, graphs, charts, photographs, recordings, designs, plans, processes, models, technical information, facilities, methods, assays, data, chemical formulas, compositions, compounds, instrumentation, trade secrets, copyrights, systems, patents, patent applications, procedures, manuals, specifications, prototypes, samples, structures, models,

any other intellectual property, and confidential reports. Notwithstanding the foregoing, Confidential Information shall not include information which the Receiving Party can demonstrate is:

- (a) already in the possession of the Receiving Party, without obligation of confidentiality, at or before the time of disclosure hereunder as shown by the Receiving Party's files existing at the time of disclosure; or
- (b) now or hereafter becomes publicly known through no wrongful act of the Receiving Party (provided that if Confidential Information becomes publicly known this shall not excuse a prior disclosure by the Receiving Party); or
 - (c) lawfully received by the Receiving Party from a Third Party not under an obligation of confidence to the Disclosing Party; or
 - (d) developed by the Receiving Party independent of the Confidential Information received hereunder; or
 - (e) approved for release by written authorization of the Disclosing Party.

Specific aspects or details of Confidential Information will not be deemed to be within the public knowledge or in the prior possession of a Person merely because such aspects or details of the Confidential Information are embraced by general disclosures in the public domain. In addition, any combination of Confidential Information will not be considered in the public knowledge or in the prior possession of either Person merely because individual elements thereof are in the public domain or in the prior possession of a Person unless (i) the combination and its principles are in the public knowledge or in the prior possession of that Person and (ii) the combination is documented, in a single contemporaneous document, as in the public knowledge or in the prior possession of a Person.

Notwithstanding anything to the contrary in this Section 8.1, Company's Confidential Information shall be limited to (i) confidential information in the reports delivered to Company in accordance with Section 4.4, (ii) confidential information discovered by Regeneron during any Site visit in accordance with Section 3.2, (iii) confidential information discovered by Regeneron during any audit conducted pursuant to Section 4.5, (iv) confidential information provided to Regeneron in connection with any claim for indemnification under ARTICLE VI, (v) confidential information provided to Regeneron pursuant to Section 7.7, (vi) confidential information related to Approved Third Parties disclosed to Regeneron pursuant to Section 3.6, and (vii) information disclosed by prior mutual agreement specifically certified by Company as being confidential prior to its disclosure, in each case, unless such information falls under the exceptions described in clause (a), (b), (c), (d), or (e) above in this Section 8.1. All other information, data or know-how disclosed by Company or its Affiliates hereunder shall be non-confidential and shall not be subject to the confidentiality obligations and restrictions on use in this Article VIII.

8.2 <u>Confidentiality and Non-Use Obligations</u>. Each Party agrees, subject to Section 8.4, that it will hold in strict confidence and not disclose, disseminate or distribute to any Third Party Confidential Information received from the Disclosing Party and use such Confidential

Information for no purpose other than those contemplated by this Agreement. Each Party agrees that access to Confidential Information will be limited to its Affiliates, Licensees and its Approved Third Parties (in each case, which are bound by the confidentiality obligations herein), as well as such Party's and its Affiliates', Licensees' and Approved Third Parties' employees (including temporary staff), agents, or other authorized representatives who: (a) need to know such Confidential Information in connection with their work and (b) have signed agreements obligating them to maintain the confidentiality of the Confidential Information, provided that each Party shall remain responsible for any failure by its Affiliates, Licensees and Approved Third Parties and their respective employees (including temporary staff), consultants, advisors, to treat such information and materials as Confidential Information. Each Party further agrees to inform such employees (including temporary staff), agents or authorized representatives of the confidential nature of Confidential Information received from the Disclosing Party and agrees to take all necessary steps to ensure that the terms of this Agreement are not violated by them.

- 8.3 Loss of Confidential Information. Each Party shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information received from the Disclosing Party and shall exert at least the same degree of care as it uses to protect its own Confidential Information. Each Party shall immediately notify the other in the event of any actual or suspected loss or unauthorized disclosure of that Party's Confidential Information. Each Party will take all reasonable further steps requested by the other Party to prevent, control or remedy such violation.
 - 8.4 Permitted Disclosure. Each Party may disclose Confidential Information to the extent that such disclosure is:
 - (a) made in response to a valid order of a court of competent jurisdiction or other competent authority; provided, however, that the Receiving Party shall first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash any such order or obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or authority or, if disclosed, be used only for the purpose for which the order was issued; and provided further that if such order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be limited to that information that is legally required to be disclosed in response to such court or governmental order.
 - (b) otherwise required by Applicable Law or the requirements of a national securities exchange or another similar regulatory body; provided, however, that the Receiving Party shall (i) provide the Disclosing Party with reasonable advance notice of and an opportunity to comment on any such required disclosure, (ii) if requested by the Disclosing Party, seek confidential treatment with respect to any such disclosure to the extent available, and (iii) consider in good faith the comments of the Disclosing Party in any such disclosure or request for confidential treatment; or
 - (c) made by Company, its Affiliates or Licensees to a regulatory authority in connection with any filing, application or request for any approval, license, registration or authorization relating to a Subject Product; provided, however, that Company will (i)

provide Regeneron with reasonable advance notice of and an opportunity to comment on any such required disclosure, (ii) seek confidential treatment with respect to any such disclosure to the extent available, and (iii) consider in good faith the comments of Regeneron in any such disclosure or request for confidential treatment;

- 8.5 <u>Return of Confidential Information</u>. Confidential Information disclosed by the Disclosing Party, including permitted copies, shall remain the property of the Disclosing Party. Subject to Section 8.6, upon termination or expiration of this Agreement, or upon written request of the Disclosing Party, the Receiving Party shall promptly return to the Disclosing Party or, at the Disclosing Party's request, destroy, all documents or other tangible materials representing the Disclosing Party's Confidential Information (or any designated portion thereof); provided that one (1) copy may be maintained in the confidential files of the Receiving Party for the purpose of complying with the terms of this Agreement. An officer of the Receiving Party also shall certify in writing that it has satisfied its obligations under this Section 8.5 within ten (10) days of a written request by the Disclosing Party.
- 8.6 <u>Retention of Confidential Information by Company</u>. Section 8.5 shall not apply to Regeneron Confidential Information during the term of this Agreement or on the expiry or termination of this Agreement if and to the extent that Company's rights under the Regeneron Technology survive such termination or expiry pursuant to Section 9.4.
- 8.7 <u>Publicity</u>. During the term of this Agreement, the content of any press release or public disclosure relating to this Agreement shall be mutually agreed by the Parties, which agreement shall not be unreasonably withheld, delayed or conditioned, except that a Party may, without the other Party's agreement, (a) issue such press release or make such public disclosure if the contents of such press release or public disclosure have previously been made public other than through a breach of this Agreement by the issuing Party or (b) subject to Section 8.4 issue such press release or make such public disclosure if such press release or public disclosure is required by Applicable Law, regulation or legal process, including without limitation by the rules or regulations of the SEC (or similar regulatory agency in a country other than the United States) or of any stock exchange or other securities trading institution. It is the intent of the Parties to issue one press release announcing the execution of this Agreement. In any press releases issued by Company regarding the discovery, development or approval of a Subject Product, Antibody or Antibody Materials, Company shall include a statement regarding the role of Regeneron Technology and Mice, which statement shall be reasonably acceptable to Regeneron. The Parties shall issue a joint press release on the Effective Date with respect to the execution of this Agreement in the form annexed hereto as Exhibit D.

8.8 Disclosure of Provisions of Agreement.

(a) Subject to Sections 8.7 and 8.8(b), each Party agrees to hold as confidential the terms of this Agreement that have not been disclosed publicly except that (i) each Party shall have the right to disclose such terms to investors, potential investors, lenders, potential lenders, acquirers, potential acquirers, investment bankers and other Third Parties in connection with financing and acquisition activities, provided that any such Third Party has entered into a written obligation with the disclosing Party to treat such information and materials as confidential which is at least as stringent as the conditions

imposed by this Agreement and (ii) each Party shall have the right to disclose such terms as required by applicable law, regulation or legal process, including without limitation by the rules or regulations of the SEC (or similar regulatory agency in a country other than the United States) or of any stock exchange or other securities trading institution.

- (b) In the event that this Agreement shall be included in any report, statement or other document filed by either Party or an Affiliate of either Party with the SEC or similar regulatory agency in a country other than the United States or any stock exchange or other securities trading institution, such Party shall consider in good faith any requests for confidential treatment as may be reasonably requested by the other Party.
- 8.9 <u>Approvals</u>. Each Party shall submit any press release or any disclosure requiring the other Party's approval pursuant to this Article VIII to the other Party, and the Party receiving such request shall have three (3) business days to review and approve any such press release or disclosure, which approval shall not be unreasonably withheld. If the Party receiving such request does not respond in writing within such three (3) business day period, the press release or disclosure shall be deemed approved. In addition, if a public disclosure is required by law, rule or regulation, including without limitation in a filing with the Securities and Exchange Commission, the disclosing Party shall provide copies of the disclosure reasonably in advance of such filing or other disclosure for the non-disclosing Party's prior review and comment, which comments shall be considered in good faith by the disclosing Party.
- 8.10 <u>Term</u>. All obligations of confidentiality imposed under this Article VIII shall only survive the expiration or early termination of this Agreement for a period of seven (7) years.

ARTICLE IX TERM AND TERMINATION

9.1 <u>Term</u>. The term of this Agreement shall commence on the Effective Date and, subject to the last sentence of Section 9.2 (d), shall expire on the sixth anniversary of the Transfer Date unless earlier terminated under the terms of this Agreement. For the avoidance of doubt, Company shall have the right but not the obligation to terminate this Agreement without cause upon written notice prior to the fourth anniversary of the Transfer Date in accordance with Section 9.2(a).

9.2 Termination.

(a) <u>Convenience</u>. Company may elect to terminate this Agreement at any time by providing ninety (90) days' prior written notice to Regeneron. If such notice is sent with an effective date of termination prior to the fourth anniversary of the Transfer Date, such notice shall be accompanied (or preceded) by the payment of all sums which were not previously paid and which have become or would have become due and payable pursuant to the first or second sentence of Section 4.1 but for the termination under this Section

- 9.2(a). For example, if the Transfer Date is April 30, 2007 and Company pays to Regeneron twenty million United States dollars (US\$20,000,000) on April 30, 2007 and on July 15, 2007 delivers a notice of termination with an effective date of termination on October 15, 2007, Company would be obligated to pay to Regeneron on July 15, 2007 sixty million United States dollars (US\$60,000,000) representing twenty million United States dollars (US\$20,000,000) that would have otherwise been payable on April 30, 2008, plus twenty million United States dollars (US\$20,000,000) that would have otherwise been payable on April 30, 2010. However, for example, if the Transfer Date is April 30, 2007 and Company has paid all amounts previously due and payable under Section 4.1 and on July 15, 2010 delivers a notice of termination with an effective date of termination on October 15, 2010, Company would not be obligated to pay to Regeneron any further sums pursuant to Section 4.1. If such notice of termination under this Section 9.2(a) is sent with an effective termination date on or after the fourth anniversary of the Transfer Date, such notice shall be accompanied (or preceded) by the payment of all sums which were not previously paid and which have become or would have become due and payable pursuant to the first, second, or third sentence of Section 4.1 but for the termination under this Section 9.2(a). For example, if the Transfer Date is April 30, 2007 (and Company has paid all amounts previously due and payable under Section 4.1) and on June 20, 2011 Company delivers a notice of termination with an effective date of termination on September 20, 2011, Company would be obligated to pay Regeneron on June 20, 2011 twenty million United States dollars
- (b) <u>Breach</u>. Either Party shall have the right (but not the obligation) to terminate this Agreement upon written notice to the other Party if the other Party materially breaches or defaults in the performance of any of the provisions of this Agreement; provided that such material breach or default has not been cured (if capable of being cured) within sixty (60) days after the giving of notice by the first Party specifying such breach or default. For purposes of this Section 9.2(b), the term "material breach" shall mean a breach or default in performance hereunder by a Party that substantially undermines the contractual rights, protections or benefits of the non-breaching Party under this Agreement.
- (c) <u>Technical Event</u>. Company may terminate this Agreement upon providing thirty (30) days prior written notice to Regeneron together with adequate written records to document its claim of the occurrence of a Technical Event. Such records shall be subject to review by an independent Third Party expert designated by Regeneron within ten (10) business days of receipt of the written notice of termination and approved by Company, such approval not to be unreasonably withheld or delayed. Such expert shall review such written records and promptly determine whether or not a Technical Event has occurred. The expert's decision shall be final and binding upon the Parties as to this issue. Following the provision of any such notice of termination all obligations to make payments due under this Agreement by the Company to Regeneron shall be suspended from the date of such notice until the date of the publication of the expert's determination. Any notice of

termination shall be deemed effective from the date of the	e notice of termination in the event that the expert determines that a Technica	al Event
has occurred. As used above, the term "Technical Event"	" shall mean, *****************************.	

9.3 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Regeneron are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States (hereinafter "IP"). The Parties agree that Company, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any other provisions of Applicable Law outside the United States that provide similar protection for IP. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Regeneron under the U.S. Bankruptcy Code or analogous provisions of Applicable Law outside the United States, Company shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such IP and all embodiments of such IP, which, if not already in Company's possession, shall be promptly delivered to it upon Company's written request therefor.

9.4 Effects of Termination.

(a) <u>Termination or Expiration of License</u>. Except as set forth below in this Section 9.4, upon expiration or termination of this Agreement, the licenses granted by Regeneron to Company under Section 2.1 shall terminate and revert to Regeneron as of the effective date of such expiration or termination. Subject to the terms of the last sentence of Section 9.4(c), upon termination of this Agreement for any reason, Company may continue to use and Exploit any Antibodies, Antibody Materials and Subject Products generated pursuant to this Agreement and Company shall pay royalties during the Royalty Term in accordance with Article IV. Upon termination of this Agreement by Company in accordance with Section 9.2(b), 9.2(c), or 9.2(d), Company shall not be required to make any further payments to Regeneron under Section 4.1, except that neither Party shall be relieved of any obligations arising prior to such termination, including any payment obligations which arose and are due with respect to any period prior to such termination. Upon termination of this Agreement by Regeneron in accordance with Section 9.2(b), (i) in addition to any other amounts payable by Company to Regeneron under this Agreement, under law or pursuant to any contractual remedies available to Regeneron (but giving full allowance in due course for any sums paid hereunder), Company shall pay the amounts otherwise payable by Company under Section 9.2(a) as if Company had terminated this Agreement for convenience, and (ii) Regeneron may seek equitable remedies from a court of competent jurisdiction, including, if appropriate, destruction of Antibodies and Antibody Materials.

(b) <u>Discontinuation of Use; Return of Material</u>. Upon expiration of the term of the Agreement or earlier termination of this Agreement, Company (and its Affiliates and, if applicable, Approved Third Parties) will discontinue use of Regeneron's Confidential Information as of the effective date of such expiration or termination, except to the extent

that such use of such Confidential Information is reasonably necessary for the Company to continue to use and Exploit all Antibodies and Antibody Materials generated using the Mice and Mice Materials prior to the date of expiration or termination, subject to Company's obligations to pay royalties to Regeneron during the Royalty Term pursuant to Article IV, and if requested by Regeneron will return Regeneron's Confidential Information to which Company does not retain any rights hereunder in accordance with Section 8.5.

- 9.5 <u>Survival</u>. The expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination. The second and third sentences of Section 3.1, Section 3.5, Article IV (to the extent applicable, including without limitation, Section 4.2 during the Royalty Term), Section 5.3, Article VI, Section 7.1, Article VIII, subject to Section 8.10, Article IX and Article X, together with any relevant defined terms, shall survive any termination or expiration of this Agreement.

ARTICLE X MISCELLANEOUS

10.1. <u>Assignment</u>; <u>Successors and Assigns</u>. (a) Company may not assign its rights or delegate its obligations under this Agreement in whole or in part without the prior written consent

of Regeneron, except that Company shall have the right, without such consent, (i) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, or (ii) on written notice to Regeneron, to assign all its rights and obligations under this Agreement to any successor in interest in connection with a merger, consolidation or sale of all or substantially all of the assets of Company; provided, that Company's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction. Company absolutely, unconditionally and irrevocably guarantees to Regeneron prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement. (b) Regeneron may not assign its rights or delegate its obligations under this Agreement in whole or in part without the prior written consent of Company, except that Regeneron shall have the right, without such consent, (i) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, or (ii) on written notice to Company, to assign all its rights and obligations under this Agreement (A) to any of its Affiliates that has the resources to meet Regeneron's obligations under this Agreement, or (B) to a successor in interest in connection with (1) a merger, consolidation or sale of all or substantially all of the assets of Regneron, or (2) the sale or license of all or substantially all of the assets of Regeneron related to the Regeneron Technology; provided that Regeneron's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction. Regeneron absolutely, unconditionally and irrevocably guarantees to Company prompt performance when due and at all times thereafter of the responsibilities, liabilities, covenants, warranties, agreements and undertakings of its Affiliates pursuant to this Agreement, (c) Any purported assignment in violation of this Section 10.1 shall be void ab initio. Without limiting the foregoing, neither Party shall cause or permit any of its Affiliates to commit any act (including any act of omission) which such Party is prohibited hereunder from committing directly. No assignment of this Agreement shall be made in bad faith to limit or restrict the contractual rights and benefits of the other Party under this Agreement.

10.2. Notices.

Notices to Company shall be addressed to:

With a copy to: Vice President, Molecular Medicine Research Labs, Drug Discovery Research

Notices to Regeneron shall be addressed to:

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York 10591-6707 USA With a copy to: Vice President & General Counsel

All notices and other correspondence sent under this Agreement shall be in English. Any Party may change its address by giving notice to the other Party in the manner herein provided. Any notice required or provided for by the terms of this Agreement shall be in writing and shall be (a) sent by registered or certified mail, return receipt requested, postage prepaid, (b) sent via a reputable international courier service, (c) sent by facsimile transmission with an original following the same day via a reputable international courier service or (d) personally delivered, in each case properly addressed in accordance with the paragraph above. The effective date of notice shall be the actual date of receipt by the Party receiving the same.

- 10.3. Governing Law. This Agreement shall be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York notwithstanding any provisions governing conflict of laws under such New York law to the contrary and without giving effect to the United Nations Convention on Contracts for the International Sale of Goods.
- 10.4. <u>Submission to Jurisdiction</u>. Each Party (a) submits to the exclusive jurisdiction of any state or federal court sitting in New York, New York, with respect to actions or proceedings arising out of or relating to this Agreement, (b) agrees that all claims in respect of such action or proceeding may be heard and determined only in any such court, subject to any rights of removal from state court in New York to federal court in New York, and (c) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court; provided that either Party may bring an action in any court of competent jurisdiction to enforce a final judgment entered by such New York courts. Each Party waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of the other Party with respect thereto. Each Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 10.2. Nothing in this Section 10.4, however, shall affect the right of any Party to serve legal process in any other manner permitted by law.
- 10.5. Force Majeure. No Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any obligation under this Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, pandemic, epidemic, embargoes, war, acts of war (whether war is declared or not), acts of terrorism insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party; provided, however, that the Party so affected shall use reasonable commercial efforts to avoid or remove such causes of nonperformance, and shall continue performance hereunder with reasonable dispatch whenever such causes are removed. Each Party shall provide the other Party with prompt written notice of any delay or failure to perform that occurs by reason of force majeure. The Parties shall mutually seek a resolution of the delay or the failure to perform as noted above.

- 10.6. <u>Independent Contractors</u>. It is understood and agreed that the relationship between the Parties hereunder is that of independent contractors and that nothing in this Agreement shall be construed as authorization for either Regeneron or Company to act as agent for the other.
- 10.7. <u>Headings</u>. The captions or headings of the sections or other subdivisions hereof are inserted only as a matter of convenience or for reference and shall have no effect on the meaning of the provisions hereof.
- 10.9. No Implied Waivers; Rights Cumulative. No failure on the part of Regeneron or Company to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein. To be effective any waiver must be in writing. No right, power, remedy or privilege herein conferred upon or reserved to a Party is intended to be exclusive of any other right, power, remedy or privilege, and each and every right, power, remedy and privilege of a Party pursuant to this Agreement or now or hereafter existing at law or in equity shall to the extent permitted by law be cumulative, concurrent and in addition to every other right, power, remedy or privilege pursuant to this Agreement or now or hereafter existing at law or in equity.
- 10.10. Severability. To the fullest extent permitted by Applicable Law, the Parties waive any provision of law that would render any provision of this Agreement invalid or illegal or unenforceable in any respect. To the fullest extent permitted by Applicable Law and if the rights or obligations of any Party will not be materially and adversely affected: (a) such provision will be given no effect by the Parties and shall not form part of this Agreement, (b) all other provisions of this Agreement shall remain in full force and effect, and (c) the Parties shall use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the Parties.
- 10.11. Execution in Counterparts; Facsimile Signatures. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the

same instrument even if both Parties have not executed the same counterpart. Signatures provided by facsimile transmission shall be deemed to be original signatures.

- 10.12. Construction. Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders and the word "or" has the inclusive meaning represented by the phrase "and/or". Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The term "including" or "includes" as used in this Agreement means including, without limiting the generality of any description preceding such term. The wording of this Agreement shall be deemed to be the wording mutually chosen by the Parties and no rule of strict construction shall be applied against any Party.
- 10.13. No Benefit to Third Parties. The provisions of this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights in any other Persons except as otherwise expressly provided in Section 10.1.
- 10.14 Limitation of Damages EXCEPT AS PROVIDED BELOW IN THIS SECTION 10.14, IN NO EVENT SHALL REGENERON OR COMPANY BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING, WITHOUT LIMITATION, LOSS OF PROFITS) SUFFERED BY THE OTHER PARTY, REGARLDESS OF THE THEORY OF LIABILITY AND REGLARDLESS OF ANY PRIOR NOTICE OF SUCH DAMAGES. HOWEVER, NOTHING IN THIS SECTION 10.14 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS AND OBLGIATIONS OF EITHER PARTY HEREUNDER WITH RESPECT TO THIRD-PARTY CLAIMS. MOREOVER, NOTHING IN THIS SECTION 10.14 IS INTENDED TO LIMIT OR RESTRICT ANY LIABILITY FOR FRAUD OR ANY LIABILITY ARISING FROM A BREACH OF SECTION 2.6 OR 5.4.
- 10.15 <u>Further Assurance</u>. Each Party shall perform all further acts and things and execute and deliver such further documents as may be necessary or as the other Party may reasonably require to implement or give effect to this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg

Name: Murray A. Goldberg

Title: Senior Vice President, Finance & Administration and Chief Financial Officer

ASTELLAS PHARMA INC.

By: /s/ Toshinari Tamura, Ph.D.

Name: Toshinari Tamura, Ph.D.

Title: Representative Director, Executive Vice President and Chief Science Officer

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$\underline{\text{EXHIBIT A}}$ REGENERON KNOW-HOW AND MICE

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EXHIBIT B

REGENERON PATENT RIGHTS

Patent No.: 6,586,251 USSN: 09/732,234

Inventors: Economides, Murphy, Valenzuela, Yancopoulos

Title: Methods of Modifying Eukaryotic Cells

Filing Date: 7 Dec 2000

Patent No.: 6,596,541 USSN: 09/784,859 PCT: 2003/6275

Inventors: Murphy, Yancopoulos

Title: Methods of Modifying Eukaryotic Cells
Filing Date: 16 Feb 2001 (continuation-in-part of 09/732,234)

Patent No.: US 7,105,348 USSN: 10/076,840

Inventors: Murphy, Yancopoulos

Title: Methods of Modifying Eukaryotic Cells

Filing Date: 15 Feb 2002

780D NZ Patent No. 527629

Granted 7 July 2005

780D SG Patent No. 100103

Granted 30 Nov 2005

780D SA Patent No. 2003/3129

Granted 29 Sept 2005

EXHIBIT C

LETTER AGREEMENT WITH APPROVED THIRD PARTIES

Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, New York USA 10591

Ladies and Gentlemen:

In connection with the [] agreement (the "Agreement") dated [] between [] ("Service Provider"), a [], with principal offices located at [] and [ASTELLAS] ("Astellas"), a [] with principal offices located at [], Service Provider hereby enters into the following agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron"), a New York corporation, with principal offices located at 777 Old Saw Mill River Road, Tarrytown, New York USA 10591:

- 2) [Service Provider agrees that it shall not use the Regeneron Mice for any purposes other than to breed the Mice solely by means of breeding Regeneron Mice with other Regeneron Mice solely in accordance with the breeding practices supplied by Astellas.] [IF APPLICABLE]
- 3) Service Provider agrees that Regeneron retains all right, title and interest in the Regeneron Mice and Mice Materials. Without limiting the foregoing, Service Provider hereby assigns to Regeneron any right, title and interest in the Regeneron Mice and Mice Materials. Service Provider agrees to execute any and all further instruments, forms of assignments and other documents, and to take such further actions as Regeneron may request, in order to transfer all of Service Provider's rights, if any, in the Regeneron Mice and Mice Materials to Regeneron without additional consideration.
- 4) Service Provider agrees that it has no right to use the Regeneron Mice or Mice Materials to discover, develop or otherwise make improvements to the Regeneron Mice or Mice Materials (referred to as "Mice Inventions"). Accordingly, Service Provider shall promptly disclose to Regeneron, in writing, any Mice Inventions and shall, and hereby does, assign, all right, title, and interest it has in Mice Inventions without additional compensation.
- 5) Service Provider agrees that it: (a) will use diligent efforts to ensure that the Regeneron Mice do not come into contact with any mice other than Regeneron Mice; and, in particular, will not intentionally or recklessly breed Regeneron Mice with any mice

other than Regeneron Mice; (b) will not make any heritable genetic modifications to the Regeneron Mice; (c) will not derive embryonic or other stem cells from the Regeneron Mice or other Mice Material that could be used to make Regeneron Mice; (d) will not use Regeneron Mice or Mice Materials to manufacture or produce products for sale; and (e) will not use Mice Materials to create Regeneron Mice, mice or any transgenic organism.

- 6) Service Provider agrees to keep Regeneron Information confidential and not disclose to any third party or use for any purpose other than the performance of the Agreement.
- 7) Service Provider will not distribute or allow the transfer of Regeneron Mice to any third party other than Astellas or its Affiliates and will destroy all Regeneron Mice and Mice Materials in its possession within five (5) business days after notice from Astellas.
- 8) This letter agreement shall be construed and the rights of the parties hereto shall be determined according to the laws of the State of New York notwithstanding any provisions governing conflict of laws under such New York law to the contrary and without giving effect to the United Nations Convention on Contracts for the International Sale of Goods.
- 9) This letter agreement may be executed in counterparts, each of which counterpart, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument even if both parties have not executed the same counterpart. Signatures provided by facsimile transmission shall be deemed to be original signatures.
- 10) For the avoidance of doubt, it is understood that Regeneron shall not be responsible for Astellas's performance of its obligations under the Agreement and Regeneron shall have no liability or responsibilities under the Agreement.

IN WITNESS WHEREOF, the parties have caused a duly authorized representative to execute this letter agreement as of the date set forth below.

1	REGENERON PHARMACEUTICALS, INC.
By:Name:	By: Name:
Title:	Title:
Date:	Date:
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EXHIBIT D

PRESS RELEASE

ASTELLAS LICENSES REGENERON'S VELOCIMMUNE® TECHNOLOGY FOR DISCOVERING HUMAN MONOCLONAL ANTIBODIES

Tokyo, Japan and Tarrytown, NY — (March xx, 2007) — Astellas Pharma Inc. ("Astellas"; Headquarters: Tokyo, Japan; President & CEO: Masafumi Nogimori) and Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) announced today that they have entered into a non-exclusive license agreement that will allow Astellas to utilize Regeneron's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibody product candidates.

Astellas will pay \$20 million upfront and will make up to five additional annual payments of \$20 million, subject to the ability to terminate the agreement after making the first three additional payments. Upon commercialization of any antibody products discovered utilizing *VelocImmune*, Astellas will pay a mid-single-digit royalty on product sales. Astellas will report the \$80 million license fee for the initial four years as an R&D expense on its income statements for the fiscal year ending March 31, 2007.

"VelocImmune is the centerpiece of Regeneron's suite of technologies for the discovery and development of fully human monoclonal antibodies," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories and Regeneron's Chief Scientific Officer. "We are pleased that Astellas, a company with a clear strategic commitment to developing therapeutic antibodies, has selected the VelocImmune platform for its internal development programs."

"We are excited about this license agreement with Regeneron," said Toshinari Tamura, Ph.D., Astellas' Executive Vice President and Chief Scientific Officer. "As described in our recently announced medium term plan, Astellas is building a new technological platform for the development of antibody drugs, and *VelocImmune* will become an important cornerstone for our R&D capabilities."

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VelocImmune

Regeneron's *VelocImmune* technology offers the potential to increase dramatically the speed and efficiency of discovering fully-human, therapeutic monoclonal antibodies. The *VelocImmune* platform generates fully human monoclonal antibodies (hMAbs) to address clinically relevant targets of therapeutic interest. The *VelocImmune* mouse, unlike other hMAb mice, mounts a robust immune response that is virtually indistinguishable from that of a wild type mouse, resulting in a reliable and efficient platform for discovering fully human monoclonal antibodies.

About Astellas Pharma Inc.

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. The organization is committed to becoming a global pharmaceutical company by combining outstanding R&D and marketing capabilities and continuing to grow in the world pharmaceutical market. For more information on Astellas Pharma Inc., please visit the company's website at http://www.astellas.com.

About Regeneron Pharmaceuticals, Inc.

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, and has preclinical programs in other diseases and disorders.

Regeneron has developed and validated a suite of inter-related technology platforms — *VelociGene®*, *VelociMouse®*, and *VelocImmune* — that the Company believes can increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated. These discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. *VelociGene* uses a proprietary process to create genetic modifications in a mouse in a precise and high-throughput manner and was recently selected by the National Institutes of Health for use in its Knockout Mouse Project. *VelociGene* allows Regeneron to produce mouse embryonic stem (ES) cells rapidly for elucidating the function of the altered genes. *VelociMouse* allows Regeneron scientists to generate mammalian models directly from ES cells without the need for chimeras or breeding. *VelocImmune* provides antibodies that address the targets identified in the mammalian models that can be

developed as potential therapeutics. For more information on Regeneron, please visit the company's website at www.regeneron.com.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or to terminate without any product success, risks associated with third party intellectual property, and other material risks. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2006. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise unless required by law.

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SAMPLE ROYALTY CALCULATION

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Three months

Regeneron Pharmaceuticals, Inc. Computation of Ratio of Earnings to Combined Fixed Charges

(Dollars in thousands)

		Year	s ended Decembe	er 31		ended March 31,
	2002	2003	2004	2005	2006	2007
Earnings:						
Income (loss) from continuing						
operations before income						
(loss) from equity investee	\$(124,350)	\$(107,395)	\$41,565	\$(95,456)	\$(103,150)	\$(29,917)
Fixed charges	13,685	14,108	14,060	13,687	13,643	3,425
Amortization of capitalized interest	(222)	33 (276)	78	78	73	6
Interest capitalized	(222)	(470)				
Adjusted earnings	\$(110,887)	\$ (93,530)	\$55,703	\$(81,691)	\$ (89,434)	\$(26,486)
Fixed charges:						
Interest expense	\$ 11,859	\$ 11,932	\$12,175	\$ 12,046	\$ 12,043	\$ 3,011
Interest capitalized	222	276				
Assumed interest component of						
rental charges	1,604	1,900	1,885	1,641	1,600	414
Total fixed charges	\$ 13,685	\$ 14,108	\$14,060	\$ 13,687	\$ 13,643	\$ 3,425
Ratio of earnings to fixed charges	(A)	(A)	3.96	(A)	(A)	(A)

⁽A) Due to the registrant's losses for the years ended December 31, 2002, 2003, 2005, and 2006, and for the three months ended March 31, 2007, the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

					Three months ended
		Years ended	December 31,		March 31,
	2002	2003	2005	2006	2007
Coverage deficiency	\$124,572	\$107,638	\$95,378	\$103,077	\$29,911

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Leonard S. Schleifer, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared:
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2007 /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Murray A. Goldberg, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about
 the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such
 evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2007

/s/ Murray A. Goldberg

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
May 4, 2007
/s/ Murray A. Goldberg

Murray A. Goldberg Chief Financial Officer May 4, 2007

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 8/3/2007

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-Q

(Mark One)		
\square	QUARTERLY REPORT PU	URSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the quarterly period ended June 30, 20	<u>07</u>
		OR
	TRANSITION REPORT PU	RSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the transition period fromt	0
	Comi	nission File Number <u>0-19034</u>
	(Exact name	HARMACEUTICALS, INC. of registrant as specified in its charter)
	New York	13-3444607
	(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
	777 Old Saw Mill River Road Tarrytown, New York	10591-6707
	(Address of principal executive offices)	(Zip Code)
		(914) 347-7000
	(Registrant's to	elephone number, including area code)
1934 during th		reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of od that the registrant was required to file such reports), and (2) has been subject to Yes No No
	neck mark whether the registrant is a large accele filer and large accelerated filer" in Rule 12b-2 of t Large accelerated filer □	rated filer, an accelerated filer, or a non-accelerated filer. See definition of he Exchange Act. Accelerated filer Non-accelerated filer
Indicate by ch	neck mark whether the registrant is a shell compa	nny (as defined in Rule 12b-2 of the Exchange Act). Yes □ No ☑
Indicate the n	number of shares outstanding of each of the issu	er's classes of common stock as of July 31, 2007:
	Class of Common Stock	Number of Shares
	Class A Stock, \$0.001 par value Common Stock, \$0.001 par value	2,260,266 63,798,205

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PART I. FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AT JUNE 30, 2007 AND DECEMBER 31, 2006 (Unaudited) (In thousands, except share data)

	June 30, 2007	December 31, 2006
ASSETS		
Current assets Cash and cash equivalents	\$ 109,643	\$ 237.876
Marketable securities	351.054	221.400
Accounts receivable	20,478	7,493
Prepaid expenses and other current assets	15,806	3,215
Total current assets	496,981	469,984
Restricted cash	1,600	1,600
Marketable securities	49,985	61,983
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization Other assets	47,647 1,64 5	49,353 2,170
Total assets	\$ 597,858	\$ 585,090
Total assets	ψ 2377,020	\$ 505,070
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities	e at nos	e 21.4773
Accounts payable and accrued expenses Deferred revenue, current portion	\$ 34,905 69,926	\$ 21,471 23,543
Total current liabilities	104,831	45,014
Deferred revenue	113,691	123,452
Notes payable	200,000	200,000
Total liabilities	418,522	368,466
Commitments and contingencies		
Stockholders' equity		
Preferred stock, \$.01 par value; 30,000,000 shares authorized, issued and outstanding-none		
Class A Stock, convertible, \$.001 par value; 40,000,000 shares authorized; shares issued and outstanding - 2,270,353 in 2007 and 2006	2	2
Common Stock, \$.001 par value; 160,000,000 shares authorized;	Σ	Z
shares issued and outstanding - 63,783,564 in 2007 and 63,130,962 in 2006	64	63
Additional paid-in capital	924,094	904,407
Accumulated deficit Accumulated other comprehensive loss	(744,308) (516)	(687,617) (231)
Total stockholders' equity	179,336	216,624
Total liabilities and stockholders' equity	\$ 597,858	\$ 585,090
Total national and stockholders equity	ψ <i>571</i> ,050	* 303,070

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share data)

	Three months end	ed June 30, 2006	Six months ende	d June 30, 2006
Revenues Contract research and development Contract manufacturing	\$ 15,917	\$ 14,991 4,267	\$ 29,562	\$ 29,578 7, 89 9
Technology licensing	6,278 22,195	19,258	8,421 37,983	37,477
Expenses Research and development Contract manufacturing General and administrative	43,864 <u>8,935</u> 52,799	34,398 2,810 6,299 43,507	85,099 17,137 102,236	66,482 4,662 12,245 83,389
Loss from operations	(30,604)	(24,249)	(64,253)	(45,912)
Other income (expense) Investment income Interest expense	6,841 (3,011) 3,830	3,684 (3,011) 673	13,584 (6,022) 7,562	7,165 (6,022) 1,143
Net loss before cumulative effect of a change in accounting principle Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")	(26,774)	(23,576)	(56,691)	(44,769) 8 13
Net loss	<u>\$ (26,774</u>)	\$ (23,576)	\$ (56,691)	\$ (43,956)
Net loss per share amounts, basic and diluted: Net loss before cumulative effect of a change in accounting principle Cumulative effect of adopting SFAS 123R Net loss	\$ (0.41) \$ (0.41)	\$ (0.41) \$ (0.41)	\$ (0.86)	\$ (0.79) 0.02 \$ (0.77)
Weighted average shares outstanding, basic and diluted	65,950	56,915	65,757	56,821

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) For the six months ended June 30, 2007 (In thousands)

							Accumulated		
	Class A	A Stock	Commo	n Stock	Additional Paid-in	Accumulated	Other Comprehensive	Total Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	<u>Capital</u>	Deficit	Loss	Equity	Loss
Balance, December 31, 2006	2,270	\$ 2	63,131	\$ 63	\$ 904,407	\$ (687,617)	\$ (231)	\$ 216,624	
Issuance of Common Stock in									
connection with exercise									
of stock options, net of									
shares tendered			588	1	4,823			4,824	
Issuance of Common Stock in connection with Company									
401(k) Savings Plan contribution			65		1,367			1,367	
Stock-based compensation expense					13,497			13,497	
Net loss Change in net unrealized loss						(56,691)		(56,691)	\$ (56,691)
on marketable securities							(285)	(285)	(285)
Balance, June 30, 2007	2,270	<u>\$ 2</u>	63,784	<u>\$ 64</u>	\$ 924,094	<u>\$ (744,308)</u>	<u>\$ (516)</u>	<u>\$ 179,336</u>	<u>\$ (56,976)</u>

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Six months er	nded June 30, 2006
Cash flows from operating activities Net loss	\$ (56,691)	\$ (43,956)
Adjustments to reconcile net loss to net cash used in operating activities	\$ (50,071)	\$ (43,730)
Depreciation and amortization	5.729	7,488
Non-cash compensation expense	13,497	8,779
Cumulative effect of a change in accounting principle		(813)
Changes in assets and liabilities	(10.005)	
(Increase) decrease in accounts receivable	(12,985)	24,380
(Increase) decrease in prepaid expenses and other assets Increase in inventory	(13,241)	627 1.279
Increase (decrease) in deferred revenue	36 622	(8,063)
Increase (decrease) in accounts payable, accrued expenses, and other liabilities	14,324	(5,118)
Total adjustments	43,946	28,559
Net cash used in operating activities	(12,745)	(15,397)
Cash flows from investing activities		
Purchases of marketable securities	(371,007)	(152,660)
Sales or maturities of marketable securities	253.719	95,292
Capital expenditures	(3,024)	(986)
Net cash used in investing activities	(120,312)	(58,354)
Cash flows from financing activities		
Net proceeds from the issuance of Common Stock	4,824	3,813
Other		390
Net cash provided by financing activities	4,824	4,203
Net decrease in cash and cash equivalents	(128,233)	(69,548)
Cash and cash equivalents at beginning of period	237,876	184,508
Cash and cash equivalents at end of period	\$ 109,643	<u>\$ 114,960</u>

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2006 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2006.

2. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and six months ended June 30, 2007 and 2006, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months E	inded June 30,
	2007	2006
Net loss (Numerator)	\$(26,774)	\$(23,576)
Weighted-average shares, in thousands (Denominator)	65,950	56,915
Basic and diluted net loss per share	\$ (0.41)	\$ (0.41)
	Six Months E	nded June 30
		indea fune 50,
	2007	2006
Net loss (Numerator)		
Net loss (Numerator) Weighted-average shares, in thousands (Denominator)	2007	2006

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the June 30, 2007 and 2006 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended June 30	
	2007	2006
Stock Options:		
Weighted average number, in thousands	15,228	14,181
Weighted average exercise price	\$ 15.91	\$ 14.32
D		
Restricted Stock:		
Weighted average number; in thousands		40
Convertible Debt:		
Weighted average number, in thousands	6,611	6,611
Conversion price	\$ 30.25	\$ 30.25
Conversion price	Φ 30.23	φ 30.23
	Six months	ended June 30,
	Six months	ended June 30, 2006
Stock Options:		
Stock Options: Weighted average number, in thousands		
	2007	2006
Weighted average number, in thousands Weighted average exercise price	2007 15,388	2006 14,291
Weighted average number, in thousands Weighted average exercise price Restricted Stock:	2007 15,388	2006 14,291 \$ 14.29
Weighted average number, in thousands Weighted average exercise price	2007 15,388	2006 14,291
Weighted average number, in thousands Weighted average exercise price Restricted Stock: Weighted average number, in thousands	2007 15,388	2006 14,291 \$ 14.29
Weighted average number, in thousands Weighted average exercise price Restricted Stock: Weighted average number, in thousands Convertible Debt:	2007 15,388 \$ 15.78	2006 14,291 \$ 14,29 47
Weighted average number, in thousands Weighted average exercise price Restricted Stock: Weighted average number, in thousands	2007 15,388	2006 14,291 \$ 14.29

3. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2007 and December 31, 2006 are \$1.3 million and \$0.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at both June 30, 2006 and December 31, 2005 are \$0.2 million of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2006 and 2005 are \$1.4 million and \$1.9 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2007 and 2006, the Company contributed 64,532 and 120,960

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at June 30, 2007 and December 31, 2006 are \$2.2 million and \$1.5 million, respectively, of accrued interest income. Included in marketable securities at June 30, 2006 and December 31, 2005 are \$0.8 million and \$1.2 million, respectively, of accrued interest income.

4. Accounts Receivable

Accounts receivable as of June 30, 2007 and December 31, 2006 consist of the following:

	June 30,	December 31,
	2007	2006
Receivable from the sanofi-aventis Group	\$ 11,410	\$ 6,900
Receivable from Bayer HealthCare LLC	7,463	
Other		593
	\$ 20,478	\$ 7,493

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2007 and December 31, 2006 consist of the following:

	June 30,	December 31,
	2007	2006
Accounts payable	\$ 18,546	\$ 4,349
Accrued payroll and related costs	7,222	9,932
Accrued clinical trial expense	4,316	2,606
Accrued expenses other	2,529	2,292
Interest payable on convertible notes	2,292	2,292
	\$ 34,905	<u>\$ 21,471</u>

6. Comprehensive Loss

Comprehensive loss represents the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. The net effect of income taxes on comprehensive loss is immaterial. For the three and six months ended June 30, 2007 and 2006, the components of comprehensive loss are:

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended June 30,	
	2007	2006
Net loss	\$ (26,774)	\$ (23,576)
Change in net unrealized gain (loss) on marketable securities	(357)	(102)
Total comprehensive loss	\$ (27.131)	\$ (23.678)
	<u></u>	An annual and a state of the st
	Six months	ended June 30,
	Six months of	ended June 30, 2006
Net loss		
Net loss Change in net unrealized gain (loss) on marketable securities		

7. Accounting for Collaboration with Bayer HealthCare

In October 2006, the Company entered into a license and collaboration agreement with Bayer HealthCare LLC to globally develop, and commercialize outside the United States, the Company's VEGF Trap for the treatment of eye disease by local administration ("VEGF Trap-Eye"). Under the terms of the agreement, Bayer made a non-refundable up-front payment to the Company of \$75.0 million. In 2007, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$50.0 million will be shared equally; Regeneron is solely responsible for the next \$40.0 million; over \$90.0 million will be shared equally. Through June 30, 2007, reimbursements from Bayer HealthCare of the Company's VEGF Trap-Eye development expenses totaled \$10.6 million, of which \$7.5 million was receivable at June 30, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

The Company and Bayer HealthCare are currently formalizing the global development plans for the VEGF Trap-Eye in the collaboration's two initial eye disease indications. The plans will include estimated development steps, timelines and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. Pending completion of these plans, all payments received or receivable by the Company from Bayer HealthCare through June 30, 2007, totaling \$85.6 million, have been fully deferred and included in deferred revenue for financial statement purposes. When the plans are formalized later this year, the Company will determine the appropriate accounting policy for payments from Bayer HealthCare and the financial statement classifications and periods in which past and future payments (including the \$75.0 million up-front payment, development and regulatory milestone payments, and reimbursements of Regeneron development expenses) will be recognized in the Company's Statement of Operations. In the period when the Company commences recognizing previously deferred payments from Bayer HealthCare, the Company anticipates recording a cumulative catch-up for the period since inception of the collaboration in October 2006, which can not be quantified at this time.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

8. 2007 License Agreements

AstraZeneca

In February 2007, the Company entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize the Company's VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable up-front payment to the Company which was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. AstraZeneca also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using the Company's VelocImmune technology. For the six months ended June 30, 2007, the Company recognized \$7.1 million of revenue in connection with the AstraZeneca license agreement. At June 30, 2007, deferred revenue was \$12.9 million.

Astellas

In March 2007, the Company entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable up-front payment to the Company, which was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. Astellas also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. These additional payments will be recognized as revenue ratably over their respective annual license periods. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's VelocImmune technology. For the six months ended June 30, 2007, the Company recognized \$1.3 million of revenue in connection with the Astellas license agreement. At June 30, 2007, deferred revenue was \$18.7 million.

9. Commitment — Purchase of Building

In June 2007, the Company exercised a purchase option on a building in Rensselaer, New York, totaling approximately 270,000 square feet, in which the Company currently leases approximately 75,000 square feet of manufacturing, office, and warehouse space. The Company anticipates completing the purchase of this building in the third quarter of 2007 at a cost of approximately \$10 million.

REGENERON PHARMACEUTICALS, INC.

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10. Income Taxes

Effective January 1, 2007, the Company adopted the provisions of Financial Accounting Standards Board ("FASB") Interpretation No. 48 ("FIN 48"), *Accounting for Uncertainty in Income Taxes* — *an interpretation of FASB Statement No. 109*. The implementation of FIN 48 had no impact on the Company's financial statements.

The Company is primarily subject to U.S. federal and New York State income tax. Tax years subsequent to 1991 remain open to examination by U.S. federal and state tax authorities.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. As of January 1 and June 30, 2007, the Company had no accruals for interest or penalties related to income tax matters.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

12. Segment Information

Through 2006, the Company's operations were managed in two business segments: research and development, and contract manufacturing.

Research and development: Includes all activities related to the discovery of pharmaceutical products for the treatment of serious medical conditions, and the development and commercialization of these discoveries. Also includes revenues and expenses related to activities conducted under contract research and technology licensing agreements.

Contract manufacturing: Includes all revenues and expenses related to the commercial production of products under contract manufacturing arrangements. During 2006, the Company produced a vaccine intermediate for Merck & Co., Inc. under a manufacturing agreement, which expired in October 2006.

Due to the expiration of the Company's manufacturing agreement with Merck in October 2006, beginning in 2007, the Company only has a research and development business segment. Therefore, segment information has not been provided for 2007 in the table below.

The following table presents information about reported segments for the three and six months ended June 30, 2006.

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Three months ended June 30, 2006			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 14,991	\$4,267		\$ 19,258
Depreciation and amortization	3,429	(1)	\$ 261	3,690
Non-cash compensation expense	4,603	97		4,700
Interest expense		_	3,011	3,011
Net (loss) income	(25,706)	1,457	673 (2)	(23,576)
Capital expenditures	323		_	323

	Six months ended June 30, 2006			
	Research &	Contract	Reconciling	
	Development	Manufacturing	Items	Total
Revenues	\$ 29,578	\$7,899		\$ 37,477
Depreciation and amortization	6,966	(1)	\$ 522	7,488
Non-cash compensation expense	8,587	192	(813-)(4)	7,966
Interest expense	_		6,022	6,022
Net (loss) income	(49,149)	3,237	1,956 (2)	(43,956)
Capital expenditures	968		_	968
Total assets	64,543	3,580	310,209 (3)	378,332

⁽¹⁾ Depreciation and amortization related to contract manufacturing was capitalized into inventory and included in contract manufacturing expense when the product was shipped.

13. Future Impact of Recently Issued Accounting Standards

In February 2007, the FASB issued SFAS 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company will be required to adopt SFAS 159 effective

Represents investment income, net of interest expense related primarily to convertible notes issued in October 2001. For the six months ended June 30, 2006, also includes the cumulative effect of adopting Statement of Financial Accounting Standards No. ("SFAS") 123R, Share-Based Payment.

⁽³⁾ Includes cash and cash equivalents, marketable securities, restricted cash (where applicable), prepaid expenses and other current assets, and other assets.

⁽⁴⁾ Represents the cumulative effect of adopting SFAS 123R.

REGENERON PHARMACEUTICALS, INC.

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(Unless otherwise noted, dollars in thousands, except per share data)

for the fiscal year beginning January 1, 2008. Management is currently evaluating the potential impact of adopting SFAS 159 on the Company's financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. The Company will be required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Management believes that the future adoption of EITF 07-3 will not have a material impact on the Company's financial statements.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc. and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and intends to commercialize pharmaceutical products for the treatment of serious medical conditions. We are currently focused on three development programs: rilonacept (IL-1 Trap) in various inflammatory indications, the VEGF Trap (aflibercept) in oncology, and the VEGF Trap-Eye formulation in eye diseases using intraocular delivery. The VEGF Trap is being developed in oncology in collaboration with the sanofi-aventis Group. The VEGF Trap-Eye is being developed in collaboration with Bayer HealthCare LLC. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases. We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our manufacturing and clinical development capabilities to build a successful, integrated biopharmaceutical company. We believe that our ability to develop product candidates is enhanced by the application of our technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (VelocImmune®) and cell line expression technologies may then be utilized to design and produce new product candidates directed against the disease target. Based on the VelocImmune platform which we believe, in conjunction with our other proprietary technologies, can accelerate the development of fully human monoclonal antibodies, we plan to move our first new antibody product candidate into clinical trials in the fourth quarter of 2007. We plan to introduce two new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Clinical Programs:

Below is a summary of the status of our clinical candidates as of June 30, 2007:

1. Rilonacept — Inflammatory Diseases

Rilonacept (IL-1 Trap) is a protein-based product candidate designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. We are evaluating rilonacept in a number of diseases and disorders where IL-1 may play an important role, including a spectrum of rare diseases called Cryopyrin-Associated Periodic Syndromes (CAPS) and other diseases associated with inflammation.

We recently submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for rilonacept in CAPS. The FDA has previously granted Orphan Drug status and Fast Track designation to rilonacept for the treatment of CAPS. In July 2007, rilonacept also received Orphan Drug designation in the European Union for the treatment of CAPS.

In October 2006, we announced positive data from our Phase 3 clinical trial, which was designed to provide two separate demonstrations of efficacy for rilonacept within a single group of adult patients suffering from CAPS. This Phase 3 trial included two studies (Part A and Part B). Both studies met their primary endpoints (Part A: p < 0.0001 and Part B: p < 0.001). The primary endpoint of both studies was the change in disease activity, which was measured using a composite symptom score composed of a daily evaluation of fever/chills, rash, fatigue, joint pain, and eye redness/pain.

The first study (Part A) was a double-blind and placebo-controlled 6-week trial, in which patients randomized to receive rilonacept had an approximately 85% reduction in their mean symptom score compared to an approximately 13% reduction in patients treated with placebo (p<0.0001). Following a 9-week interval during which all patients received rilonacept, a "randomized withdrawal" study (Part B) was performed, in which the patients in Part A were re-randomized to either switch to placebo or continue treatment with rilonacept in a double-blind manner. During the 9-week randomized withdrawal period, patients who were switched to placebo had a five-fold increase in their mean symptom score, compared with those remaining on rilonacept who had no significant change (p<0.001). Both the Part A and Part B studies achieved statistical significance in all of their pre-specified secondary and exploratory endpoints.

Preliminary analysis of the safety data from both studies indicated that there were no drug-related serious adverse events. Injection site reactions and upper respiratory tract infections, all mild to moderate in nature, occurred more frequently in patients while on rilonacept than on placebo. In these studies, rilonacept appeared to be well tolerated; 46 of 47 randomized patients completed the Part A study, and 44 of 45 randomized patients completed the Part B study. See Item 1A, "Risk Factors" under "Risks Related to Development of Our Product Candidates."

CAPS is a spectrum of rare inherited inflammatory conditions, including Familial Cold Autoinflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), and Neonatal Onset Multisystem Inflammatory Disease (NOMID). These syndromes are characterized by spontaneous systemic inflammation and are termed autoinflammatory disorders. A novel feature of these conditions (particularly FCAS and MWS) is that exposure to mild degrees of cold temperature can provoke a major inflammatory episode that occurs within hours. CAPS are caused by a range of mutations in the gene *CIAS1* (also known as NALP3) which encodes a protein named cryopyrin. Currently, there are no medicines approved for the treatment of CAPS.

We are also evaluating the potential use of rilonacept in other indications in which IL-1 may play a role. We are completing an exploratory proof of concept study of rilonacept in ten patients with chronic gout, and plan to begin a safety and efficacy study of rilonacept in gout patients in the third quarter of 2007. We are also preparing to initiate exploratory proof of concept studies of rilonacept in other indications, the first of which is planned to begin in the fourth quarter of 2007.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody, which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product. In return, we are entitled to co-promote the Novartis IL-1 antibody and to receive 45% of net profits on sales of the antibody product in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe.

In addition, under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation rilonacept following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to our rilonacept currently in clinical development.

2. VEGF Trap — Oncology

The VEGF Trap is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PlGF) is required for the growth of new blood vessels that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

The VEGF Trap (aflibercept) is being developed in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are preparing to initiate a large Phase 3 program that will evaluate the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens in five different cancer types. The first trial is planned to begin in the third quarter of 2007. The Phase 3 trials are planned in the following indications:

- first-line metastatic hormone resistant prostate cancer in combination with Taxotere®(Aventis),
- first-line metastatic pancreatic cancer in combination with gemcitabine-based regimen,
- first-line gastric cancer in combination with Taxotere® (Aventis),
- second-line non-small cell lung cancer in combination with Taxotere® (Aventis), and
- second-line metastatic colorectal cancer in combination with FOLFIRI (Folinic Acid (leucovorin), 5-fluorouracil, and irinotecan).

Currently, the collaboration is conducting Phase 2 single-agent studies in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In 2004, the FDA granted Fast Track designation to the VEGF Trap for the treatment of SMA.

In June 2007, at the annual meeting of the American Society of Clinical Oncology (ASCO), we and sanofi-aventis announced interim results from the Phase 2 studies in AOC and NSCLA. The AOC study, selected for an oral presentation at ASCO, was an interim analysis of a Phase 2 randomized, double-blind, multi-center trial investigating two doses of the VEGF Trap used as a single agent in patients with recurrent platinum-resistant epithelial ovarian cancer. While the study remains blinded with regard to dose, the combined preliminary results of the two dose levels for 162 of a planned 200 patients demonstrated anti-tumor activity as evidenced by an 8.0% partial response rate and 77% achievement of stable disease at 4 weeks in heavily pre-treated patients who had failed multiple other treatments. The VEGF Trap has been well tolerated, and the most common adverse events have been the typical class effect of anti-angiogenic agents. Of the 23 patients in the AOC study with evaluable baseline ascites, 7 patients (30%) experienced complete disappearance of the ascites, and 13 patients (57%) experienced no increase in ascites during treatment. The AOC study is ongoing and is now fully enrolled.

The NSCLA study, presented as a poster at ASCO, is a Phase 2 single-arm study conducted in patients with platinum-resistant and erlotinib-resistant adenocarcinoma of the lung (a common type of non-small cell lung cancer). In this study, the preliminary results presented at ASCO demonstrated activity in this heavily pre-treated patient base, as evidenced by a 3.7% partial response rate and 63% of patients achieving stable disease. The VEGF Trap has been well-tolerated in this trial as well. This study is ongoing and is now fully enrolled.

Sanofi-aventis has indicated that a first registration submission to a regulatory agency for the VEGF Trap is possible as early as 2008.

In addition, eight clinical studies have begun in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP). We and sanofi-aventis are working to finalize plans with NCI/CTEP to conduct additional trials in different cancer types.

Five safety and tolerability studies of the VEGF Trap in combination with standard chemotherapy regimens are continuing in a variety of cancer types to support the planned Phase 3 clinical program. In addition, sanofi-aventis has initiated the first trial of the VEGF Trap in

Japan, a Phase 1 safety and tolerability study in combination with S-1 in patients with advanced solid malignancies.

Cancer is a heterogeneous set of diseases and one of the leading causes of death in the developed world. A mutation in any one of dozens of normal genes can eventually result in a cell becoming cancerous; however, a common feature of cancer cells is that they need to obtain nutrients and remove waste products, just as normal cells do. The vascular system normally supplies nutrients to and removes waste from normal tissues. Cancer cells can use the vascular system either by taking over preexisting blood vessels or by promoting the growth of new blood vessels (a process known as angiogenesis). VEGF is secreted by many tumors to stimulate the growth of new blood vessels to supply nutrients and oxygen to the tumor. VEGF blockers have been shown to inhibit new vessel growth; and, in some cases, can cause regression of existing tumor vasculature. Countering the effects of VEGF, thereby blocking the blood supply to tumors, has demonstrated therapeutic benefits in clinical trials. This approach of inhibiting angiogenesis as a mechanism of action for an oncology medicine was validated in February 2004, when the FDA approved Genentech, Inc.'s VEGF inhibitor, Avastin®. Avastin® (Genentech) is an antibody product designed to inhibit VEGF and interfere with the blood supply to tumors.

Collaboration with the sanofi-aventis Group

In September 2003, we entered into a collaboration agreement with Aventis Pharmaceuticals, Inc. (predecessor to sanofi-aventis U.S.) to collaborate on the development and commercialization of the VEGF Trap in all countries other than Japan, where we retained the exclusive right to develop and commercialize the VEGF Trap. In January 2005, we and sanofi-aventis amended the collaboration agreement to exclude from the scope of the collaboration the development and commercialization of the VEGF Trap for intraocular delivery to the eye. In December 2005, we and sanofi-aventis amended our collaboration agreement to expand the territory in which the companies are collaborating on the development of the VEGF Trap to include Japan. Under the collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of the VEGF Trap outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of the VEGF Trap, subject to certain potential adjustments. We may also receive up to \$400.0 million in milestone payments upon receipt of specified marketing approvals. This total includes up to \$360.0 million in milestone payments related to receipt of marketing approvals for up to eight VEGF Trap oncology and other indications in the United States or the European Union. Another \$40.0 million of milestone payments relate to receipt of marketing approvals for up to five VEGF Trap oncology indications in Japan.

Under the collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of the VEGF Trap development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

3. VEGF Trap — Eye Diseases

The VEGF Trap-Eye is a form of the VEGF Trap that has been purified and formulated with excipients and at concentrations suitable for direct injection into the eye. The VEGF Trap-Eye currently is being tested in a Phase 2 trial in patients with the neovascular form of age-related macular degeneration (wet AMD) and in a small pilot study in patients with diabetic macular edema (DME).

In the clinical development program for the VEGF Trap-Eye, we and Bayer HealthCare announced that we have initiated a Phase 3 study of the VEGF Trap-Eye in wet AMD. This first trial will compare the VEGF Trap-Eye and Genentech, Inc.'s Lucentis® (ranibizumab), an anti-angiogenic agent approved for use in wet AMD. This Phase 3 trial is evaluating dosing intervals of four and eight weeks for the VEGF Trap-Eye compared with ranibizumab dosing according to its label every four weeks. Regeneron and Bayer HealthCare plan to initiate a second Phase 3 trial in wet AMD around the end of 2007.

In May 2007, at the annual meeting of the Association for Research in Vision and Ophthalmology (ARVO), we and Bayer HealthCare reported positive interim data from a pre-planned interim analysis of the Phase 2 study in wet AMD. The Phase 2 trial is a 150 patient, 12 week, study that is evaluating the safety and biological effect of treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens. In the interim data analysis, the VEGF Trap-Eye met its primary endpoint of a statistically significant reduction in retinal thickness after 12 weeks compared with baseline (all groups combined, decrease of 135 microns, p < 0.0001). Mean change from baseline in visual acuity, a key secondary endpoint of the study, also demonstrated statistically significant improvement (all groups combined, increase of 5.9 letters, p < 0.0001). Moreover, patients in the dose groups that received only a single dose, on average, compared to baseline, demonstrated a decrease in excess retinal thickness (p < 0.0001) and an increase in visual acuity (p = 0.012) at 12 weeks. There were no drug-related serious adverse events, and treatment with the VEGF Trap-Eye was generally well-tolerated. The most common adverse events were those typically associated with intravitreal injections. Detailed data from this interim analysis is scheduled for presentation at an upcoming scientific conference. All patients have now completed 12 weeks of treatment, and we and Bayer HealthCare expect to report the results at a scientific conference in the third quarter of 2007. We are also conducting a Phase 1 safety and tolerability trial of a new formulation of the VEGF Trap-Eye in wet AMD.

We are also developing the VEGF Trap-Eye in DME. In May 2007, at the ARVO meeting, the companies reported results from a small pilot study of the VEGF Trap-Eye in patients with DME. In the study, the VEGF Trap was well tolerated and demonstrated activity in five patients, with decreases in retinal thickness and improvement in visual acuity. We expect to initiate a safety and efficacy study in DME in the second half of 2007.

VEGF-A both stimulates angiogenesis and increases vascular permeability. It has been shown in preclinical studies to be a major pathogenic factor in both wet AMD and diabetic retinopathy, and it is believed to be involved in other medical problems affecting the eyes. In clinical trials, blocking VEGF-A has been shown to be effective in patients with wet AMD, and

Macugen® (OSI Pharmaceuticals, Inc.) and Lucentis® (Genentech, Inc.) have been approved to treat patients with this condition.

Wet AMD and diabetic retinopathy (DR) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. DR is a major complication of diabetes mellitus that can lead to significant vision impairment. DR is characterized, in part, by vascular leakage, which results in the collection of fluid in the retina. When the macula, the central area of the retina that is responsible for fine visual acuity, is involved, loss of visual acuity occurs. This is referred to as diabetic macular edema (DME). DME is the most prevalent cause of moderate visual loss in patients with diabetes.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of the VEGF Trap-Eye. Under the agreement we and Bayer HealthCare will collaborate on, and share the costs of, the development of the VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, diabetic eye diseases, and other diseases and disorders. The companies will share equally in profits from any future sales of the VEGF Trap-Eye outside the United States. If the VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retained exclusive commercialization rights to the VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare and can earn up to \$110.0 million in total development and regulatory milestones related to the development of the VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135.0 million in sales milestones if total annual sales of the VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200.0 million.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any sales or profits from the commercialization of any of our product candidates and may never receive such revenues. Before revenues from the commercialization of our product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through June 30, 2007, we had a cumulative loss of \$744.3 million. In the absence of revenues from the commercialization of our product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur

substantial losses over the next several years as we continue the clinical development of the VEGF Trap-Eye and rilonacept; advance new product candidates into clinical development from our existing research programs utilizing our technology for designing fully human monoclonal antibodies; continue our research and development programs; and commercialize product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events for 2007 and plans over the next 12 months are as follows:

Clinical Program	2007 Events to Date	2007-8 Plans
VEGF Trap - Oncology	 NCI/CTEP initiated eight Phase 2 studies of the VEGF Trap as a single agent Reported interim results from two Phase 2 single-agent trials in advanced ovarian cancer and in non-small cell lung adenocarcinoma Initiated Japanese Phase 1 trial of VEGF Trap in combination with S-1 in patients with solid malignancies 	 Sanofi-aventis to initiate three of five Phase 3 studies of the VEGF Trap in combination with standard chemotherapy regimens in specific cancer indications NCI/CTEP to initiate additional new exploratory safety and efficacy studies
VEGF Trap-Eye (intravitreal injection)	 Reported positive interim results of Phase 2 trial in wet AMD Reported positive results in Phase 1 trial in DME Initiated first Phase 3 trial in wet AMD 	 Report final results of Phase 2 trial in wet AMD Initiate second Phase 3 trial in wet AMD Initiate safety and efficacy trial in DME Explore additional eye disease indications
	22	

Clinical Program Rilonacept (IL-1 Trap)	 2007 Events to Date Completed the 24 week open-label safety extension phase of the Phase 3 trial in CAPS Submitted BLA to the FDA for CAPS Orphan Drug designation in CAPS granted in European Union 	 FDA acceptance of BLA submission for CAPS and establishment of target completion date for FDA review of BLA Report results of exploratory proof of concept study in patients with chronic gout Initiate safety and efficacy trial in gout Evaluate rilonacept in other disease indications in which IL-1 may play an important role
VelocImmune®		 Initiate first trial for antibody product candidate Finalize plans to initiate clinical trials for two additional antibody candidates in 2008

License Agreements

AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million non-refundable up-front payment to us. AstraZeneca also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our VelocImmune technology.

Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our VelocImmune technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million non-refundable up-front payment to us. Astellas also will make up to five additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first three additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our VelocImmune technology.

Accounting for Collaboration with Bayer HealthCare

As described above, in October 2006 we entered into a VEGF Trap-Eye license and collaboration agreement with Bayer HealthCare. Under the terms of the agreement, Bayer HealthCare made a non-refundable up-front payment to us of \$75.0 million. In 2007, agreed upon VEGF Trap-Eye development expenses incurred by both companies under a global development plan will be shared as follows: Up to the first \$50.0 million will be shared equally;

Regeneron is solely responsible for the next \$40.0 million; over \$90.0 million will be shared equally. Through June 30, 2007, reimbursements from Bayer HealthCare of our VEGF Trap-Eye development expenses total \$10.6 million, of which \$7.5 million was receivable at June 30, 2007. Neither party was reimbursed for any development expenses that it incurred prior to 2007.

We and Bayer HealthCare are currently formalizing our global development plans for the VEGF Trap-Eye in wet AMD and DME. The plans will include estimated development steps, timelines, and costs, as well as the projected responsibilities of and costs to be incurred by each of the companies. Pending completion of these plans, all payments received or receivable from Bayer HealthCare through June 30, 2007, totaling \$85.6 million, have been fully deferred and included in deferred revenue for financial statement purposes. When the plans are formalized later this year, we will determine the appropriate accounting policy for payments from Bayer HealthCare and the financial statement classifications and periods in which past and future payments from Bayer (including the \$75.0 million up-front payment, development and regulatory milestone payments, and reimbursements of Regeneron development expenses) will be recognized in our Statement of Operations. In the period when we commence recognizing previously deferred payments from Bayer HealthCare, we anticipate recording a cumulative catch-up for the period since inception of the collaboration in October 2006, which can not be quantified at this time.

Results of Operations

Three Months Ended June 30, 2007 and 2006

Net Loss:

Regeneron reported a net loss of \$26.8 million, or \$0.41 per share (basic and diluted), for the second quarter of 2007 compared to a net loss of \$23.6 million, or \$0.41 per share (basic and diluted), for the second quarter of 2006.

Revenues:

Revenues for the three months ended June 30, 2007 and 2006 consist of the following:

			Increase
(In millions)	2007	2006	(Decrease)
Contract research & development revenue			
The sanofi-aventis Group	\$ 13.5	\$ 14.8	\$ (1.3)
Other	2.4	0.2	2.2
Total contract research & development revenue	15.9	15.0	0.9
Contract manufacturing revenue		4,3	(4.3)
Technology licensing revenue	6.3		6.3
Total revenue	<u>\$ 22.2</u>	<u>\$ 19.3</u>	\$ 2.9

We recognize revenue from sanofi-aventis, in connection with the companies' VEGF Trap collaboration, in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and FASB Emerging Issue Task Force Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* (EITF 00-21). We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of

reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable up-front license payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

Sanofi-aventis Contract Research & Development Revenue

(In millions)	Three months ende	d June 30,
	2007	2006
Regeneron expense reimbursement	\$ 11.3	S 11.8
Recognition of deferred revenue related to up-front payments	2.2	3.0
Total	<u>\$ 13.5</u>	\$ 14.8

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses decreased in the second quarter of 2007 from the same period in 2006, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front payments decreased in the second quarter of 2007 from the same period in 2006, due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of June 30, 2007, \$65.5 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$1.6 million recognized in connection with our five-year grant from the National Institutes of Health (NIH), which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue for the second quarter of 2006 related to our long-term agreement with Merck & Co., Inc., which expired in October 2006, to manufacture a vaccine intermediate at our Rensselaer, New York facility. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the second quarter of 2006 was \$0.4 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the \$20.0 million non-refundable up-front payment, which we received in February 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the \$20.0 million non-refundable up-front payment, which we received in April 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. In the second quarter of 2007, we recognized \$6.3 million of technology licensing revenue related to these agreements.

Expenses:

Total operating expenses increased to \$52.8 million in the second quarter of 2007 from \$43.5 million in the same period of 2006. Our average employee headcount in the second quarter of

2007 increased to 618 from 579 in the second quarter of 2006, primarily to support our expanded development programs for the VEGF Trap-Eye and rilonacept and our plans to move our first antibody candidate into clinical trials later this year. Operating expenses in the second quarter of 2007 and 2006 include a total of \$6.9 million and \$4.6 million, respectively, of non-cash compensation expense related to employee stock option awards (Stock Option Expense), as detailed below:

(In millions)	For the three months ended June 30, 2007		
	Expenses before		
	inclusion of Stock	Stock Option	Expenses as Reported
Expenses	Option Expense	<u>Expense</u>	<u>Reported</u>
Research and development	\$ 39.9	\$ 4.0	\$ 43.9
General and administrative	6.0	2.9	8.9
Total operating expenses	<u>\$ 45.9</u>	\$ 6.9	<u>\$ 52.8</u>

(In millions)	For the three	months ended June 3	0, 2006
	Expenses before		
	inclusion of Stock	Stock Option	Expenses as Reported
Expenses	Option Expense	Expense	Reported
Research and development	\$ 31.8	\$ 2.6	\$ 34.4
Contract manufacturing	2.7	0.1	2.8
General and administrative	4.4	1,9	6,3
Total operating expenses	\$ 38.9	\$ 4.6	<u>\$ 43.5</u>

The increase in total Stock Option Expense in the second quarter of 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

Research and Development Expenses:

Research and development expenses increased to \$43.9 million in the second quarter of 2007 from \$34.4 million in the same period of 2006. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2007 and 2006:

(In millions)	Thi	ree months ended Jur	ne 30,
Research and development expenses	2007	2006	Increase
Payroll and benefits (1)	\$ 14,4	\$ 11.7	\$ 2.7
Clinical trial expenses	6.5	4.4	2.1
Clinical manufacturing costs (2)	11.5	9.1	2.4
Research and preclinical development costs	6.1	4.3	1.8
Occupancy and other operating costs	5.4	4,9	0,5
Total research and development	\$ 43.9	\$ 34.4	\$ 9.5

⁽¹⁾ Includes \$3.3 million and \$2.2 million of Stock Option Expense for the three months ended June 30, 2007 and 2006, respectively.

⁽²⁾ Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.7 million and \$0.4 million of Stock Option Expense for the three months ended June 30, 2007 and 2006, respectively.

Payroll and benefits increased primarily due to higher Stock Option Expense, as described above, and higher compensation expense due, in part, to the increase in employee headcount, as described above, and annual salary increases effective January 1, 2007. Clinical trial expenses increased due primarily to (i) higher costs related to our ongoing Phase 1 and 2 studies of the VEGF Trap-Eye in wet AMD, (ii) start-up costs related to our upcoming Phase 3 study of the VEGF Trap-Eye in wet AMD, and (iii) higher rilonacept costs. Clinical manufacturing costs increased primarily because capacity which had previously been dedicated to manufacture of a vaccine intermediate for Merck, and whose cost had been included with Contract Manufacturing Expenses in 2006, has now been designated for, and the related costs included in, clinical manufacturing. In addition, higher costs related to manufacturing rilonacept and preclinical and clinical supplies of our first antibody drug candidate were partly offset by lower costs related to manufacturing VEGF Trap. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs. In addition, higher preclinical development costs related to VEGF Trap and VEGF Trap-Eye were partly offset by lower preclinical development costs related to rilonacept.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, non-cash stock-based employee compensation expense related to stock option awards, and manufacturing and other costs related to activities that benefit multiple projects. Our estimates of research and development costs for clinical development programs are shown below:

(In millions)	Three	months ended Ju-	ne 30,
			Increase
Project Costs	2007	2006	(Decrease)
VEGF Trap — Oncology	\$ 10.0	\$ 10.1	\$ (0.1)
VEGF Trap- Eye	8.4	4.1	4.3
Rilonacept	8.1	7.4	0.7
Other research programs & unallocated costs	17.4	12.8	4.6
Total research and development expenses	<u>\$ 43.9</u>	<u>\$ 34.4</u>	<u>\$ 9.5</u>

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2 and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical

programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators, where applicable, continue to explore further development of rilonacept, VEGF Trap, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described below in Item 1A, "Risk Factors" under "Risks Related to Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows. We submitted a BLA for our rilonacept for the treatment of CAPS, a spectrum of rare genetic disorders, in the second quarter of 2007. We cannot predict whether or when the commercialization of rilonacept in CAPS will result in a material net cash inflow to the company.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased in the second quarter of 2007 compared to the same period of 2006 due to the expiration of our manufacturing agreement with Merck in October 2006.

General and Administrative Expenses:

General and administrative expenses increased to \$8.9 million in the second quarter of 2007 from \$6.3 million in the same period of 2006 primarily due to (i) higher Stock Option Expense, as described above, (ii) higher compensation expense due, in part, to increases in administrative headcount in 2007 to support our expanded research and development activities and annual salary increases effective January 1, 2007, (iii) higher recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) marketing research and related expenses incurred in 2007 in connection with our rilonacept and VEGF Trap-Eye programs.

Other Income and Expense:

Investment income increased to \$6.8 million in the second quarter of 2007 from \$3.7 million in the same period of 2006 resulting primarily from higher balances of cash and marketable securities (due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). Interest expense was \$3.0 million in the second quarter of 2007 and 2006. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

Six Months Ended June 30, 2007 and 2006

Net Loss:

Regeneron reported a net loss of \$56.7 million, or \$0.86 per share (basic and diluted), for the first half of 2007 compared to a net loss of \$44.0 million, or \$0.77 per share (basic and diluted), for the same period of 2006.

Revenues:

Revenues for the six months ended June 30, 2007 and 2006 consist of the following:

			Increase
(In millions)	2007	2006	(Decrease)
Contract research & development revenue			
The sanofi-aventis Group	\$ 25.3	\$ 28.7	\$ (3.4)
Other	4.3	0.9	3.4
Total contract research & development revenue	29.6	29.6	
Contract manufacturing revenue		7.9	(7.9)
Technology licensing revenue	8.4		8.4
Total revenue	\$ 38.0	<u>\$ 37.5</u>	<u>§ 0.5</u>

We recognize revenue from sanofi-aventis, in connection with the companies' VEGF Trap collaboration, in accordance with SAB 104 and EITF 00-21. We earn contract research and development revenue from sanofi-aventis which, as detailed below, consists partly of reimbursement for research and development expenses and partly of the recognition of revenue related to a total of \$105.0 million of non-refundable, up-front payments received in 2003 and 2006. Non-refundable up-front license payments are recorded as deferred revenue and recognized over the period over which we are obligated to perform services. We estimate our performance period based on the specific terms of each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances.

Sanofi-aventis Contract Research & Development Revenue

(In millions)	Six months ended	June 30,
	2007	2006
Regeneron expense reimbursement	\$ 20.8	\$ 22.6
Recognition of deferred revenue related to up-front payments	4.5	6.1
Total	<u>\$ 25,3</u>	<u>\$ 28,7</u>

Sanofi-aventis' reimbursement of Regeneron VEGF Trap expenses decreased in the first half of 2007 from the same period in 2006, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. Recognition of deferred revenue related to sanofiaventis' up-front payments decreased in the first quarter of 2007 from the same period in 2006, due to an extension of the estimated performance period over which this deferred revenue is being recognized. As of June 30, 2007, \$65.5 million of the original \$105.0 million of up-front payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue includes \$2.3 million recognized in the first half of 2007 related to our five-year grant from the National Institutes of Health (NIH), which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Contract manufacturing revenue for the first six months of 2006 related to our long-term manufacturing agreement with Merck, which expired in October 2006. Revenue and the related manufacturing expense were recognized as product was shipped, after acceptance by Merck. Included in contract manufacturing revenue in the second quarter of 2006 was \$0.8 million of deferred revenue associated with capital improvement reimbursements paid by Merck prior to commencement of production. We do not expect to receive any further contract manufacturing revenue from Merck.

In connection with our license agreement with AstraZeneca, as described above, the \$20.0 million non-refundable up-front payment, which we received in February 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in February 2007. In connection with our license agreement with Astellas, as described above, the \$20.0 million non-refundable up-front payment, which we received in April 2007, was deferred and is being recognized as revenue ratably over the twelve month period beginning in June 2007. In the first six months of 2007, we recognized \$8.4 million of technology licensing revenue related to these agreements.

Expenses:

Total operating expenses increased to \$102.2 million in the first half of 2007 from \$83.4 million in the same period of 2006. Our average employee headcount in the first half of 2007 increased to 602 from 583 in the first half of 2006, primarily to support our expanded development programs for the VEGF Trap-Eye and rilonacept and our plans to move our first antibody candidate into clinical trials later this year. Operating expenses for the first six months of 2007 and 2006 include a total of \$13.5 million and \$8.5 million, respectively, of Stock Option Expense, as detailed below:

(In millions) For the six months ended June 30, 2007		, 2007	
	Expenses before		
	inclusion of Stock	Stock Option	Expenses as
Expenses	Option Expense	Expense	Reported
Research and development	\$ 77.2	\$ 7.9	\$ 85.1
General and administrative	11.5	5.6	<u>17.1</u>
Total operating expenses	\$ 88.7	<u>\$ 13.5</u>	<u>\$ 102.2</u>

(In millions)	For the	six months ended June	30, 2006
	Expenses before	;	
	inclusion of Stoc	k Stock Option	Expenses as Reported
Expenses	Option Expense	Expense	Reported
Research and development	\$ 61.	9 \$ 4.6	\$ 66.5
Contract manufacturing	4.	5 0.2	4.7
General and administrative	8.	<u>5</u> <u>3.7</u>	12.2
Total operating expenses	<u>\$ 74.</u>	9 \$ 8.5	<u>\$ 83.4</u>

The increase in total Stock Option Expense in the first half of 2007 was primarily due to the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2006 in comparison to the fair market value of our Common Stock on the dates of annual employee option grants made in recent prior years.

Research and Development Expenses:

Research and development expenses increased to \$85.1 million in the first half of 2007 from \$66.5 million in the same period of 2006. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2007 and 2006:

(In millions)	Six months ended June 30,		
Research and development expenses	2007	2006	Increase
Payroll and benefits (1)	\$ 28.1	\$ 21.7	\$ 6.4
Clinical trial expenses	11.8	7.8	4.0
Clinical manufacturing costs (2)	22.0	18.4	3.6
Research and preclinical development costs	12.1	7.8	4.3
Occupancy and other operating costs	11.1	10.8	0.3
Total research and development	\$ 85.1	\$ 66.5	\$ 18.6

⁽¹⁾ Includes \$6.4 million and \$3.8 million of Stock Option Expense for the six months ended June 30, 2007 and 2006, respectively.

Payroll and benefits increased primarily due to higher Stock Option Expense, as described above, and higher compensation expense due, in part, to the increase in employee headcount, as described above, and annual salary increases effective January 1, 2007. Clinical trial expenses increased due primarily to (i) higher costs related to our ongoing Phase 1 and 2 studies of the VEGF Trap-Eye in wet AMD, (ii) start-up costs related to our upcoming Phase 3 study of the VEGF Trap-Eye in wet AMD, and (iii) higher rilonacept costs. Clinical manufacturing costs increased primarily because capacity which had previously been dedicated to manufacture of a vaccine intermediate for Merck, and whose cost had been included with Contract Manufacturing Expenses in 2006, has now been designated for, and the related costs included in, clinical manufacturing. Higher costs related to manufacturing rilonacept and preclinical and clinical supplies of our first antibody drug candidate were offset by lower costs related to manufacturing VEGF Trap. Research and preclinical development costs increased primarily due to higher costs related to our human monoclonal antibody programs. In addition, higher preclinical development

⁽²⁾ Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Stock Option Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$1.5 million and \$0.8 million of Stock Option Expense for the six months ended June 30, 2007 and 2006, respectively.

costs related to VEGF Trap-Eye and VEGF Trap-Oncology were partly offset by lower preclinical development costs related to rilonacept.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development cost for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, non-cash stock-based employee compensation expense related to stock option awards, and manufacturing and other costs related to activities that benefit multiple projects. Our estimates of research and development costs for clinical development programs are shown below:

(In millions)	Six months ended June 30,		
			Increase
Project Costs	2007	2006	(Decrease)
VEGF Trap — Oncology	\$ 17.8	\$ 19.2	\$ (1.4)
VEGF Trap- Eye	14.2	7.8	6.4
Rilonacept	15,9	14.3	1.6
Other research programs & unallocated costs	37.2	25.2	12.0
Total research and development expenses	<u>\$ 85.1</u>	<u>\$ 66.5</u>	\$ 18,6

For the reasons described above under "Research and Development Expenses" for the three months ended June 30, 2007 and 2006, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate product revenues and material net cash inflows.

Contract Manufacturing Expenses:

Contract manufacturing expenses decreased in the first half of 2007 compared to the same period of 2006 due to the expiration of our manufacturing agreement with Merck in October 2006.

General and Administrative Expenses:

General and administrative expenses increased to \$17.1 million in the first half of 2007 from \$12.2 million in the same period of 2006 primarily due to (i) higher Stock Option Expense, as described above, (ii) higher compensation expense due, in part, to increases in administrative headcount in 2007 to support our expanded research and development activities and annual salary increases effective January 1, 2007, (iii) higher recruitment and related costs associated with expanding our headcount in 2007, (iv) higher fees for consultants and other professional services on various corporate matters, and (v) marketing research and related expenses incurred in 2007 in connection with our rilonacept and VEGF Trap-Eye programs.

Other Income and Expense:

Investment income increased to \$13.6 million in the first half of 2007 from \$7.2 million in the same period of 2006 resulting primarily from higher balances of cash and marketable securities

(due, in part, to the up-front payment received from Bayer HealthCare in October 2006, as described above, and the receipt of net proceeds from the November 2006 public offering of our Common Stock). Interest expense was \$6.0 million in first half of 2007 and 2006. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in October 2008 and bear interest at 5.5% per annum.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt, payments earned under our past and present research and development and contract manufacturing agreements, including our agreements with sanofi-aventis, Bayer HealthCare, and Merck, and investment income.

Six Months Ended June 30, 2007 and 2006

At June 30, 2007, we had \$512.3 million in cash, cash equivalents, restricted cash, and marketable securities, compared with \$522.9 million at December 31, 2006. In connection with our new non-exclusive license agreements with AstraZeneca and Astellas, as described above, AstraZeneca and Astellas each made an up-front payment to us of \$20.0 million in February and April 2007, respectively.

Cash (Used in) Operations:

Net cash used in operations was \$12.7 million in the first six months of 2007, compared to \$15.4 million in the first six months of 2006. Our net losses of \$56.7 million in the first half of 2007 and \$44.0 million in the first half of 2006 included \$13.5 million and \$8.8 million, respectively, of non-cash stock-based employee compensation costs, of which \$13.5 million and \$8.5 million, respectively, represented Stock Option Expense and, in the first half of 2006, \$0.3 million represented non-cash compensation expense from Restricted Stock awards. At June 30, 2007, accounts receivable balances increased by \$13.0 million, compared to year end 2006, primarily due to amounts receivable from sanofi-aventis and Bayer HealthCare for reimbursements of our VEGF Trap-Oncology and VEGF Trap-Eye development costs, respectively. Also, our deferred revenue balances at June 30, 2007 increased by \$36.6 million, compared to year end 2006, primarily due to the \$20.0 million up-front payments received from each of AstraZeneca and Astellas, as described above. In addition, for the first six months of 2007, reimbursements from Bayer HealthCare of our 2007 VEGF Trap-Eye development expenses, totaling \$10.6 million, have been fully deferred and included in deferred revenue for financial statement purposes, as discussed above. At June 30, 2006, accounts receivable balances decreased by \$24.4 million, compared to year end 2005, primarily due to the January 2006 receipt of a \$25.0 million up-front payment from sanofi-aventis, which was receivable at December 31, 2005, in connection with an amendment to our collaboration agreement to include Japan. Also, our deferred revenue balances at June 30, 2006 decreased by \$8.1 million, compared to year end 2005, due primarily to first half 2006 revenue recognition of \$6.1 million of deferred revenue related to up-front payments from sanofi-aventis. The majority of our cash expenditures in both the first half of 2007 and 2006 were to fund research and development, primarily related to our clinical

Cash Used in Investing Activities:

Net cash used in investing activities was \$120.3 million in the first half of 2007 compared to \$58.4 million in the same period of 2006, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first half of 2007, purchases of marketable securities exceeded sales or maturities by \$117.3 million, whereas in the first half of 2006, purchases of marketable securities exceeded sales or maturities by \$57.4 million.

Cash Provided by Financing Activities:

Cash provided by financing activities increased to \$4.8 million in the first half of 2007 from \$4.2 million in the same period in 2006 due primarily to an increase in the issuance of Common Stock in connection with exercises of employee stock options.

License Agreements with AstraZeneca and Astellas:

Under these non-exclusive license agreements, AstraZeneca and Astellas each made a \$20.0 million non-refundable, up-front payment to us in February and April 2007, respectively. AstraZeneca and Astellas also will each make up to five additional annual payments of \$20.0 million, subject to each licensee's ability to terminate its license agreement with us after making the first three additional payments or earlier if the technology does not meet minimum performance criteria.

Capital Expenditures:

Our additions to property, plant, and equipment totaled \$3.5 million and \$1.0 million for the first half of 2007 and 2006, respectively. During the remainder of 2007, we expect to incur approximately \$13 million in capital expenditures primarily to support our manufacturing, development, and research activities.

During the second quarter of 2007, we exercised a purchase option on a building in Rensselaer, totaling approximately 270,000 square feet, in which we currently lease approximately 75,000 square feet of manufacturing, office and warehouse space. The acquisition of the building and related costs are expected to approximate \$10 million, which is included in our anticipated capital expenditures for the remainder of 2007, as described above. We expect to complete the purchase of this building in the third quarter of 2007. The space that we do not occupy in this building is currently leased to another tenant.

Convertible Debt:

In 2001, we issued \$200.0 million aggregate principal amount of convertible senior subordinated notes, which bear interest at 5.5% per annum, payable semi-annually, and mature in October 2008. The notes are convertible into shares of our Common Stock at a conversion price of approximately \$30.25 per share, subject to adjustment in certain circumstances. If the price per share of our Common Stock is above \$30.25 at maturity, we would expect the notes to convert into shares of Common Stock. Otherwise, we will be required to repay the \$200.0

million aggregate principal amount of the notes or refinance the notes prior to maturity; however, we can provide no assurance that we will be able to successfully arrange such refinancing.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55%-65% of our expenditures for 2007 will be directed toward the preclinical and clinical development of product candidates, including rilonacept, VEGF Trap. VEGF Trap. Eye and monoclonal antibodies; approximately 10%-15% of our expenditures for 2007 will be applied to our basic research activities and the continued development of our novel technology platforms; and the remainder of our expenditures for 2007 will be used for capital expenditures and general corporate purposes.

Under our collaboration with Bayer HealthCare, over the next several years we and Bayer HealthCare are sharing agreed upon VEGF Trap-Eye development expenses incurred by both companies, under a global development plan, as follows:

2007: Up to \$50.0 million shared equally, we are solely responsible for up to the next \$40.0 million; over \$90.0 million shared equally.

2008: Up to \$70.0 million shared equally, we are solely responsible for up to the next \$30.0 million; over \$100.0 million shared equally.

2009 and thereafter: All expenses shared equally.

In addition, under our collaboration agreements with sanofi-aventis and Bayer Healthcare, if the applicable collaboration becomes profitable, we have contingent contractual obligations to reimburse sanofi-aventis and Bayer Healthcare for 50% of agreed-upon development expenses incurred by sanofi-aventis and Bayer Healthcare, respectively. Profitability under each collaboration will be measured by calculating net sales less agreed-upon expenses. These reimbursements would be deducted from our share of the collaboration profits (and, for sanofi-aventis, royalties on product sales in Japan) otherwise payable to us unless we agree to reimburse these expenses at a faster rate at our option. Given the uncertainties related to drug development (including the development of the VEGF Trap-Oncology in collaboration with sanofi-aventis and the VEGF Trap-Eye in collaboration with Bayer Healthcare) such as the variability in the length of time necessary to develop a product candidate and the ultimate ability to obtain governmental approval for commercialization, we are currently unable to reliably estimate if our collaborations with sanofi-aventis and Bayer Healthcare will become profitable.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, supplies,

laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the clinical trials underway plus additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. In the future, if we are able to successfully develop, market, and sell certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources will enable us to meet operating needs through at least early 2010, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund preclinical and clinical development of our product candidates. Other than the \$1.6 million letter of credit issued to our landlord in connection with our new operating lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of June 30, 2007, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale back, or eliminate certain of our research and development activities or future operations. This could harm our business.

Critical Accounting Policies and Significant Judgments and Estimates

Revenue Recognition:

We recognize revenue from contract research and development and research progress payments in accordance with Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104) and Emerging Issues Task Force 00-21, Accounting for Revenue Arrangements with Multiple Deliverables (EITF 00-21). We earn contract research and development revenue and research progress payments in connection with collaboration and other agreements to develop and commercialize product candidates and utilize our technology platforms. The terms of these agreements typically include non-refundable up-front licensing payments, research progress (milestone) payments, and payments for development activities. Non-refundable up-front license payments, where continuing involvement is required of us, are deferred and recognized over the related performance period. We estimate our performance period based on the specific terms of

each agreement, and adjust the performance periods, if appropriate, based on the applicable facts and circumstances. Payments which are based on achieving a specific substantive performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, we take into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period. Payments for development activities where Regeneron is not sharing costs are recognized as revenue as earned, over the period of effort. In addition, we record revenue in connection with a government research grant as we incur expenses related to the grant, subject to the grant's terms and annual funding approvals.

In connection with non-refundable licensing payments, our performance period estimates are principally based on projections of the scope, progress, and results of our research and development activities. Due to the variability in the scope of activities and length of time necessary to develop a drug product, changes to development plans as programs progress, and uncertainty in the ultimate requirements to obtain governmental approval for commercialization, revisions to performance period estimates are possible, and could result in material changes to the amount of revenue recognized each year in the future. In addition, performance periods may be extended if we and our collaborators decide to expand our clinical plans for a drug candidate into additional disease indications. Also, if a collaborator terminates an agreement in accordance with the terms of the agreement, we would recognize any unamortized remainder of an up-front payment at the time of the termination. For the year ended December 31, 2006, changes in estimates of our performance periods, including an extension of our estimated performance period for our collaboration with sanofi-aventis, did not have a material impact on contract research and development revenue that we recognized. In 2007, we currently expect to recognize at least \$2.4 million lower contract research and development revenue, compared to amounts recognized in 2006, in connection with \$105.0 million of non-refundable up-front payments previously received from sanofi-aventis, due to an extension of our estimated performance period.

As described above, we and Bayer HealthCare are currently formalizing our global development plans for the VEGF Trap-Eye in wet AMD and DME. Pending completion of these plans, all payments received or receivable from Bayer HealthCare through June 30, 2007 have been fully deferred and included in deferred revenue for financial statement purposes. When the plans are formalized later this year, we will determine the appropriate accounting policy for payments from Bayer HealthCare and the financial statement classifications and periods in which past and future payments from Bayer (including the \$75.0 million up-front payment, development and regulatory milestone payments, and reimbursements of Regeneron development

expenses) will be recognized in our Statement of Operations. In the period when we commence recognizing previously deferred payments from Bayer HealthCare, we anticipate recording a cumulative catch-up for the period since inception of the collaboration in October 2006, which can not be quantified at this time.

Clinical Trial Expenses:

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as contract research organizations, independent clinical investigators, and other third-party service providers to assist us with the execution of our clinical studies. For each clinical trial that we conduct, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and the period over which clinical investigators or contract research organizations are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage our clinical trials are performed primarily by contract research organizations (CROs). CROs typically perform most of the start-up activities for our trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. On a budgeted basis, these start-up costs are typically 10% to 15% of the total contract value. On an actual basis, this percentage range can be significantly wider, as many of our contracts are either expanded or reduced in scope compared to the original budget, while start-up costs for the particular trial may not change materially. These start-up costs usually occur within a few months after the contract has been executed and are event driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, we accrue and recognize expenses in an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, we accrue on an estimated cost-per-patient basis an expense based on subject enrollment and activity in each quarter. The amount of clinical study expense recognized in a quarter may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop-out of the clinical study, and the number of sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those with a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, we adjust our rate of clinical expense recognition if actual results differ from our estimates. Our estimates and assumptions for clinical expense recognition could differ significantly from our actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known. No material adjustments to our past clinical trial accrual estimates were made during the year ended December 31, 2006 or the six months ended June 30, 2007.

During the three months ended June 30, 2007, there were no changes to any other "Critical Accounting Policies and Significant Judgments and Estimates" described in our Annual Report on Form 10-K for the year ended December 31, 2006.

Future Impact of Recently Issued Accounting Standards

In February 2007, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. (SFAS) 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We will be required to adopt SFAS 159 effective for the fiscal year beginning January 1, 2008. Our management is currently evaluating the potential impact of adopting SFAS 159 on our financial statements.

In June 2007, the Emerging Issues Task Force issued Statement No. 07-3, *Accounting for Non-refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* (EITF 07-3). EITF 07-3 addresses how entities involved in research and development activities should account for the non-refundable portion of an advance payment made for future research and development activities and requires that such payments be deferred and capitalized, and recognized as an expense when the goods are delivered or the related services are performed. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those fiscal years. We will be required to adopt EITF 07-3 effective for the fiscal year beginning January 1, 2008. Our management believes that the future adoption of EITF 07-3 will not have a material impact on our financial statements.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent change in interest rates would result in approximately a \$2.0 million and \$0.9 million change in the fair market value of our investment portfolio at June 30, 2007 and 2006, respectively. The increase in the potential impact of an interest rate change at June 30, 2007, compared to June 30, 2006, is due primarily to increases in our investment portfolio's balance and duration at the end of June 2007 versus June 2006.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the

end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

Item 1A. Risk Factors

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and in our Annual Report on Form 10-K for the year ended December 31, 2006 and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through June 30, 2007, we had a cumulative loss of \$744.3 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We have no products that are available for sale and do not know when we will have products available for sale, if ever. In the absence of revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We will need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources will enable us to meet operating needs through at least early 2010, without taking into consideration the \$200.0 million aggregate principal amount of convertible senior subordinated notes, which mature in October 2008; however, our projected revenue may decrease or our expenses may increase and that would lead to our capital being consumed significantly before such time. We will likely require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

We have a significant amount of debt and may have insufficient cash to satisfy our debt service and repayment obligations. In addition, the amount of our debt could impede our operations and flexibility.

We have a significant amount of convertible debt and semi-annual interest payment obligations. This debt, unless converted to shares of our common stock, will mature in October 2008. We may be unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments on our debt. Even if we are able to meet our debt service obligations, the amount of debt we already have could hurt our ability to obtain any necessary financing in the future for working capital, capital expenditures, debt service requirements, or other purposes. In addition, our debt obligations could require us to use a substantial portion of cash to pay principal and interest on our debt, instead of applying those funds to other purposes, such as research and development, working capital, and capital expenditures.

Risks Related to Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We have never developed a drug that has been approved for marketing and sale, and we may never succeed in developing an approved drug. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than

tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are studying our lead product candidates, the VEGF Trap, VEGF Trap-Eye, and rilonacept, in a wide variety of indications. We are studying the VEGF Trap in a variety of cancer settings, the VEGF Trap-Eye in different eye diseases and ophthalmologic indications, and rilonacept in a variety of systemic inflammatory disorders. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are to be studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or achieve unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting. For example, we are studying higher doses of rilonacept in different diseases after a Phase 2 trial using lower doses of rilonacept in subjects with rheumatoid arthritis failed to achieve its primary endpoint.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of the product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

The data from the Phase 3 clinical program for rilonacept in CAPS (Cryopyrin Associated Periodic Syndromes) may be inadequate to support regulatory approval for commercialization of rilonacept.

We recently submitted a BLA to the FDA for rilonacept in CAPS. However, the efficacy and safety data from the Phase 3 clinical program included in the BLA may be inadequate to support approval for commercialization of rilonacept. The FDA and other regulatory agencies may have varying interpretations of our clinical trial data, which could delay, limit, or prevent regulatory approval or clearance.

Further, before a product candidate is approved for marketing, our manufacturing facilities must be inspected by the FDA and the FDA will not approve the product for marketing if we or our third party manufacturers are not in compliance with current good manufacturing practices. Even if the FDA and similar foreign regulatory authorities do grant marketing approval for rilonacept, they may pose restrictions on the use or marketing of the product, or may require us to conduct additional post-marketing trials. These restrictions and requirements would likely result in increased expenditures and lower revenues and may restrict our ability to commercialize rilonacept profitably.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, marketing and approval for drugs, and commercial sales and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country-specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of rilonacept in those countries.

The development of serious or life-threatening side effects with any of our product candidates would lead to delay or discontinuation of development, which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. Although our current drug candidates appeared to be generally well tolerated in clinical trials conducted to date, it is possible as we test any of them in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our VEGF Trap is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF. These risks, based on the clinical and preclinical experience of systemically delivered VEGF inhibitors, including the systemic delivery of the VEGF Trap, include bleeding, hypertension, and proteinuria. These serious side effects and other serious side effects have been reported in our systemic VEGF Trap studies in cancer and diseases of the eye. In addition, patients given infusions of any protein, including the VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These include side effects that we have not yet seen in our trials such as heart attack and stroke. These and other complications or side effects could harm the development of the VEGF Trap for the treatment of cancer or the VEGF Trap-Eye for the treatment of diseases of the eye.

It is possible that safety or tolerability concerns may arise as we continue to test rilonacept in patients with inflammatory diseases and disorders. Like cytokine antagonists such as Kineret® (Amgen Inc.), Enbrel® (Immunex Corporation), and Remicade® (Centocor, Inc.), rilonacept affects the immune defense system of the body by blocking some of its functions. Therefore, rilonacept may interfere with the body's ability to fight infections. Treatment with Kineret® (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious infections have been reported in patients taking rilonacept. One subject with adult Still's diseases in a study of rilonacept developed an infection in his elbow with mycobacterium intracellulare. The patient was on chronic glucocorticoid treatment for Still's disease. The infection occurred after an intraarticular glucocorticoid injection into the elbow and subsequent local exposure to a suspected source of mycobacteria. One patient with polymayalgia rheumatica in another study developed bronchitis/sinusitis, which resulted in hospitalization. One patient in an open-label study of rilonacept in CAPS developed sinusitis and streptococcus pneumoniae meningitis and subsequently died. In addition, patients given infusions of rilonacept have developed hypersensitivity reactions or infusion reactions. These or other complications or side effects could impede or result in us abandoning the development of rilonacept.

Our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date — in some cases even after pivotal clinical trials have been completed. Of the clinical study subjects who received rilonacept for rheumatoid arthritis and other

indications, fewer than 5% of patients developed antibodies and no side effects related to antibodies were observed. Using a very sensitive test, approximately 40% of the patients in the CAPS pivotal study tested positive at least once for low levels of antibodies to rilonacept. Again, no side effects related to antibodies were observed and there were no observed effects on drug efficacy or drug levels. However, it is possible that as we continue to test the VEGF Trap and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given the VEGF Trap and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. For example, we are currently testing a new formulation of the VEGF Trap-Eye in a Phase 1 Trial. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including the VEGF Trap-Eye, and rilonacept, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our VelocImmune technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that the VEGF Trap or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert its patents are valid and cover the VEGF Trap or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell the VEGF Trap or VEGF Trap-Eye, which represents a potential competitive threat to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell the VEGF Trap or VEGF Trap-Eye or in a damage award.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval

from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. None of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims. We could also face costly and damaging claims arising from employment law, securities law, environmental law, or other applicable laws governing our operations.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

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Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated new rules and listing standards covering a variety of subjects. Compliance with these new rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective, the market value of our common stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on management's assessment and on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to our assessment and the effectiveness of our internal control over financial reporting as of December 31, 2006, which report was included in our Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an assessment or unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our common stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Risks Related to Our Dependence on Third Parties

If our collaboration with sanofi-aventis for the VEGF Trap is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap in the time expected, or at all, would be harmed.

We rely heavily on sanofi-aventis to assist with the development of the VEGF Trap oncology program. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the VEGF Trap oncology program. If the VEGF Trap oncology program continues, we will rely on sanofi-aventis to assist with funding the VEGF Trap program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and provide sales and marketing support. While we cannot assure you that the VEGF Trap will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to

develop, manufacture, and commercialize the VEGF Trap in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or manufacture of the VEGF Trap and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap oncology program.

If our collaboration with Bayer HealthCare for the VEGF Trap-Eye is terminated, our business operations and our ability to develop, manufacture, and commercialize the VEGF Trap-Eye in the time expected, or at all, would be harmed.

We rely heavily on Bayer HealthCare to assist with the development of the VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, provide assistance with the enrollment and monitoring of clinical trials conducted outside the United States, obtaining regulatory approval outside the United States, and provide sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that the VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize the VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could cause significant delays in the development and/or commercialization of the VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have no sales, marketing, or distribution capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development of the VEGF Trap-Eye development program.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience

additional costs, delays, and difficulties in the development or ultimate commercialization of our product candidates.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We may expand our own manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional funds, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Certain of our raw materials are single-sourced from third parties; third-party supply failures could adversely affect our ability to supply our products.

Certain raw materials necessary for manufacturing and formulation of our product candidates are provided by single-source unaffiliated third-party suppliers. We would be unable to obtain

these raw materials for an indeterminate period of time if these third-party single-source suppliers were to cease or interrupt production or otherwise fail to supply these materials or products to us for any reason, including due to regulatory requirements or action, due to adverse financial developments at or affecting the supplier, or due to labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We have no sales or distribution personnel or capabilities and have only a small staff with marketing capabilities. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, we will not be able to successfully sell any products that we may obtain regulatory approval for and bring to market in the future. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of the VEGF Trap in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including the VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with the same mechanism of action, and competitors may get to the marketplace before we do with better or lower cost drugs or the market for our product candidates may be too small to support commercialization or sufficient profitability.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions,

form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (Genentech), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, OSI Pharmaceuticals, and Pfizer. Many of these molecules are farther along in development than the VEGF Trap and may offer competitive advantages over our molecule. Novartis has an ongoing Phase 3 clinical development program evaluating an orally delivered VEGF tyrosine kinase inhibitor in different cancer settings. Each of Pfizer and Onyx Pharmaceuticals (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin® (Genentech), and their extensive, ongoing clinical development plan for Avastin® (Genentech) in other cancer indications, may make it more difficult for us to enroll patients in clinical trials to support the VEGF Trap and to obtain regulatory approval of the VEGF Trap in these cancer settings. This may delay or impair our ability to successfully develop and commercialize the VEGF Trap. In addition, even if the VEGF Trap is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin® (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment (Lucentis®) for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. OSI Pharmaceuticals and Pfizer are marketing an approved VEGF inhibitor for wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD that act by blocking VEGF, VEGF receptors, and through the use of soluble ribonucleic acids (sRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute recently has received funding for a Phase 3 trial to compare Lucentis® (Genentech) to Avastin® (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis® (Genentech) and the potential off-label use of Avastin® (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop the VEGF Trap-Eye. Even if the VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis® (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin® (Genentech) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott Biotechnology Ltd.), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize rilonacept. This is one of the reasons we discontinued

the development of rilonacept in adult rheumatoid arthritis. In addition, even if rilonacept is ever approved for sale, it will be difficult for our drug to compete against these FDA approved TNF-antagonists in indications where both are useful because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over rilonacept, such as requiring fewer injections.

There are both small molecules and antibodies in development by third parties that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly and Company and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. It has been reported that Novartis has commenced advanced clinical testing of its IL-1 antibody in Muckle-Wells Syndrome, which is part of the spectrum of rare genetic diseases called CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over rilonacept. The successful development of these competing molecules could delay or impair our ability to successfully develop and commercialize rilonacept. For example, we may find it difficult to enroll patients in clinical trials for rilonacept if the companies developing these competing interleukin-1 inhibitors commence clinical trials in the same indications.

We are developing rilonacept for the treatment of a spectrum of rare diseases associated with mutations in the CIAS1 gene. These rare genetic disorders affect a small group of people, estimated to be between several hundred and a few thousand. There may be too few patients with these genetic disorders to profitably commercialize rilonacept in this indication.

The successful commercialization of our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our products, if commercialized, may be significantly more expensive than traditional drug treatments. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We are seeking approval to market rilonacept for the treatment of a spectrum of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize rilonacept. Physicians may not prescribe rilonacept and CAPS patients may not be able to afford rilonacept if third party payers do not agree to reimburse the cost of rilonacept therapy and this would adversely affect our ability to commercialize rilonacept profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our

products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since our products, including rilonacept, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our common stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- public concern as to the safety or effectiveness of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- · general market conditions.

The trading price of our common stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our common stock in the market. Broad market fluctuations may also adversely affect the market price of our common stock.

Future sales of our common stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our common stock. As of April 12, 2007, our seven largest shareholders beneficially owned 44.1% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 12, 2007. As of April 12, 2007, sanofi-aventis owned 2,799,552 shares of Common Stock, representing approximately 4.4% of the shares of Common Stock then outstanding. Under our stock purchase agreement with sanofi-aventis, sanofi-aventis may sell no more than 500,000 of these shares in any calendar quarter. If sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 12, 2007, holders of Class A Stock held 26.4% of the combined voting power of all of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly

influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our company taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 12, 2007:

- our current executive officers and directors beneficially owned 13.2% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2007, and 30.4% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 12, 2007; and
- our seven largest shareholders beneficially owned 44.1% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, and P. Roy Vagelos, M.D., our Chairman, the conversion of their Class A Stock into Common Stock and the exercise of all options held by them which are exercisable within 60 days of April 12, 2007. In addition, these seven shareholders held 51.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer and our Chairman which are exercisable within 60 days of April 12, 2007.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our common stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect

of which is to require that shareholder action may only be taken at a duly convened meeting;

- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

In addition, we have a Change in Control Severance Plan and our chief executive officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

Item 4. Submission of Matters to a Vote of Security Holders

On June 8, 2007, we conducted our Annual Meeting of Shareholders pursuant to due notice. A quorum being present either in person or by proxy, the shareholders voted on the following matters:

- 1. To elect three Directors to hold office for a three-year term as Class I directors, and until their successors are duly elected and qualified.
- 2. To ratify the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for our fiscal year ending December 31, 2007.

No other matters were voted on. The number of votes cast was:

	For	Withheld
1. Election of Class I Directors		
Leonard S. Schleifer, M.D., Ph.D.	78,309,187	1,546,154
Eric M. Shooter, Ph.D.	78,754,194	1,110,147
George D. Yancopoulos, M.D., Ph.D.	78,751,885	1.103.456

The terms of office of Alfred G. Gilman, M.D., Ph.D., Joseph L. Goldstein, M.D., P. Roy Vagelos, M.D., Charles A. Baker, Michael S. Brown, M.D., Arthur F. Ryan, and George L. Sing continued after the meeting.

	For	Against	Abstain
2. Ratification of the Appointment of Independent Registered Public Accounting Firm	79,244,209	217,182	393,949
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Item 6. Exhibits

(a) Exhibits

Exhibit Number	Description
12.1	- Statement re: computation of ratio of earnings to combined fixed charges.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities and Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

By: /s/ Murray A. Goldberg

Date: August 3, 2007

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer and Duly Authorized Officer)

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Regeneron Pharmaceuticals, Inc. Computation of Ratio of Earnings to Combined Fixed Charges

(Dollars in thousands)

		Year	s ended Decembe	r 31.		Six months ended June 30,
	2002	2003	2004	2005	2006	2007
Earnings:						
Income (loss) from continuing						
operations before income						
(loss) from equity investee	\$(124,350)	\$(107,395)	\$41,565	\$(95,456)	\$(103,150)	\$(56,691)
Fixed charges	13,685	14,108	14,060	13,687	13,643	6,854
Amortization of capitalized interest		33	78	78	73	12
Interest capitalized	(222)	(276)				<u></u>
Adjusted earnings	\$(110,887)	\$ (93,530)	\$55,703	\$(81,691)	\$ (89,434)	\$(49,825)
, c				· · · · · · · · · · · · · · · · · · ·		
Fixed charges:						
Interest expense	\$ 11,859	\$ 11.932	\$12,175	\$ 12,046	\$ 12,043	\$ 6,022
Interest capitalized	222	276	Ψ1 2 ,170	V 12,0.0	ψ 12,0 is	0,022
Assumed interest component of						
rental charges	1,604	1,900	1,885	1,641	1.600	832
		/	,	/	,	
Total fixed charges	\$ 13,685	\$ 14,108	\$14,060	\$ 13,687	\$ 13,643	\$ 6,854
**************************************	* ****		W. A. FgVVVV	<i>\$</i> **,000	W *********	* *****
Datio of cornings to fixed charges	(A)	(1)	2.06	(A)	(A)	(A)
Ratio of earnings to fixed charges	(A)	(A)	3.96	(A)	(A)	(A)

⁽A) Due to the registrant's losses for the years ended December 31, 2002, 2003, 2005, and 2006, and for the six months ended June 30, 2007, the ratio coverage was less than 1:1. To achieve a coverage ratio of 1:1, the registrant must generate additional earnings of the amounts shown in the table below.

					Six months ended
		Years ended	December 31,		June 30,
	2002	2003	2005	2006	2007
Coverage deficiency	\$124,572	\$107,638	\$95,378	\$103,077	\$56,679

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Leonard S. Schleifer, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2007 /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.
President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Murray A. Goldberg, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2007 /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance &
Administration, Chief Financial Officer,
Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer August 3, 2007

/s/ Murray A. Goldberg

Murray A. Goldberg Chief Financial Officer August 3, 2007

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 4/30/2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 10-Q

(X)	(Mark One) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) EXCHANGE ACT OF 1934) OF THE SI	SECURITIES	
	For the quarterly period ended March 31, 2009	C	OD	
()	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) EXCHANGE ACT OF 1934		OR SECURITIES	
	For the transition period fromto			
	Commiss	sion File Nu	umber <u>0-19034</u>	
			ACEUTICALS, INC. s specified in its charter)	
	New York		13-3444607	
	(State or other jurisdiction of		(I.R.S. Employer Identification No.)	
	incorporation or organization)			
	777 Old Saw Mill River Road			
	Tarrytown, New York		<u>10591-6707</u>	
	(Address of principal executive offices)		(Zip Code)	
		(914) 347-		
	(Registrant's teleph	hone numbe	per, including area code)	
1934	ate by check mark whether the registrant (1) has filed all rep during the preceding 12 months (or for such shorter period t filing requirements for the past 90 days.	oorts requir that the reg	red to be filed by Section 13 or 15(d) of the Securities Egistrant was required to file such reports), and (2) has b	xchange Act of been subject to
		Yes <u>X</u>	No	
reaui	ate by check mark whether the registrant has submitted electived to be submitted and posted pursuant to Rule 405 of Regular period that the registrant was required to submit and post	ulation S-T	「 (§232.405 of this chapter) during the preceding 12 mon	active Data File hs (or for such
		Yes	No	
indica comp	ate by check mark whether the registrant is a large accelerance. See definitions of "large accelerated filer", "accelerated	erated filer d filer", and	r, an accelerated filer, a non-accelerated filer, or a sr d "smaller reporting company" in Rule 12b-2 of the Exch	naller reporting ange Act.
Large	e accelerated filer X		Accelerated filer	
Non-	accelerated filer (Do not check if a smaller reporting co	ompany)	Smaller reporting company	
Indica	ate by check mark whether the registrant is a shell company	(as defined	d in Rule 12b-2 of the Exchange Act).	
		Yes _	No <u>X</u>	
Numl	ber of shares outstanding of each of the registrant's classes o	of common	n stock as of April 14, 2009:	
	Class of Common Stock		Number of Shares	
	Class A Stock, \$0.001 par valu	ue	2,246,698	
	Common Stock, \$0.001 par val		77,845,431	

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PART I. FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AT MARCH 31, 2009 AND DECEMBER 31, 2008 (Unaudited) (In thousands, except share data)

	March 31, 2009	December 31, 2008
ASSETS Current assets		
Cash and rash equivalents Marketable securities	\$ 199.097 216,785	8 247 796 226,954
Accounts receivable from the sanoti-aventis Group	44,576	33,302
Accounts receivable - other Prepaid expenses and other current assets	3,633 19,700	1,910 11.4 8 0
Total current assets	483,791	521,442
Restricted cash Marketable securities	1.650 78,460	1 650 51,061
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization.	109.840	87.853
Other assets Total assets	7,680 \$ 681,421	8,032 \$ 670.038
LIABILITIES and STOCKHOLDERS' EQUITY		
Current liabilities Accounts payable and accrued expenses	\$ 44.832	\$ 36,168
Deferred revenue from sanofi-aventis, current portion Deferred revenue— other, current portion	21,525 36 ,756	21,390 26,1 ‡4
Total current liabilities	103,113	83,672
Deferred revenue from sanofi: aventis Deferred revenue - other	100 474 54,364	105,586 56,835
Other long term Babilities Total liabilities	13.150 271,101	5. 093 251,186
Commitments and contingencies	271,101	201,100
Stockholdars equity Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and		
outstanding-none Class A Stock convertible \$ 001 par value, 40,000,000 shares authorized: shares issued and outstanding 2,246,698 in 2009 and 2,248,698 in 2008 Common Stock, \$.001 par value; 160,000,000 shares authorized;	2	2
shares issued and outstanding - 77,841,540 in 2009 and 77,642,203 in 2008	78	78
Additional pend-in capital Accumulated deficit	1. 304.896 (893,408)	1,294,813 (875,927)
Accumulated other comprehensive loss Total stockholders' equity	410,320	418,852
Total liabilities and stockholders' equity	5 681 421	\$ 670,038

	Three months	ended March 31,
	2009	2008
Revenues		
Contract research and development from sanofi-aventis	\$ 49,660	\$ 35,734
Other contract research and development	11.430	10,649
Technology licensing	10,000	10,000
Net product sales	3,891	
	74,981	56,383
Expenses		
Research and development	82,146	61,270
Selling, general, and administrative	11,674	11.024
Cost of goods sold	392	
	94,212	72,294
Loss from operations	119,231)	(15.911)
Other income (expense) Investment income	1.750	7,304
Interest expense	1,730	(3.011)
Bacardon Capado	1,750	4,293
	1,730	4,233
Net loss	\$ (17.481)	\$ (11,618)
Net loss per share, busic and diluted	\$ (7) 324	\$ (0.15)

Weighted average shares outstanding, basic and diluted	79.498	78.493

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) For the three months ended March 31, 2009 (In thousands)

							Accumulated		
					Ad ditional		Other	Total	
	Class I	A Stock	Commo	n Stock	Paid-in	Accumulated	Comprehensive	Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Loss	Equity	Loss
Balance, December 31, 2008	2,249	8 2	77.642	3 78	8 1,294,814	8 (875,927)	\$ (114)	3 418.852	
Issuance of Common Stock in connection with									
exercise of stock options, net of shares tendered	i		117		1,038			1,038	
Issuance of Common Stock in connection with									
Company 401(I.) Savings Plan contribution			81		1,363			1,391	
Conversion of Class A Stock to Common Stock	(2)		2						
Stock - based compensation expense					7.854			7.654	
Net loss						(17,481)		(17,481)	\$ (17,481)
Change in net unrealized loss on									
marketable securities							(1.134)	(1.134)	(1.194)
Balance, March 31, 2009	2,247	\$ 2	77,842	\$ 78	\$ 1,304,896	\$ (893,408)	\$ (1,248)	\$ 410,320	\$ (18,615)

	Three months e	ended March 31, 2008
Cash flows from operating activities Net loss	\$ (17,481)	\$ (11,618)
Adjustments to reconcile net loss to net cash used in operating activities	(11,131)	(11,110)
Depreciation and amortization Non-cash compensation expense	2,724 7.654	2,946 8.28 6
Changes in assets and liabilities		
Increase in accounts receivable (Increase) decrease in prepaid expenses and other assets	(12.997) (8,611)	(14,640) 1,493
Increase in deferred revenue Increase (decrease) in accounts payable, accrued expenses,	3.194	3,200
and other liabilities	15,318	(7,564)
Total adjustments Net cash used in operating activities	(10,199)	(17,897)
Cash flaws from investing activities Purchases of marketable securities	(100,315)	(91,518)
Sales or maturities of marketable securities	82.694	132,509
Capital expenditures Net cash (used in) provided by investing artivities	(21,917) (39,538)	(3,047)
Cash flows from financing activities Net proceeds from the issuance of Common Stock	1.038	1,903
Net cash provided by financing activities	1,038	1,903
Net (decrease) increase in cash and cash equivalents	(48.699)	21.950
Cash and cash equivalents at beginning of period	247.796	498.925
Cash and cash equivalents at end of period	\$ 199.097	<u>\$ 520.875</u>

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2008 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2008.

Included in research and development expenses is the Company's share of VEGF Trap-Eye development expenses incurred by Bayer HealthCare LLC, including the Company's share of Bayer HealthCare's estimated VEGF Trap-Eye development expenses for the most recent interim fiscal quarter. The Bayer HealthCare estimate is adjusted to agree with actual expenses for such quarter in the subsequent interim fiscal quarter.

Effective in the first quarter of 2009, the estimated useful lives of laboratory and other equipment, which is a component of property, plant, and equipment, has been extended from 3 – 5 years to 3 – 10 years. The effect of this change in estimate was to lower depreciation expense by \$0.2 million for the first quarter of 2009. There was no impact on the net loss per share as a result of this change in estimate.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the FDA for ARCALYST for the treatment of CAPS. For the three months ended March 31, 2009, the Company recognized as revenue \$3.9 million of ARCALYST net product sales for which the right of return no longer existed and rebates could be reasonably estimated. At March 31, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled \$4.2 million and \$0.8 million, respectively.

Cost of goods sold related to ARCALYST sales totaled \$0.4 million for the three months ended March 31, 2009 and consisted primarily of royalties. To date, ARCALYST shipments to the Company's customers consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST; therefore, the costs of these supplies were not included in costs of goods sold. At March 31, 2009, the Company had \$0.3 million of inventoried work-in-process costs related to ARCALYST, which is included in prepaid expenses and other current assets. There were no capitalized inventory costs at December 31, 2008.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three months ended March 31, 2009 and 2008, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended March		
	2009	2008	
Net loss (Numerator)	\$ (17.481) \$	(11.618)	
Weighted-average shares, in thousands (Denominator)	79.498	78.493	
Basic and diluted net less per share	\$ (0.22)	(0.15)	

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the March 31, 2009 and 2008 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months en	nded March 31,
	2009	2008
Stock Options		
Weighted average number, in thousands	20,216	17,680
Weighted average exercise price	8 17.55	5 17.16
Restricted Stock		
Weighted average number, in thousands	500	500
Convertible Debt		
Weighted average number, in thousands	•••••	6,611
Conversion price		\$ 30.25

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2009 and December 31, 2008 were \$9.8 million and \$7.0 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2008 and December 31, 2007 were \$1.5 million and \$1.7 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2008 and 2007 were \$1.5 million and \$1.1 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2009 and 2008, the Company contributed 81,086 and 58,575 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at March 31, 2009 and December 31, 2008 were \$2.5 million and \$1.7 million, respectively, of accrued interest income. Included in marketable securities at March 31, 2008 and December 31, 2007 were \$2.1 million and \$2.2 million, respectively, of accrued interest income.

5. Fair Value of Financial Assets

The Company's assets that are measured at fair value on a recurring basis, and subject to the disclosure requirements of Statement of Financial Accounting Standards No. ("SFAS") 157, Fair Value Measurements, at March 31, 2009 and December 31, 2008, were as follows:

		Fair Value Measurements at Reporting Date Using		
		Quoted Prices in	Significant Other	Significant
	Fair Value at	Active Markets for	Observable	Unobservable
	March 31,	Identical A ssets	Inputs	Inputs
Description	2009	(Level 1)	(Level 2)	(Level 3)
Available-for-sale marketable securities	\$ 295,245	\$ 3,138	\$ 292,007	\$ 100
		Fair Value Measu	rements at Reportin	g Date Using
		Quoted Prices in	Significant Other	Significant
	Fair Value at	Active Markets for	Observable	Unobservable
	December 31,	Identical A ssets	Inputs	Inputs
Description	2008	(Level 1)	(Level 2)	(Level 3)
Available-for-sale marketable securities	\$ 278.015	\$ 3,608	8 247.307	\$ 100

There were no realized or unrealized gains or losses related to the Company's Level 3 marketable securities for the three months ended March 31, 2009 and 2008. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities, and no transfers of marketable securities between the Level 2 and Level 3 classifications, during the quarters ended March 31, 2009 and 2008.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. During the three months ended March 31, 2009 and 2008, the Company did not record any charges for other-than-temporary impairment of its marketable securities. However, the current economic environment, the deterioration in the credit quality of some of the issuers of securities that the Company holds, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in the Company's investment portfolio and that such declines could result in charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2009 and December 31, 2008 consist of the following:

	March 31,	December 31,
	2009	2008
Acrounts payable	8 17.779	\$ 6266
Payable to Bayer HealthCare		9,799
Accrued payroll and related costs	8,352	5.948
Accrued clinical trial expense	6,558	4,273
Accrued property, plant, and equipment expenses	8.069	5 994
Accrued expenses, other	4,074	3,886
	\$ 44.832	\$ 36,168

7. Comprehensive Loss

The Company presents comprehensive income (loss) in accordance with SFAS 130, *Reporting Comprehensive Income*. Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. For the three months ended March 31, 2009 and 2008, the components of comprehensive loss are:

	Three months ended March 31,	
	2009	2008
Net loas	\$ (17.481)	\$ (11,618)
Change in net unrealized gain (loss) on marketable securities	(1,134)	658
Total comprehensive loss	5 (18.615)	\$ (10,960)

8. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

9. Future Impact of Recently Issued Accounting Standards

In April 2009, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position ("FSP") FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. This FSP amends SFAS 107, *Disclosures about Fair Value of Financial Instruments*, to require entities to provide disclosures about the fair value of financial instruments in interim financial information. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. In addition, an entity shall disclose in the body or in the accompanying notes of its summarized financial information for interim reporting periods and in its financial statements for annual reporting periods the fair value of all financial instruments for which it is practicable to estimate that value, whether recognized or not recognized in the statement of financial position, as required by SFAS 107. The Company is required to adopt FSP FAS 107-1 and APB 28-1 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 107-1 and APB 28-1 will have a material impact on the Company's financial statements.

In April 2009, the FASB issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. This FSP changes existing guidance for determining whether an impairment to debt securities is other than temporary; replaces the existing requirement that management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert, (a) it does not have the intent to sell the security; and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis; requires that an entity recognize noncredit losses on held-to-maturity debt securities in other comprehensive income and amortize that amount over the remaining life of the security in a prospective manner by offsetting the recorded value of the asset unless the security is subsequently sold or there are additional credit losses; and requires entities to present the total other-than-temporary impairment in the statement of earnings with an offset for the amount recognized in other comprehensive income. When adopting FSP FAS 115-2 and FAS 124-2, entities are required to record a cumulative-effect adjustment as of the beginning of the period of adoption to reclassify the noncredit component of a previously recognized other-temporary impairment from retained earnings to accumulated other comprehensive income if the entity does not intend to sell the security and it is not more likely than not that the entity will be required to sell the security before recovery. The Company is required to adopt FSP FAS 115-2 and FAS 124-2 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 115-2 and FAS 124-2 will have a material impact on the Company's financial statements.

In April 2009, the FASB issued FSP FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly.* This FSP affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell the asset in an orderly transaction; clarifies and includes additional factors for determining whether there has been a significant decrease in market activity for an asset when the market for that asset is not active; and eliminates the proposed presumption that all transactions are distressed (not orderly) unless proven otherwise. The FSP instead requires an entity to base its conclusion about whether a transaction was not orderly on the weight of the evidence. The Company is required to adopt FSP FAS 157-4 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 157-4 will have a material impact on the Company's financial statements.

10. Subsequent Event - Amendment to Operating Lease

The Company leases laboratory and office facilities in Tarrytown, New York. In December 2006, the Company entered into a new agreement (which was amended in October 2007 and September 2008) to lease laboratory and office space at the Company's current Tarrytown location, including space that is now under construction and expected to be completed in mid-2009 (the "new facilities"). The term of the lease commenced effective June 2008 and will expire in June 2024. In April 2009, the Company amended the operating lease agreement to increase the amount of space the Company will lease. As amended, the lease contains early termination options for the portion of the space that excludes the new facilities. Other terms and conditions, as previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, remain unchanged. In connection with the lease amendment, in April 2009, the Company terminated an April 2008 sublease for space in Tarrytown, New York.

In connection with the April 2009 amendment to the operating lease, the Company's total estimated future minimum noncancelable lease commitments under operating leases, previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, will increase to \$9.4 million, \$14.5 million, \$14.7 million, \$13.7 million, and \$15.1 million for the years ended December 31, 2009, 2010, 2011, 2012, and 2013, respectively, and increase to \$182.5 million, in the aggregate, for years subsequent to 2013.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We also have six clinical development programs, including three late-stage clinical programs. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST, which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis, REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed in collaboration with sanofi-aventis.

We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted primarily in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, and cardiovascular diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our clinical development and manufacturing capabilities to build a successful, integrated biopharmaceutical company. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*TM technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (*Velocimmune*®) and cell line expression technologies (*VelociMab*TM) may then be utilized to design and produce new product candidates directed against the disease target. Our first three antibody product candidates currently in clinical trials were developed using *Velocimmune*. Over the course of the next several years, we plan to advance an average of two to three new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Commercial Product:

ARCALYST® (rilonacept) - Cryopyrin-Associated Periodic Syndromes (CAPS)

In February 2008, we received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We shipped \$10.7 million of ARCALYST to our distributors in 2008, and \$4.3 million during the first quarter of 2009. ARCALYST is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST is the only therapy approved in the United States for patients with CAPS, a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as *CIAS1*) which encodes a protein named cryopyrin. In addition to FCAS and MWS, CAPS includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST has not been studied for the treatment of NOMID.

In March 2008, ARCALYST became available for prescription in the United States and we transitioned the patients who participated in the CAPS pivotal study from clinical study drug to commercial supplies. In 2009, we expect to ship \$15-20 million of ARCALYST to our U.S. distributors. In July 2008, we submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMEA) for ARCALYST for the treatment of CAPS in the European Union.

Clinical Programs:

1. Aflibercept (VEGF Trap) - Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF) and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PIGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are enrolling patients in four Phase 3 trials that are evaluating combinations of aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer (called VELOUR) in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial is evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine (VANILLA). A third trial is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel (VITAL). The fourth trial is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone (VENICE). All four trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. At the end of the first quarter of 2009, each of the four Phase 3 trials was approximately one-half enrolled, and initial data from the Phase 3 program are expected are 2010. In addition, a Phase 2 study of aflibercept in 1st-line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin (AFFIRM) began recruiting patients in January 2009.

Aflibercept is also being studied in a Phase 2 single-agent study in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA). This trial is now fully enrolled and initial data from this trial are expected by mid-2009. The FDA has granted Fast Track designation to aflibercept for the treatment of SMA.

In addition, multiple exploratory studies are being conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) collaborate on the development and commercialization of aflibercept globally. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

2. VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare also initiated a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME) in late 2008. Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. We and Bayer HealthCare have also announced plans to initiate a Phase 3 program later this year of VEGF Trap-Eye in the treatment of Central Retinal Vein Occlusion (CRVO). Dosing of the first patient in this Phase 3 program will entitle us to receive a \$20.0 million milestone payment.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and ranibizumab (Lucentis®, a registered trademark of Genentech, Inc./Roche), an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 mg and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with ranibizumab dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies. We and Bayer Healthcare expect to complete enrollment of the VIEW 1 and VIEW 2 trials in 2009 and initial data are expected in late 2010.

We and Bayer HealthCare have conducted a Phase 2 study in wet AMD which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year. Study results were reported at the 2008 annual meeting of the Retina Society.

In this double-masked Phase 2 trial, known as CLEAR-IT 2, 157 patients were initially treated for 3 months with VEGF Trap-Eye: two groups received monthly doses of 0.5 or 2.0 mg (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg (at baseline and week 12). Following the initial 3-month fixed-dosing phase, patients continued to receive VEGF Trap-Eye at the same dose on a PRN dosing schedule through one year, based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria.

Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 milligrams (mg) for 12 weeks followed by PRN dosing achieved mean improvements in visual acuity versus baseline of 9.0 letters (p<0.0001 versus baseline) and 5.4 letters (p<0.085 versus baseline), respectively, at the end of one year. The proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) increased from 23% at baseline to 45% at week 52 in patients initially treated with 2.0 mg monthly and from 16% at baseline to 47% at week 52 in patients initially treated with 0.5 mg monthly. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg also achieved mean decreases in retinal thickness versus baseline of 143 microns (p<0.0001 versus baseline) and 125 microns (p<0.0001 versus baseline) at week 52, respectively.

After week 12 to week 52 in the PRN dosing period, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 additional injections.

While PRN dosing following a fixed quarterly dosing regimen (with dosing at baseline and week 12) also yielded improvements in visual acuity and retinal thickness versus baseline at week 52, the results generally were not as robust as those obtained with initial fixed monthly dosing.

All patients who completed the one year CLEAR-IT 2 study were eligible to participate in an extension stage of the study. Eighteen month results of the extension stage are scheduled to be presented on May 4, 2009 at the 2009 Association for Research in Vision and Ophthalmology (ARVO) meeting. After receiving VEGF Trap-Eye for one year, the 117 patients who elected to enter the extension stage were dosed on a 2.0 mg PRN basis, irrespective of the dose at which they were treated earlier in the study. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters (p<0.0001 versus baseline) at the 3-month primary endpoint of the original Phase 2 study, 8.4 letters (p<0.0001 versus baseline) at one year, and 7.1 letters (p<0.0001 versus baseline) at month 6 of the extension stage. Thus, after 18 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 3.5 injections over the 15-month PRN dosing phase that extended from month 3 to month 18.

Among all the patients in the Phase 2 wet AMD study, VEGF Trap-Eye was generally well tolerated and there were no drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye and two arterial thrombotic events; these were deemed not to be drug-related. Three deaths were reported—one patient with pancreatic cancer, one patient with squamous cell carcinoma of the lung, and one patient with pulmonary hypertension (a pre-existing condition). The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

The recently initiated Phase 2 DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study is expected to complete enrollment of approximately 200 patients in the U.S., Canada, European Union, and Australia by the end of 2009. The patients in the study will be treated for 52 weeks followed by six additional months of safety evaluation. The primary efficacy endpoint is the change in best corrected visual acuity (BCVA) from baseline to week 24.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and other diseases and disorders. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare. In 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in the Phase 3 study of VEGF Trap-Eye in wet AMD, and can earn up to \$90 million in additional development and regulatory milestones related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

3. ARCALYST® (rilonacept) - Inflammatory Diseases

We are evaluating ARCALYST in gout, a disease where as in CAPS, IL-1 may play an important role in pain and inflammation. In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of ARCALYST versus placebo in the prevention of gout flares induced by the initiation of urate-lowering drug therapy that is used to control gout. In this 83-patient, double-blind, placebo-controlled study, the mean number of flares per patient over the first 12 weeks of urate-lowering therapy was 0.79 with placebo and 0.15 with ARCALYST (p=0.0011), an 81% reduction. This was the primary endpoint of the study. All secondary endpoints also were met with statistical significance. In the first 12 weeks of treatment, 45.2% of patients treated with placebo experienced a gout flare and, of those, 47.4% had more than one flare. Among patients treated with ARCALYST, only 14.6% experienced a gout flare (p=0.0037 versus placebo) and none had more than one flare. Injection-site reaction was the most commonly reported adverse event with ARCALYST and no serious drug-related adverse events were reported.

Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

During the first quarter of 2009, we initiated a Phase 3 clinical development program with ARCALYST for the treatment of gout. The program includes four clinical trials, three of which are currently enrolling patients. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) will evaluate ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) will evaluate treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The Phase 3 clinical development program also includes a separate placebo-controlled safety study (RE-SURGE). We expect to report initial data from the Phase 3 program in 2010.

Under a March 2003 collaboration agreement with Novartis Pharma AG, we retain the right to elect to collaborate in the future development and commercialization of a Novartis IL-1 antibody which is in clinical development. Following completion of Phase 2 development and submission to us of a written report on the Novartis IL-1 antibody, we have the right, in consideration for an opt-in payment, to elect to co-develop and co-commercialize the Novartis IL-1 antibody in North America. If we elect to exercise this right, we are responsible for paying 45% of post-election North American development costs for the antibody product, in return, we are entitled to co-promote the Novartis IL-1 antibody, and to receive 45% of net profits on sales of the antibody product, in North America. Under certain circumstances, we are also entitled to receive royalties on sales of the Novartis IL-1 antibody in Europe. Under the collaboration agreement, Novartis has the right to elect to collaborate in the development and commercialization of a second generation IL-1 Trap following completion of its Phase 2 development, should we decide to clinically develop such a second generation product candidate. Novartis does not have any rights or options with respect to ARCALYST.

4. Monoclonal Antibodies

We and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated using our *VelocImmune®* technology. The first therapeutic antibodies to enter clinical development under the collaboration are REGN88 and REGN475. REGN88, an antibody to the interleukin-6 receptor (IL-6R) is being evaluated in rheumatoid arthritis. REGN475, an antibody to Nerve Growth Factor (NGF) that binds NGF selectively without cross-reacting with other members of the neurotrophin family (such as neurotrophin-3, neurotrophin-4, and BDNF), is being developed for the treatment of pain. In addition, a Phase 1 trial is in the process of being initiated to evaluate REGN421, an antibody to Delta-like ligand-4 (Dll4), in patients with advanced malignancies. Over the course of the next several years, we and sanofi-aventis plan to advance an average of two to three new fully human monoclonal antibodies into clinical development each year.

Research and Development Technologies:

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of secreted proteins can have clinical benefit.

Regeneron scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST[®] (rilonacept), as well as aflibercept, and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite* is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies.

$VelociSuite^{TM}$

VelociSuite consists of VelocImmune®, VelociGene®, VelociMouse®, and VelociMabTM. The VelocImmune mouse platform is utilized to produce fully human monoclonal antibodies. VelocImmune was generated by exploiting our VelociGene technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. VelocImmune with the velociSuite offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the VelocImmune technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body, during normal body functioning, as well as in disease processes. For the optimization of pre-clinical development and toxicology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

The *VelociMouse* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, Regeneron's VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *Velocimmune* human monoclonal antibodies.

Antibody Collaboration with sanofi-aventis

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$75 million of research from the collaboration's inception through December 31, 2008 and will fund up to \$100 million per year in 2009 through 2012. Sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/45% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of \$21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofiaventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

License Agreement with AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made \$20.0 million annual, non-refundable payments to us in February 2007, 2008, and 2009. AstraZeneca is required to make up to three additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the next additional payment or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

License Agreement with Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made two \$20.0 million annual, non-refundable payments to us, one in April 2007 and the other in June 2008. Astellas is required to make up to four additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the first two additional payments or earlier if the technology does not meet minimum performance criteria. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

Academic VelocImmune® Investigators' Program

In September 2008, we entered into an agreement that will provide researchers at Columbia University Medical Center with access to our *VelocImmune* technology platform. In March 2009, we entered into a similar agreement with The University of Texas Southwestern Medical Center at Dallas. Under the agreements, scientists at these academic institutions will use *VelocImmune* mice to generate antibodies against their research targets and will conduct research to discover potential human therapeutics based on the antibodies. We have an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products and will pay to the appropriate institution a low single-digit royalty on ensuing product sales.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We are using our *VelociGene*® technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our *VelociGene* technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse ES cells which can be used to produce knockout mice. These materials are available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, as amended in September 2008, we are entitled to receive a minimum of \$24.5 million over the five-year period beginning September 2006, including \$1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which are being supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Research Programs:

Oncology and Angiogenesis

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In 1994, we discovered a second family of angiogenic growth factors, termed angiopoietins, and we have received patents covering members of this family. Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. Angiopoietins are being evaluated in preclinical research by us and our academic collaborators. Our preclinical studies have revealed that VEGF and angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Manipulation of both VEGF and angiopoietins seems to be of value in either promoting or blocking vessel growth. We have research programs focusing on several targets in the areas of oncology and angiogenesis.

Tumors depend on the growth of new blood vessels (a process called "angiogenesis") to support their continued growth. Therapies that block tumor angiogenesis, specifically those that block VEGF, the key initiator of tumor angiogenesis, recently have been validated in human cancer patients. However, anti-VEGF approaches do not work in all patients, and many tumors can become resistant to such therapies.

In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. We are in the process of initiating Phase 1 clinical development of a fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune*® technology.

Metabolic and Related Diseases

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in integrating peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program in this area encompasses the study of peripheral (hormonal) regulators of food intake and metabolism in health and disease. We have identified several targets in these therapeutic areas and are evaluating lead monoclonal antibodies in relevant preclinical models.

Muscle Diseases and Disorders

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle research program is currently focused on conducting in vivo and in vitro experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. We have several molecules in late stage research and are evaluating them for possible further development.

Other Therapeutic Areas

We also have research programs focusing on ophthalmology, inflammatory and immune diseases, bone and cartilage, pain, and cardiovascular diseases

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2009, we had a cumulative loss of \$893.4 million. In the absence of significant revenues from the commercialization of ARCALYST or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST in other indications; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2009 and plans over the next 12 months are as follows:

Clinical Program ARCALYST® (rilonacept; also known as IL-1 Trap)	2009 Events to Date Initiated patient enrollment in the Phase 3 program evaluating ARCALYST in the prevention of gout flares associated with the initiation of urate-lowering drug therapy and in the treatment of acute gout attacks	 2009-10 Plans (next 12 months) Continue enrollment in the Phase 3 program in gout
Aflibercept (VEGF Trap – Oncology)	 Initiated a Phase 2 1st-line study in metastatic colorectal cancer in combination with chemotherapy Achieved approximately 50% enrollment in each of the Phase 3 studies 	 Report results of a Phase 2 single-agent study in SMA Continue enrollment of the four Phase 3 studies
VEGF Trap-Eye (intravitreal injection)		 Complete enrollment in VIEW 1 and VIEW 2 trials Continue enrolling patients in the Phase 2 DME trial Initiate a Phase 3 CRVO program
Monoclonal Antibodies	Initiated a Phase 1 trial for REGN475 (anti-NGF) in healthy volunteers	 Initiate a Phase 1 trial for REGN421(anti Dll4) in oncology Report data from a Phase 1 trial of REGN88 (anti-IL-6R) in rheumatoid arthritis Initiate multiple Phase 2 trials for REGN475 in pain indications Advance additional antibody candidate(s) into clinical development
	20	

Results of Operations

Three Months Ended March 31, 2009 and 2008

Net Loss:

Regeneron reported a net loss of \$17.5 million, or \$0.22 per share (basic and diluted), for the first quarter of 2009 compared to a net loss of \$11.6 million, or \$0.15 per share (basic and diluted), for the first quarter of 2008. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher contract research and development revenue in connection with our antibody collaboration with sanofi-aventis and net product sales of ARCALYST® (rilonacept) for the treatment of CAPS.

Revenues:

Revenues for the three months ended March 31, 2009 and 2008 consist of the following:

(In millions)	2009	2008
Contract research & development revenue		
Sanofi-aventis \$	49.6	\$35.7
Bayor HealthCare	100	9.0
Other	1.5	1.7
Total contract research & development revenue	61.1	46.4
Technology licensing revenue	10.0	10.0
Net product sales	3.9	
Total revenue \$	75.0	\$56.4
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The contract and research development revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

Sanofi-aventis Contract Research & Development Revenue	Three mont	ths ended
(In millions)	March	1 31,
Aflibercept:	2009	2008
Regeneron expense reimbursement	\$ 5.4	\$ 11.7
Recognition of deferred revenue related to up-front payments	2.5	2.1
Total affibercept	7.9	13.8
Antibody:		
Regeneran expense reimbursement	38.4	19.3
Recognition of deferred revenue related to up-front payment	2.6	2.6
Recognition of revenue related to VelociCene® agreement	0.7	
Total antibody	41.7	21.9
Total sanofi-aventis contract research & development revenue	\$ 49.6	5 35.7

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in the first quarter of 2009, compared to the same period in 2008, primarily due to lower costs related to manufacturing aflibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments increased in the first quarter of 2009 compared to the same period in 2008 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of March 31, 2009, \$49.9 million of the original \$105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In the first quarter of 2009, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of \$22.7 million under the discovery agreement and \$15.7 million of development costs under the license agreement, compared to \$15.1 million and \$4.2 million, respectively, in the first quarter of 2008. Higher sanofi-aventis' reimbursements in the first quarter of 2009 compared to the same period in 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for REGN88, REGN421, and REGN475 under the license agreement.

Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' \$85.0 million up-front payment. As of March 31, 2009, \$71.0 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in August, 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the three months ended March 31, 2009, we recognized \$0.7 million of revenue related to this agreement.

The contract research and development revenue we earn from Bayer HealthCare, as detailed below, consists partly of cost sharing of Regeneron VEGF Trap-Eye development expenses and partly of recognition of revenue related to a non-refundable \$75.0 million up-front payment and \$20.0 million non-substantive milestone payment.

	Three mor	nths ended
Bayer HealthCare Contract Research & Development Revenue	Marc	ch 31,
(In millions)	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	γ 75	§ 57
Recognition of deferred revenue related to up-front and milestone payments	2.5	3.3
Total Bayer HealthCare contract research & development revenue	\$ 10.0	\$ 9.0

In the first quarter of 2009, cost-sharing of Regeneron VEGF Trap-Eye development expenses increased, compared to the same period in 2008, primarily due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD and Phase 2 trial in DME. Recognition of deferred revenue related to Bayer's up-front and milestone payments decreased in the first quarter of 2009 compared to the same period in 2008 due to an extension of the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of March 31, 2009, \$64.2 million of the up-front licensing and milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue in the first quarter of 2009 and 2008 includes \$1.5 million and \$1.1 million, respectively, in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

In connection with our *VelocImmune* license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the first quarter of both 2009 and 2008, we recognized \$10.0 million of technology licensing revenue related to these agreements.

For the three months ended March 31, 2009, we recognized as revenue \$3.9 million of ARCALYST[®] (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated. At March 31, 2009, deferred revenue related to ARCALYST net product sales totaled \$4.2 million.

Expenses:

Total operating expenses increased to \$94.2 million in the first quarter of 2009 from \$72.3 million in the same period of 2008. Our average headcount increased to 938 in the first quarter of 2009 from 714 in the same period of 2008 principally as a result of our expanding research and development activities which are primarily attributable to the sanofi-aventis antibody collaboration.

Operating expenses in the first quarter of 2009 and 2008 include a total of \$7.7 million and \$8.3 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended March 31, 2009		
	Expenses before		_
	inclusion of Non-cash	Non-cash	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported
Research and development	\$ 77.4	\$ 4.7	582.1
Selling, general, and administrative	8.7	3.0	11.7
Cost of goods sold	0.4		0.4
Total operating expenses	\$ 86.5	\$ 7.7	\$94.2
	<u> </u>		
For the three months ended March 31, 2008			
	Expenses before		
	inclusion of Non-cash	Non-cash	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported

Research and Development Expenses:

Research and development

Selling, general, and administrative

Total operating expenses

Research and development expenses increased to \$82.1 million in the first quarter of 2009 from \$61.3 million in the same period of 2008. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2009 and 2008:

56 4

7.6

64.O

49

3.4

8.3

861.3

11.0

\$72.3

_	For the three months ended March 31,		
Research and Development Expenses			Increase
(In millions)	2009	2008	(Decrease)
Payroll and benefits (1)	\$22.9	\$19.2	\$ 3.7
Clinical trial expenses	19.3	8.5	10.8
Clinical manufacturing costs (2)	14.1	14.7	(0.6)
Research and preclinical development costs	8.4	5.5	2.9
Occupancy and other operating costs	10.4	6.8	36
Cost-sharing of Bayer HealthCare VEGF			
Trap-Eye development expenses (3)		<u>6.6</u>	<u>0.4</u>
Total research and development	<u>\$82.1</u>	\$61.3	\$20.8

Includes \$4.0 million and \$4.2 million of Non-cash Compensation Expense for the three months ended March 31, 2009 and 2008,

Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.7 million of Non-cash Compensation Expense for both the three months ended March 31, 2009 and 2008. Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development

expenses that we are obligated to reimburse.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD and Phase 2 trial in DME, (ii) ARCALYST, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibodies, primarily related to REGN88 in rheumatoid arthritis. Clinical manufacturing costs decreased due to lower costs related to manufacturing aflibercept clinical supplies, partially offset by higher costs related to manufacturing clinical supplies of ARCALYST and monoclonal antibodies, including REGN88. Research and preclinical development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new operating lease for our Tarrytown, New York facilities, which commenced in June 2008. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses slightly increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD, which is being conducted by Bayer HealthCare.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs (including ARCALYST for the treatment of CAPS prior to receipt of marketing approval from the FDA in February 2008) are shown below:

Project Costs	For the three months ended March 31,		
			Increase
(In millions)	2009	2008	(Decrease)
ARCALYST® (riionacept)	\$17.9	\$ 8.0	\$ 9.9
Aflibercept	4.2	10.1	(5.9)
VEGF Trap Eye	20.8	16.6	4.2
REGN88	9.0	3.8	5.2
REGN421 and REGN475	4.9		4.9
Other research programs & unallocated costs	25.3	22.8	2.5
Total research and development expenses	<u> 382.1</u>	361.3	<u>520.8</u>

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborators where applicable, continue to explore further development of ARCALYST, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In the first quarter of 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. As a result, we can not predict whether the commercialization of ARCALYST in CAPS will result in a significant net cash benefit to us.

Selling, General, and Administrative Expenses:

Selling, general, and administrative expenses increased to \$11.7 million in the first quarter of 2009 from \$11.0 million in the same period of 2008 due to (i) higher selling expenses related to ARCALYST, (ii) higher compensation expense due primarily to increases in administrative headcount to support our expanded research and development activities, and (iii) higher administrative facility-related costs arising principally in connection with our higher headcount and the new operating lease for our Tarrytown, New York facilities, which commenced in June 2008.

Cost of Goods Sold:

In the third quarter of 2008, we began recognizing revenue and cost of goods sold from product sales of ARCALYST. We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not being included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold for the first quarter of 2009 was \$0.4 million and consisted primarily of royalty and other period costs related to ARCALYST commercial supplies.

Other Income and Expense:

Investment income decreased to \$1.8 million in the first quarter of 2009 from \$7.3 million in the comparable quarter of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in the first quarter of 2009 compared to the same quarter of 2008. Interest expense was \$3.0 million in the first quarter of 2008 and related to \$200.0 million of formerly outstanding 5.5% Convertible Senior Subordinated Notes which we either repurchased or repaid in full during 2008.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, and our technology licensing agreements, ARCALYST product revenue, and investment income.

Three months ended March 31, 2009 and 2008

At March 31, 2009, we had \$496.0 million in cash, cash equivalents, restricted cash, and marketable securities compared with \$527.5 million at December 31, 2008. In February 2009, we received a \$20.0 million annual, non-refundable payment in connection with our non-exclusive license agreement with AstraZeneca.

Cash Used in Operations:

Net cash used in operations was \$10.2 million in the first quarter of 2009 compared to \$17.9 million in the first quarter of 2008. Our net losses of \$17.5 million in the first quarter of 2009 and \$11.6 million in the first quarter of 2008 included \$7.7 million and \$8.3 million, respectively, of Non-cash Compensation Expense.

At March 31, 2009, accounts receivable increased by \$13.0 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, prepaid expenses and other assets increased by \$8.6 million at March 31, 2009 compared to end-of-year 2008 due primarily to higher prepaid clinical trial costs. At March 31, 2009, accounts payable, accrued expenses, and other liabilities increased by \$15.3 million compared to end-of-year 2008. The increase was due primarily to higher liabilities for clinical trial and payroll costs, and capital expenditures, primarily for tenant improvements and related costs in connection with our new leased facilities in Tarrytown, New York, partially offset by a lower cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration.

At March 31, 2008, accounts receivable increased by \$14.6 million, compared to end-of-year 2007, primarily due to higher receivable balances related to our collaborations with sanofi-aventis. Accounts payable, accrued expenses, and other liabilities decreased by \$7.6 million at March 31, 2008, compared to end-of-year 2007, due primarily to reductions in accrued payroll costs and the amount of the cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was \$39.5 million in the first quarter of 2009 compared to net cash provided by investing activities of \$37.9 million in the same period of 2008, due primarily to an increase in purchases of marketable securities net of sales or maturities. In the first quarter of 2009, purchases exceeded sales or maturities of marketable securities by \$17.6 million, whereas in the first quarter of 2008, sales or maturities exceeded purchases of marketable securities by \$41.0 million. In addition, cash used for capital expenditures totaled \$21.9 million in the first three months of 2009, primarily for tenant improvements and related costs in connection with our new leased facilities in Tarrytown.

Cash Provided by Financing Activities:

Cash provided by financing activities decreased to \$1.0 million in the first quarter of 2009 from \$1.9 million in the same period in 2008 due to a decrease in issuances of Common Stock in connection with exercises of employee stock options.

Fair Value of Marketable Securities:

At March 31, 2009 and December 31, 2008, we held marketable securities whose aggregate fair value totaled \$295.2 million and \$278.0 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

March 31, 2009		December 31, 2008	
Fair Value	Percent	Fair Value	Percent
\$ 131.0	44%	\$ 113.9	41%
59.9	20%	58.3	21%
48.9	17%	29.8	11%
11.3	4%	17.4	6%
32.1	11%	37.1	13%
8.8	3%	17.8	7%
3.2	190	37	
\$ 295.2	100%	\$ 278.0	100%
	Fair Value \$ 131.0 59.9 48.9 11.3 32.1 8.8 3.2	Fair Value Percent 8 131.0 44% 59.9 20% 48.9 17% 11.3 4% 32.1 11% 8.8 3% 3.2 136	Fair Value Percent Fair Value \$ 131.0 44% \$ 113.9 59.9 20% 58.3 48.9 17% 29.8 11.3 4% 17.4 32.1 11% 37.1 8.8 3% 17.8 3.2 196 3.7

In addition, at March 31, 2009 and December 31, 2008, we had \$200.8 million and \$249.5 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During the first quarter of 2009, as marketable securities in our portfolio matured or paid down, we purchased primarily U.S. Treasury securities, U.S. government agency obligations and U.S. government-guaranteed debt. This shift toward higher quality securities, which we initiated in 2008, continues to reduce the risk profile, as well as the overall yield, of our portfolio. In particular, we continue to reduce the proportion of asset-backed securities and corporate bonds in our portfolio.

Capital Expenditures:

Our additions to property, plant, and equipment totaled \$24.7 million and \$2.8 million for the first three months of 2009 and 2008, respectively. During the remainder of 2009, we expect to incur, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and the new Tarrytown facilities approximately \$80 to \$90 million in capital expenditures of which up to approximately \$50 million is reimbursable at our option from our landlord under the terms of our Tarrytown operating lease.

Amendment to Operating Lease - Tarrytown, New York Facilities:

We currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York. In December 2006, we entered into a new operating lease agreement (as amended in October 2007 and September 2008) to lease approximately 348,000 square feet of laboratory and office space at our current Tarrytown location, including approximately 230,000 square feet in new facilities that are currently under construction and expected to be completed in mid-2009. The term of the lease commenced effective June 2008 and will expire in June 2024. In April 2009, we amended the operating lease agreement to increase the amount of space we will lease to approximately 389,500 square feet. As amended, the lease contains early termination options on approximately 159,500 square feet of space. Other terms and conditions, as previously described in our Annual Report on Form 10-K for the year ended December 31, 2008, remain unchanged. In connection with the lease amendment, in April 2009, we terminated a sublease for 16,200 square feet of space in Tarrytown, New York.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 55-65% of our expenditures for 2009 will be directed toward the preclinical and clinical development of product candidates, including ARCALYST® (rilonacept), aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88, REGN421, and REGN475); approximately 15-20% of our expenditures for 2009 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2009 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

We currently anticipate that in 2009 sales of ARCALYSTfor the treatment of CAPS will not materially enhance or otherwise materially impact our cash flows.

In connection with the April 2009 amendment to our operating lease agreement in Tarrytown, New York, as described above, our funding requirements for operating leases, previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008, will increase (i) from \$9.1 million to \$9.4 million for the year ending December 31, 2009, (ii) from \$26.8 million to \$29.2 million for the two-year period beginning January 1, 2010, (iii) from \$27.2 million to \$28.8 million for the two-year period beginning January 1, 2012, and (iv) from \$167.0 million to \$182.5 million for the fiscal years beginning January 1, 2014 and thereafter.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patent and other intellectual property claims will continue to be substantial as a result of patent filings and prosecutions in the United States and foreign countries.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we believe we would prioritize available capital to fund selected preclinical and clinical development programs.

Other than letters of credit totaling \$1.7 million, including a \$1.6 million letter of credit issued to our landlord in connection with our operating lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of March 31, 2009, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In April 2009, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position ("FSP") FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. This FSP amends SFAS 107, *Disclosures about Fair Value of Financial Instruments*, to require entities to provide disclosures about the fair value of financial instruments in interim financial information. This FSP also amends APB Opinion No. 28, *Interim Financial Reporting*, to require those disclosures in summarized financial information at interim reporting periods. In addition, an entity shall disclose in the body or in the accompanying notes of its summarized financial information for interim reporting periods and in its financial statements for annual reporting periods the fair value of all financial instruments for which it is practicable to estimate that value, whether recognized or not recognized in the statement of financial position, as required by SFAS 107. We are required to adopt FSP 107-1 and APB 28-1 will have a material impact on our financial statements.

In April 2009, the FASB issued FSP FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*. This FSP changes existing guidance for determining whether an impairment to debt securities is other than temporary; replaces the existing requirement that management assert it has both the intent and ability to hold an impaired security until recovery with a requirement that management assert: (a) it does not have the intent to sell the security; and (b) it is more likely than not it will not have to sell the security before recovery of its cost basis; requires that an entity recognize noncredit losses on held-to-maturity debt securities in other comprehensive income and amortize that amount over the remaining life of the security in a prospective manner by offsetting the recorded value of the asset unless the security is subsequently sold or there are additional credit losses; and requires entities to present the total other-than-temporary impairment in the statement of earnings with an offset for the amount recognized in other comprehensive income. When adopting FSP FAS 115-2 and FAS 124-2, entities are required to record a cumulative-effect adjustment as of the beginning of the period of adoption to reclassify the noncredit component of a previously recognized other-temporary impairment from retained earnings to accumulated other comprehensive income if the entity does not intend to sell the security and it is not more likely than not that the entity will be required to sell the security before recovery. We are required to adopt FSP FAS 115-2 and FAS 124-2 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 115-2 and FAS 124-2 will have a material impact on our financial statements.

In April 2009 the FASB issued FSP FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly.* This FSP affirms that the objective of fair value when the market for an asset is not active is the price that would be received to sell the asset in an orderly transaction; clarifies and includes additional factors for determining whether there has been a significant decrease in market activity for an asset when the market for that asset is not active; and eliminates the proposed presumption that all transactions are distressed (not orderly) unless proven otherwise. The FSP instead requires entities to base its conclusion about whether a transaction was not orderly on the weight of the evidence. We are required to adopt FSP FAS 157-4 for the quarter ended June 30, 2009. Management does not anticipate that the adoption of FSP FAS 157-4 will have a material impact on our financial statements

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate, asset-backed, and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent unfavorable change in interest rates would result in approximately a \$1.6 million and \$1.8 million decrease in the fair value of our investment portfolio at March 31, 2009 and 2008, respectively.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. In 2007, we recognized a \$5.9 million charge related to marketable securities from two issuers which we considered to be other than temporarily impaired in value. In 2008, an additional \$0.7 million impairment charge was recognized related to one of these securities and a \$1.8 million charge was recognized related to another marketable security which we considered to be other than temporarily impaired in value.

Item 4. Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2009, we had a cumulative loss of \$893.4 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of March 31, 2009, cash, cash equivalents, restricted cash, and marketable securities totaled \$496.0 million and represented 73% of our total assets. We have invested available cash balances primarily in money market funds and U.S. Treasury, U.S. government agency, corporate, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by Statement of Financial Accounting Standards No. (SFAS) 115, Accounting for Certain Investments in Debt and Equity Securities. Marketable securities totaled \$295.2 million at March 31, 2009, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss that is charged against income. For example, during the year ended December 31, 2008, we recorded charges for other-than-temporary impairments totaling \$2.5 million related to two marketable securities in our investment portfolio. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are studying aflibercept, VEGF Trap-Eye, ARCALYST® (rilonacept), and our antibody candidates in a wide variety of indications. Many of these current trials are exploratory studies designed to identify what diseases and uses, if any, are best suited for our product candidates. It is likely that our product candidates will not demonstrate the requisite efficacy and/or safety profile to support continued development for most of the indications that are being, or are planned to be, studied. In fact, our product candidates may not demonstrate the requisite efficacy and safety profile to support the continued development for any of the indications or uses.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Our aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST in only a small number of patients with CAPS. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (Amgen, Inc.), Enbrel® (Immunex Corporation), and Remicade® (Centocor, Inc.), ARCALYST affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST may interfere with the body's ability to fight infections. Treatment with Kineret (Amgen), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. These side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in approved indications.

ARCALYST® (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST. Nineteen of 55 subjects (35%) who received ARCALYST for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune®* technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech/Roche that claim certain chimeric VEGF receptor compositions. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech/Roche could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye. Genentech/Roche may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech/Roche's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech/Roche and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST® (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech/Roche patent, then we may need to obtain a license from Genentech/Roche, should one be available. Genentech/Roche has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech/Roche's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. Although we obtained regulatory approval for ARCALYST® (rilonacept) for the treatment of CAPS in the United States, we may be unable to obtain regulatory approval of ARCALYST in any other country or in any other indication. Regulatory agencies outside the United States may require additional information or data with respect to any future submission for ARCALYST for the treatment of CAPS.

If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current good manufacturing practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST for the treatment of CAPS or any of our product candidates in those countries.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST[®] (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated rules and listing standards covering a variety of subjects. Compliance with these rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2008, which report is included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates:
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that
 would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies; and
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and possible legislation which could ease the entry of competing follow-on biologics into the marketplace are examples of changes and possible changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofiaventis has committed to pay up to \$400 million between 2009 and 2012 to fund our efforts to identify and validate drug discovery targets and preclinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or optsout of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® (rilonacept) and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or at all, we could experience additional costs, delays, and difficulties in the manufacture, development, or ultimate commercialization of our product candidates.

We rely on third party service providers to support the distribution of ARCALYST and many other related activities in connection with the commercialization of ARCALYST for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures or a business interruption at our manufacturing facility in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST and our product candidates at our manufacturing facility in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, or other problems at the facility.

Certain raw materials necessary for manufacturing and formulation of ARCALYST and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of affibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept) in this indication.

Our only approved product is ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. As a result, there may be too few patients with CAPS to profitably commercialize ARCALYST in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech/Roche has an approved VEGF antagonist, Avastin® (bevacizumab), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline plc. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech/Roche's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech/Roche) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech/Roche are collaborating on the commercialization and further development of a VEGF antibody fragment, ranibizumab (Lucentis®), for the treatment of age-related macular degeneration (wet AMD) and other eye indications that was approved by the FDA in June 2006. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party reformatted version of Genentech/Roche's approved VEGF antagonist, Avastin®, with success for the treatment of wet AMD. The National Eye Institute is conducting a Phase 3 trial comparing Lucentis (Genentech/Roche) to Avastin (Genentech/Roche) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech/Roche) and the potential off-label use of Avastin (Genentech/Roche) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech/Roche), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech/Roche) in patients with wet AMD presents a further competitive challenge in this indication.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (Immunex), Remicade® (Centocor), and Humira® (Abbott Laboratories), and the IL-1 receptor antagonist Kineret® (Amgen), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® (rilonacept). This is one of the reasons we discontinued the development of ARCALYST in adult rheumatoid arthritis. In addition, even if ARCALYST is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma, and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis has filed applications in the U.S. and Europe seeking regulatory approval of its IL-1 antibody in CAPS. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. Novartis has stated that its IL-1 antibody demonstrated long-lasting clinical remission in patients with CAPS and that its clinical candidate could develop into a major therapeutic advance in the treatment of CAPS. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. The successful development of these competing molecules could impair our ability to successfully commercialize ARCALYST.

We have plans to develop ARCALYST for the treatment of certain gout indications. Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST in these diseases.

The successful commercialization of ARCALYST® (rilonacept) and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have announced plans to initiate a Phase 3 program studying the use of ARCALYST for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST in the United States for the treatment of a group of rare genetic disorders called CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST. Physicians may not prescribe ARCALYST, and CAPS patients may not be able to afford ARCALYST, if third party payers do not agree to reimburse the cost of ARCALYST therapy and this would adversely affect our ability to commercialize ARCALYST profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since ARCALYST and our product candidates in clinical development, will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Our move to new facilities in mid-2009 could lead to disruptions in our business operations.

We plan to move most of our laboratories and headquarters to new facilities in mid-2009. There is a risk that this physical move could lead to damage to equipment or other business assets or the loss of important data, or that we could encounter problems with our new facilities, which could disrupt or delay our business operations.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their party patents;
- public concern as to the safety or effectiveness of ARCALYST® (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- · general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 14, 2009, our five largest shareholders plus Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, beneficially owned 52.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2009. As of April 14, 2009, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 19.0% of the shares of Common Stock then outstanding. Under our investor agreement with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2012 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 14, 2009, holders of Class A Stock held 22.4% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, plus any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority approval of the combined classes, including mergers and other business combinations. This may result in us taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of April 14, 2009:

- our current executive officers and directors beneficially owned 13.3% of our outstanding shares of Common Stock, assuming conversion of
 their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April
 14, 2009, and 28.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of
 all options held by such persons which are exercisable within 60 days of April 14, 2009; and
- our five largest shareholders plus Leonard S. Schleifer, M.D., Ph.D., our Chief Executive Officer, beneficially owned 52.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2009. In addition, these six shareholders held 57.2% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 14, 2009.

Pursuant to an investor agreement, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit

Number	Descrip	tion
10.1	-	Form of option agreement and related notice of grant for use in connection with the grant of time based vesting stock options to the Registrant's non-employee directors and executive officers.
10.2	-	Form of option agreement and related notice of grant for use in connection with the grant of performance based vesting stock options to the Registrant's executive officers.
10.3	-	Third Amendment to lease, by and between BMR-Landmark at Eastview LLC and Regeneron Pharmaceuticals, Inc., entered into as of April 29, 2009.
31.1	-	Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	-	Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	-	Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
		44

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: April 30, 2009

By: /s/ Murray A. Goldberg

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer and Duly Authorized Officer)

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Notice of Grant of Stock Options and Option Agreement for Time Vesting Option Awards	Regeneron Pharmaceuticals, Inc. ID: [] 777 Old Saw Mill River Road Tarrytown, New York 10591			
[OPTIONEE NAME] [OPTIONEE ADDRESS	Option Number: Plan: ID	[04 []	
Effective <date> (the Grant Date) you have been grant shares of Regeneron Pharmaceuticals, Inc. (the Comp.</date>		Stock C per sha	-	[Incentive Stock Option] to buy []
The total option price of the shares granted is $[\$]$.				
[Shares in each period will become fully vested on the	e date shown.			
[Shares Vest Type	Full	Vest		Expiration Date
** On Vest Date ** On Vest Date	[/	/ <u></u>]** / 1*>		[10 years from Grant Date] [10 years from Grant Date]
** On Vest Date		_/ J		[10 years from Grant Date]
** On Vest Date		_/]*>	×	[10 years from Grant Date]]
The [Non-Qualified Stock Option] [Incentive Stock Opti	on] expires on []*	** (the '	'Expirat	tion Date").
You and the Company agree that these options are granted und Restated 2000 Long-Term Incentive Plan and the enclosed Opti				
*** Options for executive officers will vest in approxifirst, second, third and fourth anniversaries of the approximately equal annual 33-1/3% installments. of the Grant Date. *** Date to be 10 years from the Grant Date.	Grant Date. Options	for non	ı-empl	ovee directors will vest in

REGENERON PHARMACEUTICALS, INC. OPTION AGREEMENT PURSUANT TO THE 2000 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT, made as of the date on the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee (or member of the Board of Directors) named on the *Notice of Grant of Stock Options* (the "Grantee");

WHEREAS, the Grantee is an employee or member of the Board of Directors of the Company and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the 2000 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's Common Stock (\$.001 par value) (the "Common Stock") as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

- 1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth here, the option to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share (the "Option") as shown on the *Notice of Grant of Stock Options*. No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").
- 2. Vesting; Exercise. (a) The Option is exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Section 7 (c) (1) & (2), the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c) (3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. In addition to the methods of payment described in Section 7(c) (3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having a Fair Market Value (as measured on the date of exercise) equal to the Option exercise price. The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.
- (b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall be entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (collectively, the Company and all Subsidiaries shall be referred to herein as the "Employer" and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on the Full Vest Dates. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by the Employer (or providing services as a member of the Board of Directors, as the case may be) and all unvested Options shall be forfeited at such time.

- (c) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of termination of the Grantee's employment with the Employer (or services as a member of the Board of Directors) if the Grantee's employment with the Employer (or services a member of the Board of Directors) is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Grantee for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment (or service as member of the Board of Directors) (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Internal Revenue Code Section 4999 (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; <u>provided</u>, <u>however</u>, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed between the
- 3. **Option** Term. (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as set forth in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7 (e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii)(A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement, or long-term disability, (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement, (C) one year after the termination if such termination is due to the Grantee's death or long-term disability, (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered) or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is by the Employer without Cause or by the Grantee for Good Reason.
- (b) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Company and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer, including without limitation, repeated refusal to follow the reasonable directions of the Employer, knowing violation of law in the course of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, and intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours (other than any such failure resulting from his or her incapacity due to physical or mental illness); (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

- (c) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by the Grantee within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Grantee to the Employer that Grantee intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Grantee's duties and responsibilities from that which exists immediately prior to a Change in Control (except in each case in connection with the termination of the Grantee's employment for Cause or as a result of the Grantee's death, or temporarily as a result of the Grantee's illness or other absence), or (2) the assignment to the Grantee of duties and responsibilities materially inconsistent with the position held by the Grantee: (B) any material breach by the Employer of any material provision of any written agreement with the Grantee or failure to timely pay any compensation obligation to the Grantee; (C) a reduction in the Grantee's annual base salary or target bonus opportunity (if any) from that which exists immediately prior to a Change in Control; or (D) if the Grantee is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Grantee's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or simil
- 4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.
- 5. Rights of a Stockholder. The Grantee shall have no rights as a stockholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates for such shares. No adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor.
- 6. Compliance with Law and Regulations. This award and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates bear such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.

- 7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof. The Plan is incorporated herein by reference, and any capitalized term used but not defined herein shall have the same meaning as in the Plan. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.
- 8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment or service, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.
- 9. No Obligation to Continue Employment. This Agreement does not guarantee that the Employer will employ the Grantee for any specified time period, nor does it modify in any respect the Grantee's employment or compensation.

Notice of Grant of Stock Options and Option Agreement for Performance Vesting Option Awards Regeneron Pharmaceuticals, Inc.
ID: []
777 Old Saw Mill River Road
Tarrytown, New York 10591

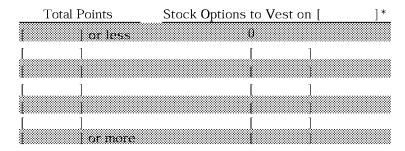
[OPTIONEE NAME]
[OPTIONEE ADDRESS

Option Number: []
Plan: 04
ID []

Effective <date> (the Grant Date) you have been granted a Non-Qualified Stock Option to buy [] shares of Regeneron Pharmaceuticals, Inc. (the Company) stock at [\$] per share.

The total option price of the shares granted is [\$]

Stock options granted pursuant to this award will be eligible to vest on []*. The number of stock options that will vest on that date will be determined based on the total number of points that are earned according to the table below during the period commencing on []* (the Performance Measurement Period):



Total points in the table set forth above will be calculated based on the following criteria as achieved during the Performance Measurement Period:

[Description of performance criteria and allocation of points for achieving specific milestones]

[For the avoidance of doubt, points may be earned upon achievement of the specified criteria by or on behalf of the Company or any subsidiary of the Company, including by any other entity pursuant to or in connection with any license or collaboration agreement under which such entity has rights to develop the Drug Candidate.]

[Notwithstanding the foregoing, if [insert certain criteria] have not been achieved during the Performance Measurement Period, then the number of stock options from this award that will vest on []* may not exceed [] unless otherwise determined by the Compensation Committee or there is an acceleration of this stock option award following a Change in Control pursuant to any employment agreement, change in control agreement or similar agreement in effect between the Grantee and the Company.

Notwithstanding anything to the contrary set forth herein, the Compensation Committee of the Board of Directors of the Company shall have the discretion to cause or accelerate the vesting of any or all of the stock options granted pursuant to this award.

The Compensation Committee of the Board of Directors of the Company shall have the authority in its sole discretion to determine whether the criteria required for earning the points in the table set forth above were achieved.

The Non-Qualified Stock Option expires on [10 years from the Grant Date].

You and the Company agree that these options are granted under and governed by the terms and conditions of the Company's Amended and Restated 2000 Long-Term Incentive Plan and the enclosed Option Agreement, both of which are attached and made a part of this document.

^{*} This date will be the last day of the Performance Measurement Period.

REGENERON PHARMACEUTICALS, INC. OPTION AGREEMENT PURSUANT TO THE 2000 LONG-TERM INCENTIVE PLAN

THIS AGREEMENT, made as of the date on the *Notice of Grant of Stock Options*, by and between Regeneron Pharmaceuticals, Inc., a New York corporation (the "Company"), and the employee [(or member of the Board of Directors)]* named on the *Notice of Grant of Stock Options* (the "Grantee");

WHEREAS, the Grantee is an employee [or member of the Board of Directors]* of the Company and the Company desires to afford the Grantee the opportunity to acquire or enlarge the Grantee's stock ownership in the Company so that the Grantee may have a direct proprietary interest in the Company's success; and

WHEREAS, the Committee administering the 2000 Long-Term Incentive Plan (as amended from time to time, the "Plan") has granted (as of the effective date of grant specified in the *Notice of Grant of Stock Options*) to the Grantee a Stock Option to purchase the number of shares of the Company's Common Stock (\$.001 par value) (the "Common Stock") as set forth in the *Notice of Grant of Stock Options*.

NOW, THEREFORE, in consideration of the covenants and agreements herein contained, the parties agree as follows:

- 1. Grant of Award. Pursuant to Section 7 of the Plan, the Company grants to the Grantee, subject to the terms and conditions of the Plan and subject further to the terms and conditions set forth here, the option to purchase from the Company all or any part of an aggregate of shares of Common Stock at the purchase price per share (the "Option") as shown on the Notice of Grant of Stock Options. [No part of the Option granted hereby is intended to qualify as an Incentive Stock Option under Section 422 of the Internal Revenue Code of 1986, as amended (the "Code").]* [Notwithstanding the foregoing, the Option will not qualify as an Incentive Stock Option, among other events, (i) if the Grantee disposes of the Common Stock acquired pursuant to the Option at any time during the two year period following the date of this Agreement or the one year period following the date on which the Option is exercised, or (ii) if the Grantee is not employed by the Company or a subsidiary of the Company within the meaning of Section 424 of the Code (a "Subsidiary") at all times during the period beginning on the date of this Agreement and ending on the day three months before the date of exercise of the Option, or (iii) to the extent the aggregate fair market value (determined as of the time the Option is granted) of the stock subject to Incentive Stock Options which become exercisable for the first time in any calendar year exceeds \$100,000. To the extent that the Option does not qualify as an Incentive Stock Option, it shall constitute a separate Non-Qualified Stock Option.]**
- 2. Vesting; Exercise. (a) The Option is exercisable in installments as provided on the *Notice of Grant of Stock Options*. To the extent that the Option has become exercisable with respect to the number of shares of Common Stock as provided on the *Notice of Grant of Stock Options* and subject to the terms and conditions of the Plan, including without limitation, Section 7 (c)(1) & (2), the Option may thereafter be exercised by the Grantee, in whole or in part, at any time or from time to time prior to the expiration of the Option in accordance with the requirements set forth in Section 7(c)(3) of the Plan, including, without limitation, the filing of such written form of exercise notice as may be provided by the Company, and in accordance with applicable tax and other laws. [In addition to the methods of payment described in Section 7(c)(3) of the Plan, the Grantee shall be eligible to pay for shares of Common Stock purchased upon the exercise of the Option by directing the Company to withhold shares of Common Stock that would otherwise be issued pursuant to the Option exercise having a Fair Market Value (as measured on the date of exercise) equal to the Option exercise price.]* The Company shall have the right to require the Grantee in connection with the exercise of the Option to remit to the Company in cash an amount sufficient to satisfy any federal, state and local withholding tax requirements related thereto.
- (b) The *Notice of Grant of Stock Options* indicates each date upon which the Grantee shall be entitled to exercise the Option with respect to the number of shares of Common Stock granted as indicated provided that the Grantee has not incurred a termination of employment or service with the Company and all Subsidiaries (collectively, the Company and all Subsidiaries shall be referred to herein as the "Employer" and no termination of employment or service shall be deemed to take place unless the Grantee is no longer employed by or providing service to the Employer) prior to such date. There shall be no proportionate or partial vesting in the periods between the Full Vest Dates specified in the *Notice of Grant of Stock Options* and all vesting shall occur only on the Full Vest Dates. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7(e) of the Plan, no vesting shall occur after such date as the Grantee ceases to be employed by the Employer [(or providing services as a member of the Board of Directors, as the case may be)]* and all unvested Options shall be forfeited at such time.

- (c) Notwithstanding anything herein (except the following sentence) or in the *Notice of Grant of Stock Options* to the contrary, the Option shall be fully vested on the date of termination of the Grantee's employment with the Employer [(or services as a member of the Board of Directors)]* if the Grantee's employment with the Employer [(or services a member of the Board of Directors)]* is terminated on or within two years after the occurrence of a Change in Control by the Employer (other than for Cause) or by the Grantee for Good Reason. Except as otherwise provided in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, if the application of the provision in the foregoing sentence, similar provisions in other stock option or restricted stock grants, and other payments and benefits payable to the Grantee upon termination of employment [(or service as member of the Board of Directors)]* (collectively, the "Company Payments") would result in the Grantee being subject to the excise tax payable under Internal Revenue Code Section 4999 (the "Excise Tax"), the amount of any Company Payments shall be automatically reduced to an amount one dollar less than an amount that would subject the Grantee to the Excise Tax; provided, however, that the reduction shall occur only if the reduced Company Payments received by the Grantee (after taking into account further reductions for applicable federal, state and local income, social security and other taxes) would be greater than the unreduced Company Payments to be received by the Grantee minus (i) the Excise Tax payable with respect to such Company Payments and (ii) all applicable federal, state and local income, social security and other taxes on such Company Payments. If the Company Payments are to be reduced in accordance with the foregoing, the Company Payments shall be reduced as mutually agreed betwee
- 3. **Option** Term. (a) Except as otherwise provided in the next sentence or in the Plan, the Option shall expire on the tenth anniversary of the grant of the Option as shown on the *Notice of Grant of Stock Options*. In the event of termination of employment or service with the Employer, except as set forth in any employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options*, or as may be otherwise determined by the Committee in accordance with Section 7 (e) of the Plan, the vested portion of the Option shall expire on the earlier of (i) the tenth anniversary of this grant, or (ii) (A) subject to (E) below, three months after such termination if such termination is for any reason other than death, retirement, or long-term disability, (B) the tenth anniversary of this grant if such termination is due to the Grantee's retirement, (C) one year after the termination if such termination is due to the Grantee's death or long-term disability, (D) the occurrence of the Cause event if such termination is for Cause or Cause existed at the time of such termination (whether then known or later discovered) or (E) one year after such termination if such termination is at any time within two years after the occurrence of a Change in Control and is by the Employer without Cause or by the Grantee for Good Reason.
- (b) For purposes of this Agreement, "Cause" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Company and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* (or where there is such an agreement or plan but it does not define "cause" (or words of like import)) (A) the willful and continued failure by the Grantee substantially to perform his or her duties and obligations to the Employer, including without limitation, repeated refusal to follow the reasonable directions of the Employer, knowing violation of law in the course of performance of the duties of the Grantee's employment with the Employer, repeated absences from work without a reasonable excuse, and intoxication with alcohol or illegal drugs while on the Employer's premises during regular business hours (other than any such failure resulting from his or her incapacity due to physical or mental illness); (B) fraud or material dishonesty against the Employer; or (C) a conviction or plea of guilty or nolo contendere to a felony or a crime involving material dishonesty or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the *Notice of Grant of Stock Options* that defines "cause" (or words of like import), as defined under such agreement or plan. For purposes of this Section 3(b), no act, or failure to act, on a Grantee's part shall be considered "willful" unless done, or omitted to be done, by the Grantee in bad faith and without reasonable belief that his or her action or omission was in the best interest of the Employer. Any determination of Cause made prior to a Change in Control shall be made by the Committee in its sole discretion.

- (c) For purposes of this Agreement, "Good Reason" shall mean (i) in the case where there is no employment agreement, consulting agreement, change in control agreement or similar agreement or plan in effect between the Employer and the Grantee on the date of grant specified in the Notice of Grant of Stock Options (or where there is such an agreement or plan but it does not define "good reason" (or words of like import)) a termination of employment by the Grantee within one hundred twenty (120) days after the occurrence of one of the following events after the occurrence of a Change in Control unless such events are fully corrected in all material respects by the Employer within thirty (30) days following written notification by the Grantee to the Employer that Grantee intends to terminate his employment hereunder for one of the reasons set forth below: (A) (1) any material diminution in the Grantee's duties and responsibilities from that which exists immediately prior to a Change in Control (except in each case in connection with the termination of the Grantee's employment for Cause or as a result of the Grantee's death, or temporarily as a result of the Grantee's illness or other absence), or (2) the assignment to the Grantee of duties and responsibilities materially inconsistent with the position held by the Grantee: (B) any material breach by the Employer of any material provision of any written agreement with the Grantee or failure to timely pay any compensation obligation to the Grantee; (C) a reduction in the Grantee's annual base salary or target bonus opportunity (if any) from that which exists immediately prior to a Change in Control; or (D) if the Grantee is based at the Employer's principal executive office, any relocation therefrom or, in any event, a relocation of the Grantee's primary office of more than fifty (50) miles from the location immediately prior to a Change in Control; or (ii) in the case where there is an employment agreement, consulting agreement, change in control agreement or similar
- 4. Restrictions on Transfer of Option. The Option granted hereby shall not be transferable other than by will or by the laws of descent and distribution. During the lifetime of the Grantee, this Option shall be exercisable only by the Grantee. In addition, except as otherwise provided in this Agreement, the Option shall not be assigned, negotiated, pledged or hypothecated in any way (whether by operation of law or otherwise), and the Option shall not be subject to execution, attachment or similar process. Upon any other attempt to transfer, assign, negotiate, pledge or hypothecate the Option, or in the event of any levy upon the option by reason of any execution, attachment, or similar process contrary to the provisions hereof, the Option shall immediately become null and void. Notwithstanding the foregoing provisions of this Section 4, subject to the approval of the Committee in its sole and absolute discretion and to any conditions that the Committee may prescribe, the Grantee may, upon providing written notice to the Company, elect to transfer the Option to members of his or her immediate family, including, but not limited to, children, grandchildren and spouse or to trusts for the benefit of such immediate family members or to partnerships in which such family members are the only partners; provided, however, that no such transfer may be made in exchange for consideration.
- 5. Rights of a Stockholder. The Grantee shall have no rights as a stockholder with respect to any shares of Common Stock subject to this Option prior to the date of issuance to the Grantee of a certificate or certificates for such shares. No adjustment shall be made for dividends in cash or other property, distributions, or other rights with respect to such shares for which the record date is prior to the date upon which the Grantee shall become the holder of record therefor.

- 6. Compliance with Law and Regulations. This award and any obligation of the Company hereunder shall be subject to all applicable federal, state and local laws, rules and regulations and to such approvals by any government or regulatory agency as may be required. The Company shall be under no obligation to effect the registration pursuant to federal securities laws of any interests in the Plan or any shares of Common Stock to be issued hereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued or delivered any certificates evidencing shares of Common Stock pursuant to this Agreement unless and until the Company is advised by its counsel that the issuance and delivery of such certificates is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which shares of Common Stock are traded. The Committee may require, as a condition of the issuance and delivery of certificates evidencing shares of Common Stock pursuant to the terms hereof, that the recipient of such shares make such agreements and representations, and that such certificates bear such legends, as the Committee, in its sole discretion, deems necessary or desirable. Except to the extent preempted by any applicable federal law, this Agreement shall be construed and administered in accordance with the laws of the State of New York without reference to its principles of conflicts of law.
- 7. Grantee Bound by Plan. The Grantee acknowledges receipt of a copy of the Plan and agrees to be bound by all the terms and provisions thereof. The Plan is incorporated herein by reference, and any capitalized term used but not defined herein shall have the same meaning as in the Plan. To the extent that this Agreement is silent with respect to, or in any way inconsistent with, the terms of the Plan, the provisions of the Plan shall govern and this Agreement shall be deemed to be modified accordingly.
- 8. Notices. Any notice or communication given hereunder shall be in writing and shall be deemed given when delivered in person, or by United States mail, at the following addresses: (i) if to the Employer, to: Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, Attention: Secretary, and (ii) if to the Grantee, to: the Grantee at Regeneron Pharmaceuticals, Inc., 777 Old Saw Mill River Road, Tarrytown, NY 10591, or, if the Grantee has terminated employment or service, to the last address for the Grantee indicated in the records of the Employer, or such other address as the relevant party shall specify at any time hereafter in accordance with this Section 8.
- 9. No Obligation to Continue Employment. This Agreement does not guarantee that the Employer will employ the Grantee for any specified time period, nor does it modify in any respect the Grantee's employment or compensation.

^{*} For Non-Qualified Stock Option Awards.

^{**} For Incentive Stock Option Awards.

THIRD AMENDMENT TO LEASE

THIS THIRD AMENDMENT TO LEASE (this "<u>Amendment</u>") is entered into as of this 29^{th} day of April, 2009 ("<u>Execution Date</u>"), by and between BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("<u>Landlord</u>"), and REGENERON PHARMACEUTICALS, INC., a New York corporation ("<u>Tenant</u>").

RECITALS

- A. WHEREAS, Landlord and Tenant entered into that certain Lease dated as of December 21, 2006 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of October 24, 2007 (the "First Amendment"), and that certain Second Amendment to Lease dated as of September 30, 2008 (the "Second Amendment" and, collectively with the Original Lease and the First Amendment, and as the same may have been further amended, supplemented or otherwise modified from time to time, the "Lease"), whereby Tenant leases certain premises (the "Premises") from Landlord at 735, 745, 765 and 777 Old Saw Mill River Road in Tarrytown, New York (collectively, the "Buildings", and each a "Building");
- B. WHEREAS, Emisphere Technologies, Inc. ("<u>Emisphere</u>"), leases certain space from Landlord at 765 Old Saw Mill River Road (the "<u>765 Building</u>") pursuant to that certain Lease dated as of March 31, 1997, as the same may have been amended, supplemented or otherwise modified from time to time, the "<u>Emisphere Lease</u>");
- C. WHEREAS, Emisphere, as sublessor, subleases to Tenant, as sublessee, approximately 13,652 rentable square feet of space (the "Regeneron Sublease Premises") in the Quad I & II Premises (as defined below) pursuant to that certain Sublease Agreement dated as of April 15, 2008 (the "Regeneron Sublease");
- D. WHEREAS, Emisphere, as sublessor, subleases to PsychoGenics Inc. (" $\underline{PsychoGenics}$ "), as sublessee, approximately 2,275 rentable square feet of space (the " $\underline{PsychoGenics\ Premises}$ ") in the Quad III & IV Premises (as defined below) pursuant to that certain Sublease dated as of January $\underline{}$;
- E. WHEREAS, as of the date hereof, Landlord and Emisphere have terminated the Emisphere Lease and, consequently, the Regeneron Sublease and PsychoGenics Sublease have been terminated;
- F. WHEREAS, Tenant desires to continue to occupy and lease directly from Landlord the Regeneron Sublease Premises, to surrender certain other space within the Buildings and to lease additional space in the 765 Building from Landlord; and
- G. WHEREAS, Landlord and Tenant desire to modify and amend the Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

- 1. <u>Definitions</u>. For purposes of this Amendment, capitalized terms shall have the meanings ascribed to them in the Lease unless otherwise defined herein. The Lease, as amended by this Amendment, is referred to herein as the "<u>Amended Lease</u>."
- 2. <u>Swap Premises</u>. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord (y) as of the Execution Date, the Regeneron Sublease Premises, and (z) as of May 1, 2009 (the "<u>Swap Premises Commencement Date</u>"), the portions of the following premises that are not part of the Regeneron Sublease Premises. The Quad I & II Premises and Quad III & IV Premises (including the Regeneron Sublease Premises) are referred to herein collectively as the "<u>Swap Premises</u>." The Swap Premises consist of approximately 77,178 rentable square feet.
- a. <u>Quad I Premises</u>. Approximately 13,462 rentable square feet of space located on the second floor of the 765 Building, as shown on <u>Exhibit A</u> attached hereto (the "<u>Quad I Premises</u>");
- b. <u>Quad II Premises</u>. Approximately 22,219 rentable square feet of space located on the second floor of the 765 Building, as shown on <u>Exhibit A</u> attached hereto (the "<u>Quad II Premises</u>" and, collectively with the Quad I Premises, the "<u>Quad I Premises</u>"):
- c. <u>Quad III Premises</u>. Approximately 20,748 rentable square feet of space located on the second floor of the 765 Building, as shown on <u>Exhibit A</u> attached hereto (the "<u>Quad III Premises</u>"); and
- d. Quad IV Premises. Approximately 20,749 rentable square feet of space located on the second floor of the 765 Building, as shown on Exhibit A attached hereto (the "Quad IV Premises" and, collectively with the Quad III Premises, the "Quad III & IV Premises").
- 3. <u>Surrender Premises</u>. The parties acknowledge that, as part of the Additional Premises, Tenant currently leases approximately 35,681 rentable square feet in the North portion of the Building located at 777 Old Saw Mill River Road, as shown on <u>Exhibit B</u> attached hereto (the "<u>Surrender Premises</u>"). The Additional Premises less the Surrender Premises shall be referred to herein as the "<u>Modified Additional Premises</u>." Notwithstanding anything to the contrary in the Lease, the Term for the Surrender Premises shall expire on August 31, 2009, and Landlord and Tenant shall be released from each of their respective obligations under the Lease with respect to the Surrender Premises (including the payment of Rent), except for those obligations that expressly survive the expiration or earlier termination of the Lease.

4. <u>Tenant's Pro Rata Shares</u>. From and after the Execution Date until the Swap Premises Commencement Date, (a) the Premises shall be deemed to include the Regeneron Sublease Premises, (b) Tenant's Pro Rate Share of the 765 Building shall increase from 15.25% to 22.94%, (c) Tenant's Pro Rata Share of the Existing Project (based on Retained Premises, Additional Premises and Regeneron Sublease Premises only) shall increase from 15.75% to 17.57%, and (iv) Tenant's Pro Rata Share of the Entire Project shall increase from 31.29% to 32.52%. From and after the Swap Premises Commencement Date, <u>Section 2.2</u> of the Lease is hereby deleted and replaced in its entirety with the following:

The Premises, the Buildings, and certain related terms are defined as follows. In these definitions, each Rentable Area is expressed in rentable square footage. Rentable Area and Tenant's Pro Rata Shares are all subject to adjustment under this Lease, including under <u>Section 9.2</u>.

Definition or Provision	Means the Following (As of the Swap
	Premises Commencement Date)
"Premises"	Retained Premises, New Premises, Additional Premises, and Swap Premises
"Buildings"	735 Building, 745 Building, 765 Building and 777 Building
Rentable Area of Premises	389,529
Rentable Area of Buildings	117,935 for 735 Building
	111,708 for 745 Building
	177,203 for 765 Building
	311,104 for 777 Building
Rentable Area of Existing Project	751,648
Rentable Area of New Project	360,520
Rentable Area of Entire Project	1,112,168
Tenant's Pro Rata Share of Buildings	100% of 735 Building
	100% of 745 Building
	58.80 % of 765 Building
	17.90% of 777 Building
Tenant's Pro Rata Share of the Existing Project	21.27%
(Based on Retained Premises, Additional	
Premises and Swap Premises only)	
Tenant's Pro Rata Share of the New Project	63.70%
(Based on New Premises only)	
Tenant's Pro Rata Share of Entire Project	35.02%

5. Rent.

a. Basic Annual Rent. Commencing as of (i) the Swap Premises Commencement Date with respect to the Quad I Premises and (ii) September 1, 2009, with respect to the remainder of the Swap Premises (the relevant dates in (i) and (ii), the "Swap Premises" ($\frac{1}{2}$) ($\frac{1}$

<u>Premises Rent Commencement Date</u>"), and continuing through the Term, Tenant shall pay Landlord Basic Annual Rent for the Swap Premises ("<u>Swap Premises Basic Annual Rent</u>") in the following amounts (in addition to Rent otherwise due under the Lease) and in accordance with the terms for payment of Basic Annual Rent set forth in the Lease:

	Qu	ad I Premises				
Date	Rentable s.f.	Per Rentable s.f. Annually	Total Annual	Total Monthly		
Swap Premises Commencement Date – August 31, 2009	13,462	\$26.50	\$356,743.00 (to be prorated)	\$29,728.58		
September 1, 2009 – June 30, 2010	13,462	\$28.00	\$376,936.00 (to be prorated)	\$31,411.33		
July 1, 2010 – remainder of the Term	13,462	Swap Premises Basic Annual Rent to increase annually every July 1 by 2.5% of the then-current Swap Premises Basic Annual Rent applicable to Quad I Premises				
	Qua	ad II Premises				
Date	Rentable s.f.	Per Rentable s.f. Annually	Total Annual	Total Monthly		
Swap Premises Rent Commencement Date - June 30, 2010	22,219	\$28.00	\$622,132.00	\$51,844.33		
July 1, 2010 – remainder of the Term	22,219	Swap Premises Basic Annual Rent to increase annually every July 1 by 2.5% of the then-current Swap Premises Basic Annual Rent applicable to Quad II Premises				
	Qua	d III Premises				
Date	Rentable s.f.	Per Rentable s.f. Annually	Total Annual	Total Monthly		
Swap Premises Rent Commencement Date – June 30, 2010	20,748	\$26.50	\$549,822 (to be prorated)	\$45,818		
July 1, 2010–June 30, 2011	20,748	\$27.16	\$563,515.68	\$46,959.64		
July 1, 2011–June 30, 2012	20,748	\$27.84	\$577,624.32	\$48,135.36		
July 1, 2012–June 30, 2013	20,748	\$28.00 \$580,944 \$48,412.00				

July 1, 2013–June 30, 2014	20,748	\$28.00	\$580,944	\$48,412.00		
July 1, 2014-remainder of	20,748	Swap Premises Basic Annual Rent to increase				
Term		annually eve	ry July 1 by 2.5% of the th	en-current		
		Swap Premi	ises Basic Annual Rent ap	plicable to		
			Quad III Premises			
	Qua	nd IV Premises				
Date	Rentable	Per Rentable	Total Annual	Total Monthly		
	s.f.	s.f.				
		Annually				
Swap Premises Rent	20,749	\$26.50	\$549,848.50 (to	\$45,820.71		
Commencement Date - June			be prorated)			
30, 2010						
July 1, 2010–June 30, 2011	20,749	\$27.16	\$563,542.84	\$46,961.90		
July 1, 2011–June 30, 2012	20,749	\$27.84	\$577,652.16	\$48,137.68		
July 1, 2012–June 30, 2013	20,749	\$28.00	\$580,972.00	\$48,414.33		
July 1, 2013–June 30, 2014	20,749	\$28.00	\$580,972.00	\$48,414.33		
July 1, 2014-remainder of	20,749	Swap Premises Basic Annual Rent to increase				
Term		annually every July 1 by 2.5% of the then-current				
		Swap Premises Basic Annual Rent applicable to				
		Quad IV Premises				

b. Operating Expenses.

- i. In addition to Swap Premises Basic Annual Rent, commencing as of the Swap Premises Rent Commencement Date, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the applicable portion of the Swap Premises.
- ii. Notwithstanding anything in the Amended Lease to the contrary, and solely with respect to the Quad II Premises and the Quad III & IV Premises, commencing as of the Swap Premises Commencement Date and continuing until (but not including) the Swap Premises Rent Commencement Date, Tenant shall pay to Landlord monthly, on the first day of each month as Additional Rent, a fixed amount of One Hundred Twenty Thousand Five Hundred Dollars (\$120,500). The parties hereby agree and confirm that the foregoing amount shall be the sole obligation of Tenant with respect to Operating Expenses for the Quad II Premises and the Quad III & IV Premises during such period.
- iii. For the avoidance of doubt, HVAC for the Additional Premises and the Swap Premises shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises.

- 6. Rent Credit. Tenant shall be entitled to the following Rent credits:
- a. Effective as of December 1, 2009, a Rent credit equal to Five Hundred Thousand Dollars (\$500,000) to be applied against any portion of Rent due to Landlord under the Amended Lease; and
- b. Effective as of December 1, 2012, a Rent credit equal to One Million Fifty Thousand Three Hundred Dollars (\$1,050,300) to be applied against any portion of Rent due to Landlord under the Amended Lease (except that the foregoing credit shall not be applicable to cure a monetary default of Tenant).
- 7. <u>Swap Premises Term Expiration Date</u>. The Term for the Swap Premises shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in <u>Article 44</u> of the Lease (as amended by this Amendment), and (b) Tenant's termination options set forth in <u>Section 13</u> below.
- 8. <u>Lease Extension Options</u>. From and after the Swap Premises Commencement Date, the first paragraph of <u>Article 44</u> of the Lease is hereby deleted and replaced with the following:
 - 44. Option to Extend Term. Tenant shall have three (3) options (each, an "Option") to extend the Term of this Lease (and, in each case, the Term Expiration Date) by five (5) years, in each case on the same terms and conditions as this Lease, except as provided below. If Tenant desires to exercise any Option, Tenant must do so by giving Landlord written notice of such exercise at least one (1) year before the Term would otherwise expire. Tenant may exercise its Option to extend the Term only as to any one or more of the following: (a) the entire Retained Premises, (b) the entire New Whole Building Premises, (c) the entire New Multiple Tenant Building Premises, (d) the Modified Additional Premises or (e) the Swap Premises. If Tenant fails to exercise an Option with respect to less than all of the Premises and the time to do so has lapsed (or if a Retained Premises Early Termination or a termination pursuant to a Swap Premises Termination Option (as defined below)has occurred), then Tenant shall no longer have an Option with respect to those portions of the Premises for which it failed to exercise an Option. Tenant's Options for the remaining Premises shall remain in full force and effect.

9. Delivery of Possession.

a. Tenant acknowledges that it is currently in possession of and occupies the Regeneron Sublease Premises. Landlord shall deliver to Tenant (i) on the Execution Date, the Regeneron Sublease Premises for construction of the Swap Premises Tenant Improvements (as defined below), and (ii) on the Swap Premises Commencement Date, the remainder of the Swap Premises for possession, occupancy and construction of the Swap Premises Tenant Improvements. As of each such date, Tenant's possession and occupancy of the applicable portions of the Swap Premises shall be governed by and pursuant to the Amended Lease; provided, however, that Tenant shall have no obligation to pay Swap Premises Basic Annual Rent with respect to its occupancy and possession of the Swap Premises prior to the applicable Swap Premises Rent Commencement Date. Landlord shall permit Tenant, accompanied by an employee of Landlord, to enter the portion of the Swap Premises that is not the Regeneron Sublease Premises at a time mutually acceptable to Landlord and Tenant (but in no event more than three (3) days prior to the Swap Premises Commencement Date) for the purpose of Tenant planning its move into the Swap Premises.

b. If Landlord fails to deliver all or a portion of the Swap Premises to Tenant on the Swap Premises Commencement Date (such portion, the "<u>Late Delivery Premises</u>"), then Tenant shall not be obligated to pay Base Rent or Operating Expenses with respect to the Late Delivery Premises until Landlord delivers the Late Delivery Premises to Tenant.

10. Tenant Improvements.

- a. Landlord shall make available to Tenant a tenant improvement allowance of Ten Dollars (\$10) per rentable square foot of the Quad I & II Premises (the "Quad I & II Premises TI Allowance") at any time after the Swap Premises Commencement Date until such time as Tenant has exercised a Quad I & II Termination Option (as defined below). Further, Landlord shall make available to Tenant a tenant improvement allowance of Twenty Dollars (\$20) per rentable square foot of the Quad III & IV Premises (the "Quad III & IV Premises TI Allowance"). Up to Ten Dollars (\$10) per rentable square foot of the Quad III & IV Premises TI Allowance") shall be available to Tenant at any time after the Swap Premises Rent Commencement Date. The balance of the Quad III & IV Premises TI Allowance (not to exceed an additional Ten Dollars (\$10) per rentable square foot (the "Phase 2 Quad III & IV Premises TI Allowance")) shall be available to Tenant at any time during the Term after June 30, 2013; provided that Tenant has not exercised a Quad III & IV Termination Option (as defined below). If Tenant has exercised a Quad III & IV Termination Option with respect to the Quad III Premises or the Quad IV Premises only, then Tenant shall still be entitled to its pro rata amount of the Phase 2 Quad III & IV Premises TI Allowance allocable to the non-terminated portion of the Quad III & IV Premises.
- b. The Quad I & II Tenant Improvement Allowance and the Quad III & IV Tenant Improvement Allowance (collectively, the "Swap Premises TI Allowance") shall be disbursed in the same manner as the Base TI Allowance under the applicable provisions of Article-5 of the Lease, including, without limitation, the Disbursement Conditions, in order to finance improvements to the Swap Premises consistent with the provisions of the Lease and the Permitted Use (such improvements, the "Swap Premises Tenant Improvements"). Tenant shall be responsible for performing and completing the Swap Premises Tenant Improvements, and Tenant shall pay Landlord a construction oversight fee of two and one-half percent (2.5%) of the total cost of the Swap Premises Tenant Improvements, including, without limitation, the Swap Premises TI Allowance to the extent disbursed to Tenant, which construction oversight fee may be paid out of the Swap Premises TI Allowance.
- 11. <u>Reduction in Additional Premises TI Allowance</u>. The Additional Premises TI Allowance, as set forth in <u>Section 10</u> of the Second Amendment, is hereby reduced by Three Hundred Fifty-Six Thousand Eight Hundred Ten Dollars (\$356,810). For the avoidance of doubt, Landlord and Tenant acknowledge that the reduction in the Additional Premises TI Allowance results from Tenant surrendering the Surrender Premises, and that Tenant shall continue to have available to it, to the extent not previously disbursed, Ten Dollars (\$10) per rentable square foot of the Modified Additional Premises.

12. <u>Parking</u>. The parties acknowledge that, in accordance with the Lease, Tenant shall be entitled to its pro rata share of unreserved parking spaces on the South side of the Entire Project with respect to the Swap Premises. As of the Swap Premises Rent Commencement Date, Tenant shall be entitled to an additional two (2) parking spaces per thousand (1,000) rentable square feet of Swap Premises. In addition, Tenant's pro rata share of unreserved parking spaces on the North side of the Entire Project shall be reduced proportionately to reflect Tenant's surrendering of the Surrender Premises.

13. <u>Termination Options</u>:

- a. Tenant shall be entitled to terminate the Lease with respect to (i) the entire Quad III Premises, (ii) the entire Quad III & IV Premises or (iii) the entire Quad III & IV Premises (each, a "Quad III & IV Termination Option," and collectively, the "Quad III & IV Termination Options"). In each case, upon not less than eighteen (18) months' prior written notice to Landlord, effective as of (I) June 30, 2013, upon payment to Landlord of Fifteen and 57/100 Dollars (\$15.57) per rentable square foot of terminated space, (m) June 30, 2014, upon payment to Landlord of Fourteen and 16/100 Dollars (\$14.16) per rentable square foot of terminated space, (n) December 31, 2015, upon payment to Landlord of Twelve and 03/100 Dollars (\$12.03) per rentable square foot of terminated space, or (o) December 31, 2016, upon payment to Landlord of Ten and 62/100 Dollars (\$10.62) per square foot of terminated space. If Tenant terminates less than all of the Quad III & IV Premises prior to June 30, 2014, then Tenant's right to exercise its remaining Quad III & IV Termination Options with respect to the portion of the Quad III & IV Premises not terminated shall survive until June 30, 2015 (i.e., eighteen (18) months prior to the last termination date). If Tenant receives any portion of the Phase 2 Quad III & IV Premises TI Allowance, then the payment required to terminate the Quad III & IV Premises shall increase by the unamortized portion of the Phase 2 Quad III & IV TI Allowance allocable to the terminated portion or portions of the Quad III & IV Premises as of the applicable termination date using straight-line amortization (such amortization period to commence as of the Swap Premises Rent Commencement Date). If Tenant timely exercises a Quad III & IV Termination Option, then Tenant shall (y) surrender the applicable Premises to Landlord on the applicable surrender date in the condition required by the Amended Lease for surrendering Premises upon the expiration or earlier termination of the Term, and (z) if less than all of the Quad
- b. Additionally, Tenant shall be entitled to terminate the Lease with respect to the entire Quad I & II Premises (the "Quad I & II Termination Option" and, together with the Quad III & IV Premises Termination Options, the "Swap Premises Termination Options") upon not less than eighteen (18) months' prior written notice to Landlord, effective as of (a) June 30, 2014, upon payment to Landlord of Twenty-Nine and 45/100s Dollars (\$29.45) per rentable square foot of terminated space, (b) December 31, 2015, upon payment to Landlord of Twenty and 02/100s Dollars (\$20.02) per rentable square foot of terminated space, or (c) December 31, 2016 upon payment to Landlord of Ten and 50/100s Dollars (\$10.50) per square foot of terminated space.

14. Emisphere Lease; Regeneron Sublease.

- a. Landlord represents and warrants that, as of the date hereof, Landlord and Emisphere have executed a lease termination agreement (the "Emisphere Termination Agreement") that terminated the Emisphere Lease, except for those provisions that, by their express terms, survive the expiration or earlier termination thereof. Landlord shall use commercially reasonable efforts to enforce any obligations of Emisphere under the Emisphere Termination Agreement to the extent necessary to deliver the Swap Premises to Tenant on the Swap Premises Commencement Date. In addition, Landlord agrees that it shall provide copies of any cleaning records, surveys, swipes or other reports that it obtains from Emisphere as a result of the Emisphere Termination Agreement regarding the presence of Hazardous Materials in the Swap Premises.
- b. Landlord represents and warrants that, to its knowledge, as of the Execution Date, no Hazardous Materials exist in the Swap Premises in violation of Applicable Laws.
- c. Tenant hereby represents and warrants to Landlord that, with respect to the Regeneron Sublease, (a) Tenant has not prepaid to Emisphere more than one (1) month's Rent, (b) Landlord shall have no liability for any security deposits or other amounts Tenant has paid to Emisphere, (c) Tenant shall look solely to Emisphere (not Landlord) for reimbursement of any prepaid Rent or return of any security deposit and (d) to its knowledge, there are no defaults, or conditions existing that with the passage of time may become a default, whether on behalf of Tenant or Emisphere.
- 15. <u>Condition of Premises</u>. Tenant acknowledges that (a) it is in possession of and is fully familiar with the condition of that portion of the Swap Premises occupied by Tenant pursuant to the Regeneron Sublease, (b) is familiar with the condition of the remainder of the Swap Premises and, notwithstanding anything contained in the Amended Lease to the contrary, agrees to take the Swap Premises in its condition "as is" as of the Swap Premises Commencement Date: <u>provided</u>, however, that Landlord shall deliver the Swap Premises (other than the Regeneron Sublease Premises) in broom clean condition, taking into account that Tenant has entered into a separate agreement with Emisphere to have those certain items of Emisphere's personal property set forth in the attached <u>Exhibit C</u> (the "<u>Emisphere FF&E</u>") remain in the Swap Premises after the termination of the Emisphere Lease. Landlord shall have no liability with respect to the Emisphere FF&E, except to the extent that the same form a part of the Buildings or the Common Areas and Landlord would otherwise be required to repair and maintain the same pursuant to <u>Section 19.1</u> of the Amended Lease, in which case Landlord shall be obligated to fulfill such repair and maintenance obligations. For the avoidance of doubt, Landlord and Tenant agree that: (y) Landlord shall have no liability for the existence or condition of the Emisphere FF&E as of the Swap Premises Commencement Date and (z) the following items being left in the Swap Premises by Emisphere shall constitute and form a part of the Building: base building HVAC systems, elevators, restrooms, and exhaust fans and stacks.

16. <u>Hazardous Materials</u>. From and after the Swap Premises Commencement Date, the second to last sentence of <u>Section 40.1</u> of the Lease shall be deleted and replaced in its entirety with the following:

Landlord acknowledges that Tenant shall not be responsible for environmental conditions or contamination now or hereafter existing on, under or in the Entire Project, in the New Whole Building, in the New Multiple Tenant Building, in the Retained Premises, in the Additional Premises or in the Swap Premises caused by Landlord or tenants other than Tenant or by third parties in the Entire Project prior to the Execution Date or after such date, or for environmental conditions or contamination coming from off-site so long as Tenant, Tenant's Affiliates, its permitted sublessees or its agents did not cause or contribute to such environmental conditions or contamination.

- 17. <u>PsychoGenics License Agreement</u>. Landlord and Tenant acknowledge that Tenant, as an accommodation to Landlord, intends to enter into a license agreement with PsychoGenics Inc. in substantially the form attached hereto as <u>Exhibit D</u> (the "<u>PsychoGenics License Agreement</u>"). Landlord, Tenant and PsychoGenics shall, prior to execution of the PsychoGenics License Agreement, enter into a consent to the PsychoGenics License Agreement on Landlord's customary form, a copy of which has been provided to Tenant prior to the date hereof.
- 18. <u>Broker</u>. Each of Landlord and Tenant represents and warrants to the other that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Amendment, other than Studley ("<u>Broker</u>"), and each agrees to indemnify, defend and hold the other harmless from any and all cost or liability for compensation claimed by any such broker or agent, other than Broker, employed or engaged by it or claiming to have been employed or engaged by it. Broker is entitled to a leasing commission in connection with this Amendment, and Landlord shall pay such commission to Broker pursuant to a separate agreement between Landlord and Broker, which commission shall be calculated on the rentable square footage of the Quad III & IV Premises only.
- 19. <u>No Default; Authority; Non-Contravention</u>. Each of Landlord and Tenant represents, warrants and covenants that, to the best of its respective knowledge, neither Landlord nor Tenant is in default of any of its respective obligations under the Lease and no event has occurred that, with the passage of time or the giving of notice (or both), would constitute a default by either Landlord or Tenant thereunder. Each of Landlord and Tenant further represents, warrants and covenants that it has the full power and authority to execute, deliver and comply with the terms of this Amendment, and doing so will not conflict with or result in the violation of or default under any provision of any agreement or other instrument to which it is a party (including without limitation, with respect to Landlord, the Emisphere Lease and the Emisphere Termination Agreement).

- 20. Effect of Amendment. Except as modified by this Amendment, the Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. The covenants, agreements, terms, provisions and conditions contained in this Amendment shall bind and inure to the benefit of the parties hereto and their respective successors and, except as otherwise provided in the Lease, their respective assigns. In the event of any conflict between the terms contained in this Amendment and the Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties. From and after the date hereof, the term "Lease" as used in the Lease shall mean the Lease, as modified by this Amendment.
- 21. <u>Miscellaneous</u>. This Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Amendment are included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference.
- 22. <u>Counterparts</u>. This Amendment may be executed in one or more counterparts that, when taken together, shall constitute one original.

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IN WITNESS WHEREOF, Landlord and Tenant have hereunto set their hands as of the date and year first above written, and acknowledge that they possess the requisite authority to enter into this transaction and to execute this Amendment.

LANDLORD:

BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company

By: /s/ Kevin M Simonsen
Name: Kevin M. Simonsen

Title: VP, Real Estate Counsel

TENANT:

REGENERON PHARMACEUTICALS, INC., a New York corporation

By: /s/ Murray A. Goldberg

Name: Murray A. Goldberg

Title: Senior Vice President, Finance & Administration and Chief Financial Officer

EXHIBIT A

SWAP PREMISES

[DIAGRAM]

EXHIBIT B

SURRENDER PREMISES

[Diagram]

$E\textbf{X}HIBIT\ C$

EMISPHERE FF&E

Item .	Qt y .
VWR double-door refrigerator	
Revco laboratory freezer	1
Fisher Scientific Isotemp Plus, double door	1
NuAire biological safety cabinet	2
lee machine	1
Misc. stainless steel tables	14
Mobile benches	15
Bedding dump station	1
Narcotics safe	ı
Flammable cabinets	10
Corrosive & acid cabinets	3
Cagewasher	1
Lab casework, Incl. fume hoods	throughout
Cold room	1
Downdraft table	1
Animal watering system	1
Liebert air handling system in data center	1
Office furniture (not including chairs)	throughout

EXHIBIT D

FORM OF PSYCHOGENICS LICENSE AGREEMENT

LICENSE AGREEMENT

This LICENSE AGREEMENT (this " $\underline{\text{Agreement}}$ ") is made as of this $\underline{\text{License}}$ day of April, 2009 (the " $\underline{\text{Effective Date}}$ ") by and between REGENERON PHARMACEUTICALS, INC. (" $\underline{\text{Licensor}}$ ") and PSYCHOGENICS INC. (" $\underline{\text{Licensee}}$ ").

BACKGROUND

A. The Licensor is a tenant in the Building located at 765 Old Saw Mill River Road (the "Building"), located within the project the ("Project") known as The Landmark at Eastview, in the Towns of Mt. Pleasant and Greenburgh, New York. As tenant, Licensor has entered into a lease (as amended, supplemented or modified, the "Lease") with BMR-Landmark at Eastview, LLC (the "Landlord") for certain premises within the Project and, as of the Effective Date, is entering into an amendment of the Lease (the "Amendment") to lease from Landlord additional premises thereunder, comprising approximately 77,178 rentable square feet in the Building (the "Leased Premises").

B. Prior to the date hereof, Licensee occupied an approximately 2,275 rentable square foot portion of the Leased Premises as more precisely described and designated on $\underline{\text{Exhibit A}}$ attached hereto and made a part hereof (the " $\underline{\text{License}}$ Area") pursuant to a sublease (the " $\underline{\text{Sublease}}$ "), by and between Licensee, as subtenant and Emisphere Technologies Inc., as sublessor, which Sublease has been terminated as of the date hereof. Licensee desires to continue to occupy the License Area and, in furtherance thereof, to obtain a license from the Licensor for the temporary occupancy of the License Area. Licensor is willing to grant a license to Licensee, all subject to the terms and conditions set forth in this Agreement.

TERMS

NOW THEREFORE, in consideration of the mutual promises and agreements set forth herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Licensor hereby grants to Licensee a license (the "<u>License</u>")to use the Licensed Area, subject to the following conditions:

- 1. <u>License Area</u>. Licensor hereby grants to Licensee a non-transferable right and revocable license for the temporary use of the License Area. Nothing in this Agreement shall be construed to create any relationship between the parties other than that of licensor and licensee.
- 2. <u>Term</u>. The term of the License (the "<u>Term</u>") shall commence on May 1, 2009 (the "<u>Commencement Date</u>") and shall expire on January 15, 2010, unless sooner terminated as provided in this Agreement (the "<u>Expiration Date</u>"). If Licensee remains in the License Area after the Expiration Date, then, in addition to all other remedies Licensor may have at law, in equity or under this Agreement, Licensee shall be deemed to be a licensee at sufferance only and the License Fee (as such term is defined in paragraph 4 below) shall be increased to two hundred percent (200%) of the License Fee (as such term is defined below). If Licensee fails to surrender and vacate the License Area upon the termination or expiration of this Agreement, then Licensee shall indemnify, defend and hold Licensor harmless from and against all loss and liability, including, without limitation, all costs to remove Licensee's personal property and any claims made by any succeeding licensee, subtenant, or any other occupant founded on or resulting from such failure to surrender or vacate, including, without limitation, any attorneys' fees, disbursements or other costs associated therewith.

3. <u>Use</u>. Licensee shall occupy and use the License Area during the term of this Agreement for the sole purposes of general, administrative, and executive use in rooms 721, 722 and 723, and laboratory use in Rooms 724, 726 and 727, and no other purpose without Licensor's prior written consent.

4. <u>Fees</u>.

A. Licensee shall pay to Licensor a monthly license fee of Eight Thousand, Six Hundred Twenty-Six and 40/100 Dollars (\$8,626.40) (the "Fixed Fee"), provided that the following additional amounts shall also be due hereunder: (i) for the payment due on September 1, 2009 an additional amount equal to One Thousand, Two Hundred Sixty-Three and 35/100 Dollars (\$1,263.35), and (ii) for the payment due on January 1, 2009, an additional amount equal to One Hundred Ninety-Seven and 12/100 Dollars (\$197.12) (such additional amounts, together with the Fixed Fee, the "License Fee").

- B. The License Fee for the month of May, 2009 shall be paid by Licensee on the date of the full execution of this Agreement, and thereafter, the License Fee shall be payable in advance on a monthly basis during the Term, on the first day of each month commencing on June 1, 2009, without notice, demand, set-off, claim, or counterclaim, by check or money order, made payable to Licensor at Licensor's address set forth below. If the first month or the last month of the Term shall be partial months, the License Fee for any such partial month shall be prorated on a daily basis.
- 5. Security Deposit. Licensee has deposited with Licensor a security deposit in the amount of Twenty Thousand Dollars (\$20,000) (the "Security Deposit"), which sum shall be held by Licensor as security for the faithful performance by Licensee of all of the terms, covenants and conditions of this Agreement to be kept and performed by Licensee during the term. If Licensee defaults with respect to any provision of this Agreement, including, but not limited to, any provision relating to the payment of the License Fee, then Licensor may (but shall not be required to) use, apply or retain all or any part of the Security Deposit for the payment of any License Fees or any other sum in default, or to compensate Licensor for any other loss or damage that Licensor may suffer by reason of Licensee's default. If any portion of the Security Deposit is so used or applied, then Licensee shall, within ten (10) days following demand therefor, deposit cash with Licensor in an amount sufficient to restore the Security Deposit to its original amount, and Licensee's failure to do so shall be a material breach of this Agreement. Licensor shall not be required to keep this Security Deposit separate from its general funds, and Licensee shall not be entitled to interest on the Security Deposit. In the event of bankruptcy or other debtor-creditor proceedings against Licensee, the Security Deposit shall be deemed to be applied first to the payment of License Fee and other charges due Licensor for all periods prior to the filing of such proceedings. If Licensee shall fully and faithfully perform every provision of this Agreement to be performed by it, then the Security Deposit, or any balance thereof, shall be returned to Licensee within thirty (30) days after the expiration or earlier termination of this Agreement.

- 6. <u>Late Charges</u>. Late payment by Licensee to Licensor of the License Fee or any other sums due shall cause Licensor to incur costs not contemplated by this Agreement, the exact amount of which shall be extremely difficult and impracticable to ascertain. Such costs include, but are not limited to, processing and accounting charges and late charges that may be imposed on Licensor by the terms of its Lease. Therefore, if any installment of License Fee or other fees due from Licensee pursuant to this Agreement is not received by Licensor within five (5) days after the date such payment is due, Licensee shall pay to Licensor an additional sum of six percent (6%) of the overdue amount as a late charge. The parties agree that this late charge represents a fair and reasonable estimate of the costs that Licensor shall incur by reason of late payment by Licensee. In addition to the late charge, amounts not paid when due shall bear interest from the fifth (5th) day after the date due until paid at the lesser of (a) twelve percent (12%) per annum or (b) the maximum rate permitted by applicable laws.
- 7. <u>Common Areas</u>. Licensee shall have the right, subject to the provisions of this License, to use, without additional charge, on a non-exclusive basis, the common areas leased by Licensor pursuant to the Lease and the areas of the Leased Premises specified as "common areas" in the attached <u>Exhibit A</u>. Licensee shall be responsible for any and all damage caused by Licensee or its employees, agents and invitees in or to such common areas. Licensee shall not permit any of its files, furniture, personal property or other matters to be placed in such common areas, and shall keep such common areas free of debris and refuse. In addition to the foregoing, Licensee shall be entitled to access to the portion of the Leased Premises specified as "restricted access area" in the attached <u>Exhibit A</u>. Access to such restricted access areas shall be permitted only if (i) a representative of Licensor is present at all times during such access, and (ii) such access is solely for the purpose of allowing Licensee to use the elevator. Licensee agrees that it shall make available a representative for the purpose of such access during reasonable business hours and upon one (1) business days' advance notice, provided that Licensor shall use reasonable efforts (but shall not be obligated) to provide a representative on shorter notice, should exigent circumstances require the same.
- 8. <u>Licensee's Maintenance</u>; No <u>Improvements</u>. Licensee shall at all times maintain the License Area, and any equipment or property used or installed by Licensee in the License Area, in good, clean and safe condition, free of all debris and trash. Licensee shall not make any improvements, alterations or changes of any kind to the License Area without Licensor's prior written approval. In addition to all of Licensor's remedies under this Agreement, if (a) Licensee does not maintain the License Area as required under this Section or (b) repairs or replacement of any portion of the License Area is made necessary by any act, omission or negligence of Licensee or its agents, employees or invitees, then Licensor may make such repairs or provide such maintenance without liability to Licensee for any loss or damage to Licensee or its merchandise, fixtures or other property, or to Licensee's business by reason of such repairs or maintenance. Further, upon completion of any such repairs or maintenance, Licensee shall pay upon demand, as additional License Fee, one hundred percent of Licensor's costs for making such repairs or providing such maintenance, evidenced by invoices, together with Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal to twenty percent (20%) of the total cost of such repair. Licensee shall not make any changes, alterations, installations, additions or improvements to the License Area without first obtaining the written consent of Licensor, which consent may be granted or withheld in the sole discretion of Licensor.

9. Hazardous Materials. Licensee shall not cause or permit any Hazardous Materials (as hereinafter defined) to be brought upon, kept or used in or about the License Area, the Building or the Project in violation of Applicable Laws (as hereinafter defined) by Licensee, its agents, employees, contractors or invitees. If Licensee breaches such obligation, or if the presence of Hazardous Materials as a result of such a breach results in contamination of the License Area, the Leased Premises, the Building, the Project or any adjacent property, or if contamination of the License Area, the Leased Premises, the Building, the Project or any adjacent property by Hazardous Materials otherwise occurs during the Term or any extension or renewal hereof or holding over hereunder due to such breach by Licensee, then Licensee shall indemnify, save, defend and hold Licensor, its agents and contractors harmless from and against any and all losses, costs, damages or judgments (including sums paid in settlement, attorneys' fees, consultants' fees and experts' fees) that arise during or after the Term as a result of such breach or contamination. This indemnification of Licensor by Licensee includes, without limitation, costs incurred in connection with any investigation of site conditions or any cleanup, remedial, removal or restoration work required by any federal, state, regional, local or municipal governmental authority, agency or subdivision (collectively, the "Governmental Authorities") because of Hazardous Materials present in the air, soil or groundwater above, on or under the License Area, the Leased Premises, the Building, the Project or any adjacent property, Without limiting the foregoing, if the presence of any Hazardous Materials in, on, under or about the License Area, the Leased Premises, the Building, the Project or any adjacent property caused or permitted by Licensee results in any contamination of the License Area, the Leased Premises, the Building, the Project or any adjacent property to their respective conditi

- 10. <u>Damage and Repairs</u>. Any damage, destruction, graffiti or debris around, to, or on the License Area, the Leased Premises, the Building or the Project caused by Licensee, its agents, employees or invitees shall be Licensee's responsibility. If Licensee fails to repair, clean or replace any such damage or debris within two (2) days of Licensor's demand to do so, then Licensor may make such repairs, clean-up or replacement. Upon completion of any such repairs, clean-up or replacement, Licensee shall pay upon demand, as additional License Fee, one hundred percent (100%) of Licensor's costs for making such repairs or providing such clean-up or replacement, evidenced by invoices, together with Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal one twenty percent (20%) of the total cost of such repairs, clean-up or replacement. Any damage to the License Area caused directly by Licensor shall be Licensor's responsibility to repair and maintain.
- 11. <u>Fire and Casualty Damage</u>. If the License Area is rendered partially or wholly untenantable by fire or other casualty, this License shall terminate as to such affected License Area as of the date of such fire or casualty as if that date had been originally fixed in this Agreement for the Expiration Date for the affected License Area.
- 12. <u>Transfer and Assignment</u>. Licensee shall have no right to assign or transfer this License or rights arising under this License. Any assignment by operation of law or otherwise shall be deemed a prohibited assignment hereunder. In the event of a transfer or such assignment, this License shall automatically terminate and thereafter shall be considered null and void.
- 13. <u>Inspections</u>. Provided that Licensor uses reasonable efforts not to interfere with Licensee's use of the Licensed Area, Licensor shall have the right to enter the License Area at any reasonable time for the following purposes: (a) to ascertain the condition of the License Area; (b) to determine whether Licensee is diligently fulfilling Licensee's responsibilities under this License, or; (c) to do any other act or thing which Licensor deems reasonably necessary to preserve the Licensed Area or to comply with its obligations hereunder or under the Lease.
- 14. <u>Termination of Agreement</u>. On the Expiration Date, Licensee shall (a) return the License Area to Licensor in good, sanitary and satisfactory condition and (b) remove its equipment and any other of its property from the License Area, the Leased Premises, the Building and the Project, unless otherwise agreed to by Licensor. Licensee acknowledges and agrees that it shall reimburse Licensor upon demand for one hundred percent (100%) of Licensor's costs to repair any damage caused by such removal by Licensee, evidenced by invoices, together with Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal to twenty percent (20%) of the total costs such repair. Any equipment or property not removed within two (2) days of the date of termination or expiration of this Agreement shall be deemed abandoned by Licensee, and Licensor shall have the right, but not the obligation, to remove and dispose of such abandoned equipment or property at Licensee's sole cost and risk, and Licensor shall be entitle to Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal to twenty percent (20%) of the total costs such removal and disposal.

- 15. <u>Personal Property Taxes</u>. Licensee shall pay all sales and use taxes, if any, imposed as a result of Licensee's business conducted on the License Area and all taxes assessed against property of Licensee situated thereon during the Term.
- 16. Compliance with Laws; Liens. Licensee shall at all times observe and comply with all federal, state and local laws, ordinances, rules, regulations and code requirements (collectively, the "Applicable Laws"). Licensee shall obtain all permits and licenses for the operation of its business at the Building or its use or occupancy of the License Area and shall comply with all current and future rules and regulations of Landlord for tenants or licensees of the Leased Premises, the Building, or the Project. Licensee shall at all times maintain sufficient supervision and control of its employees and invitees. Licensee shall not (a) obstruct the free flow of pedestrian or vehicular traffic in any area of the Property, (b) harm the License Area, commit any waste, create a nuisance or make any use of the License Area that is offensive or (c) act or fail to act in any manner that could result in injury or harm to any person in or about the Property. Licensee shall, and shall instruct its employees, agents and invitees to, act in accordance with Landlord's rules and regulations as they may be promulgated by Landlord from time to time, provided Licensee is given copies thereof. Licensee shall keep the License Area free and clear of any mechanics' liens and other liens. Nothing in this Agreement shall be construed as consent on the part of Licensor to subject the Leased Premises, the Building or the Project to any lien or liability under the lien laws of the State of New York.
- 17. <u>Insurance</u>. Licensee shall, at all times during the Term, and at its own cost and expense, procure and continue in force insurance in the amounts and on the terms set forth in this Section 17. Said insurance shall name Landlord and Licensor as additional insureds and shall be subject to reasonable approval of Licensor and Landlord. Licensee shall obtain from the insurance companies, or cause the insurance companies to furnish, certificates of coverage. The delivery of proof of such insurance is a condition precedent to this Agreement. All certificates of insurance shall provide that the insurer will provide Licensor twenty (20) days notice of cancellation of or any change of said policies by certified mail, return receipt requested or via established overnight courier. In the event Licensee shall fail to comply with any or all of the provisions of this paragraph, Licensor is hereby authorized to purchase said insurance and charge Licensee for the premiums of same and any other costs incurred thereon, and such sums shall be deemed additional Licensee Fee and may be collected by Licensor as such in the next ensuing installment of License Fee. At a minimum, Licensee shall procure Comprehensive General Liability Insurance, in the broadest form available in New York State, with a minimum amount of \$3,000,000 combined single limit and which shall contain personal injury liability, fire damage liability on real property (with sublimits for such events in amounts no less than the minimum amount of \$3,000,000), Workers Compensation Insurance, and such other insurance as was required pursuant to the Sublease.

Licensee agrees to use commercially reasonable efforts to include in each of its policies insuring against loss, damage or destruction by fire or other casualty, a waiver of the insurer's right of subrogation against Licensor. If such waiver shall not be, or shall cease to be, obtainable without additional charge, or is otherwise not available at all, Licensee shall promptly so notify Licensor. In such case, if the other party shall so elect and shall pay the insurer's additional charge therefore, such waiver shall be included in the policy.

- 18. <u>Consent of Landlord</u>. This Agreement is subject to the written consent of Landlord (the "<u>Consent</u>"), which consent shall be evidenced by Landlord's customary form of consent, with such changes as may be agreed to by the parties thereto. In the event Landlord rejects this Agreement, neither party shall have any rights against the other, and this Agreement shall be deemed null and void.
- 19. <u>Utilities, Services</u>. Licensor shall use commercially reasonable efforts to cause Landlord to furnish the License Area with all services required by the Lease to the extent Licensee was receiving the same pursuant to the Sublease. Licensor shall not be liable to Licensee for any loss, injury or damage to persons or property caused by or resulting from any variation, failure, or interruption of any services or utilities to be provided by Landlord under the Lease due to any cause whatsoever. Licensee's use or occupancy of the License Area shall not in any manner (i) cause the design loads for the Building or the systems providing exhaust, heating, cooling, ventilation, electrical, life safety, water, sewer or other utility or safety services to be exceeded or (ii) adversely affect the Building or the operation of said systems in the License Area, the Leased Premises or the Building or cause deterioration or damage to the Building or such systems.
- 20. Access and Parking. Licensee and its agents, employees and invitees may have access to the License Area during its above term twenty-four (24) hours a day. Licensee agrees that it shall not park in any reserved spot on the Property or in front of any roll access/loading doors to the other buildings. Licensee must also keep a fire lane available around the Building. Any costs or liability associated with enforcing this parking access shall be Licensee's or violator's sole responsibility.
- 21. <u>Default</u>. Any failure by Licensee to perform any term or condition of this Agreement shall constitute a default under this Agreement and, in such event, Licensor may exercise any remedy available to it under this Agreement, at law or in equity. Without limiting the foregoing, in the event any such default is not cured within forty-eight (48) hours of Licensor's notice to Licensee thereof, Licensor may, at its option, terminate this Agreement and revoke the license granted hereby. Licensee shall reimburse Licensor for any and all costs and expenses (including attorneys' fees and costs) that Licensor incurs in connection with enforcing Licensee's obligations under this Agreement.
- 22. <u>Limitation of Recovery; Waiver</u>. There shall be no personal liability of Licensor with respect to any of the terms of this Agreement. In the event of any breach or default by Licensor under this Agreement, Licensee shall look solely to the equity of Licensor in the Building for satisfaction of Licensee's remedies. Licensee releases and waives all right of recovery that it might otherwise have against Licensor, or other tenants or licensees of the Building, and their respective agents and employees, by reason of any loss or damage resulting from any recovery, claim, action or cause of action against Licensor, damage or injury or other occurrence no matter how caused, to the extent the same is either covered by Licensee's insurance (assuming no deductible) or would have been covered had Licensee complied with the requirements of this Agreement.
- 23. <u>Entire Agreement</u>. Other than Licensee's lease agreement with Licensor, this Agreement contains the entire agreement between the parties and all prior understandings and agreements between the parties are merged into this Agreement. This Agreement may be modified only by a writing signed by both of the parties hereto.

- 24. <u>Acceptance of License Area</u>. By taking possession of the License Area, Licensee shall be deemed to have inspected the License Area and accepted the License Area "as is" in its present condition. Licensee acknowledges and agrees that neither Licensor, nor any employee, agent nor representative of Licensor, has made any representation or warranty, express or implied, of any kind as to the condition of the License Area or its suitability for Licensee's proposed use. Licensee further acknowledges and agrees that Licensor has no obligation to improve, maintain or repair the License Area unless said obligation is expressly set forth in this Agreement.
- 25. Waiver of Responsibility; Indemnification. Licensee shall assume liability for, and shall indemnify, defend and hold harmless Licensor and its shareholders, members, officers, directors, employees, contractors, subcontractors, agents, customers, mortgagees, lenders and invitees from and against any and all liabilities, obligations, losses, fines, damages, claims, demands, judgments, penalties, expenses (including, without limitation, attorneys' fees and costs) arising, directly or indirectly, from (a) any labor dispute involving Licensee or its contractors or agents, (b) the use or enjoyment of the License Area or the Project by Licensee or its contractors, agents, employees and/or customers or invitees, (c) injury to or death of any person or persons, or damage to or destruction of any property (including, without limitation, the cost of investigation, removal or remedial action and disposal of any Hazardous Materials) occurring in, on or about the License Area or (d) a breach of this Agreement by Licensee or any act or omission of Licensee or its agents, employees or contractors ("Claims"). Notwithstanding anything to the contrary in this Section, nothing in this Section shall relieve Licensor from responsibility for its proportionate share of fault attributable to its negligence in causing any Claims. To the maximum extent permitted by law, Licensee's activities on and use of the License Area and the Property shall be at Licensee's sole risk. Licensee's obligations under this Section shall survive the Expiration Date.

26. Representations and Warranties.

- A. Licensee represents and warrants to Licensor that, as of the Effective Date, the Sublease has been terminated and Licensee waives all rights of possession and occupancy of any portion of the Leased Premises pursuant thereto.
- 27. Licensor hereby represents and warrants to Licensee that (i) as of the Effective Date, the Lease and the Amendment are in full force and effect and grant to Licensor a leasehold interest in and to the Leased Premises, and (ii) the Amendment does not materially modify the Lease with respect to Licensee's obligations under the Consent. Licensor shall provide Licensee with a fully-executed copy of the Amendment within five (5) business days of the date on which the same is made a part of the public record.
- 28. <u>Signage</u>. Licensee is responsible for all of Licensee's signage. All signage must be pre-approved in writing by Licensor and Landlord and hand-written signs are not permitted.
 - 29. Miscellaneous.

A. Whenever under this License Agreement provision is made for any demand, notice, requests or declaration of any kind, or where it is deemed desirable or necessary by either party to give or serve any such notice, demand, request or declaration to the other party, it shall be in writing and such notices shall be deemed given when personally delivered, or the next business day after delivery to a reputable overnight delivery service such as Federal Express or United Parcel Service to the following addresses:

To the Licensor at:

REGENERON PHARMACEUTICALS, INC. 777 Old Saw Mill River Road Tarrytown, New York 10591 Attn: General Counsel

with copy to:

REGENERON PHARMACEUTICALS, INC. 777 Old Saw Mill River Road Tarrytown, New York 10591 Attn: Joanne Deyo, Vice President Facilities

To Licensee at:

PSYCHOGENICS INC. 765 Old Saw Mill River Road Tarrytown, New York 10591 Attn: William Fasnacht, CFO/COO

- B. The terms, provisions and covenants and conditions contained in this License shall apply to, inure to the benefit of, and be binding upon, the parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns.
 - C. All obligations of Licensee hereunder not fully performed as of the Expiration Date shall survive the Expiration Date.
- D. Licensor and Licensee agree to indemnify the other for any claims made by any other brokers arising under the acts of such party.
 - E. Licensee represents that it has used no broker in connection with this transaction.
 - F. This Agreement may be signed in counterparts; each, when taken together, shall constitute one instrument.
- G. If any term, provision or condition of this License shall, to any extent, be finally adjudicated to be invalid or unenforceable, the remainder of this License (or the application of such term, provision or condition to persons or circumstances other than those in respect of which it is finally adjudicated to be invalid or unenforceable) shall not be affected thereby and each and every other term, provision and condition of this License shall be valid and enforceable to the fullest extent permitted by law.

- H. Licensee shall pay to Licensor all costs and expenses, including reasonable attorneys' fees and costs, incurred by Licensor in connection with any action between Licensor and Licensee arising out of this License or incurred by Licensor as a result of any litigation to which Licensor becomes a party as a result of this Licensee or Licensee's use and occupancy of the Licensed Area or any portion thereof.
- I. Licensor and Licensee waive trial by jury in the event of any action, proceeding or counterclaim brought by either Licensor or Licensee against the other in connection with this License.
- J. If Licensee fails timely to perform any of its duties under this License, Licensor shall have the right (but not the obligation), after the expiration of any grace or notice and cure period elsewhere under this License expressly granted to Licensee for the performance of such duty, to perform such duty on behalf and at the expense of Licensee (but only upon prior notice to Licensee), and all sums expended or expenses incurred by Licensor in performing such duty together with Licensor's administrative costs related thereto, which administrative costs the parties agree to be an amount equal to twenty percent (20%) of Licensor's cost of performing such duty, shall be deemed to be additional License Fee under this License and shall be due and payable upon demand by Licensor.
- K. This Agreement shall be governed by, and construed and interpreted in accordance with New York law, without regard to conflicts of law principles.

[REMAINDER OF THIS PAGE INTENTIONALLY LEFT BLANK]

<u>LICENSOR</u> :	
REGENERON PHARMACEUTICALS, INC., a New York corporation	
Ву:	_
Name: Murray A. Goldberg	
Title: Senior Vice President,	
Finance & Administration	
and Chief Financial Officer	
LICENSEE:	
PSYCHOGENICS INC., a Delaware corporation	
Ву:	
Name: William Fasnacht	•
Title: CFO/COO	

IN WITNESS WHEREOF, Licensor and Licensee have hereunto set their hands as of the date and year first above written, and acknowledge that they possess the requisite authority to enter into this transaction and to execute this Agreement.

EXHIBIT A

LICENSE AREA

[Diagram]

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 30, 2009 /s/ LEONARD S. SCHLEIFER

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 30, 2009 /s/ MURRAY A. GOLDBERG

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LEONARD S. SCHLEIFER

Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer April 30, 2009

/s/ MURRAY A. GOLDBERG

Murray A. Goldberg Chief Financial Officer April 30, 2009

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 11/3/2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 10-Q

(X)	(Mark One) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 1 EXCHANGE ACT OF 1934	5(d) OF THE SEC	CURITIES	
	For the quarterly period ended <u>September 30, 2009</u>			
		OR		
()	TRANSITION REPORT PURSUANT TO SECTION 13 OR 1 EXCHANGE ACT OF 1934	5 (d) OF THE SE	CURITIES	
	For the transition period fromtoto			
	Commission	File Number <u>0-1</u>	9034	
	REGENERON PH (Exact name of registr	HARMACEUTICA Cant as specified	LS, INC. in its charter)	
	New York		<u>13-3444607</u>	
	(State or other jurisdiction of		(I.R.S. Employer Identification No.)	
	incorporation or organization)			
	777 Old Saw Mill River Road			
	Tarrytown, New York		<u>10591-6707</u>	
	(Address of principal executive offices)		(Zip Code)	
	(Registrant's telephone			
ndica Excha repor	ate by check mark whether the registrant (1) has filed all lange Act of 1934 during the preceding 12 months (or f ts), and (2) has been subject to such filing requirements	l reports require or such shorter for the past 90 o	ed to be filed by Section 13 or $15(d)$ of the Seperiod that the registrant was required to flays.	ecuritie ile suc
	Yes	<u>X</u> No		
Intera	ate by check mark whether the registrant has submitted active Data File required to be submitted and posted pur receding 12 months (or for such shorter period that the r	rsuant to Rule 40	05 of Regulation S-T (§232.405 of this chapter	
	Yes	No		
Indica repor of the	ate by check mark whether the registrant is a large accel- ting company. See definitions of "large accelerated filer e Exchange Act.	lerated filer, an a ", "accelerated :	accelerated filer, a non-accelerated filer, or a filer", and "smaller reporting company" in Rul	smalle le 12b-
Large	e accelerated filer X		Accelerated filer	
_	accelerated filer (Do not check if a smaller reporting	g company)	Smaller reporting company	
Indica	ate by check mark whether the registrant is a shell compa	any (as defined i	n Rule 12b-2 of the Exchange Act).	
	Yes	No <u>X</u>		
Numl	per of shares outstanding of each of the registrant's class		tock as of October 15, 2009:	
	<u>Class of Common Stock</u>	<u>IN</u>	umber of Shares	

Class A Stock, \$0.001 par value

APOTEX V. REGENERON IPR2022-01524 REGENERON EXHIBIT 2008 PAGE 5182

2,246,698

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PART I. FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2009 AND DECEMBER 31, 2008 (Unaudited) (In thousands, except share data)

	September 30, 2009	December 31, 2008 (Revised -
ASSETS Current assets		see Note 9)
Cash and cash equivalents Marketable securities Accounts receivable from the sanofi-avents Group	\$ 25 0.321 129,475 63.953	\$ 247.795 226,954 33.3 02
Accounts receivable - other Prepaid expenses and other current assets	3,813 14,032	1,910 11,480
Total current assets Restricted cash	461,594 1. 600	521,442 1.6 5 0
Marketable securities Property plant and equipment at cost net of accumulated depreciation and amortization Other assets	57,200 215,169 6,629	51,061 142,035 8,032
Total assets	<u>\$ 742,192</u>	<u>\$ 724,220</u>
LIABILITIES and STOCKHOLDERS' EQUITY Current liabilities		
Accounts payable and accrued expenses Deferred revenue from sanofi-aventis, current portion Deferred revenue other current portion Total current liabilities	\$ 55.291 21,580 37,294 114,165	\$ 36,168 21,390 26,114 83,672
Deferred revenue from sanoff-aventis Deferred revenue - other Facility lease obligation Other long-term liabilities	90.251 49.421 62.571 3,341	\$05,586 56,835 54,182 2,431
Total liabilities Commitments and contingencies	319 749	302 706
Stockholders: equity Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and		
outstanding - none Class A Stock, convertible \$ 001 par value, 40 000 000 shares authorized; shares issued and outstanding = 2 246 698 in 2009 and 2 248 698 in 2008 Common Stock, \$.001 par value; 160,000,000 shares authorized;	ę	ę
shares issued and outstanding - 78,243,286 in 2009 and 77,642,203 in 2008 Additional paid-in capital Accumulated deficit	78 1,3 23,43 2 (904,606)	78 1,294.813 (873,265)
Accumulated other comprehensive income (loss) Total stockholders' equity Total liabilities and stockholders' equity	3.537 422,443 8 742,192	421,514 5 724,220

The accompanying notes are an integral part of the financial statements.

	Three months e	nded September 30,	Nine months ende	Septe mb er 30,	
	2009	2008	2009	2008	
		(Revised -		(Revised -	
		see Note 9)		see Note 9)	
Revenues Contract research and development from					
sanofi-aventis	\$ 68,536	\$ 42,006	\$ 178,928	\$ 116,346	
Other contract research and development	***************************************	10 872	40.176	33,568	
Research progress payments	20,000		20,000		
Technology licensing	10,000	10,000	30,000	30,000	
Net product sales	4,973	2,706	13,364	2,706	
	117,455	65.584	282.468	182,620	
Expenses					
Research and development	105,434	72,089	279,972	200,335	
Selling general and administrative	12.840	11.103	15.892	35.652	
Cost of goods sold	472	292	1,299	292	
	118.746	83.484	317.163	236,279	
Loss from operations	(1.291)	(17.900)	(34.695)	(53.659)	
Other income (expense)					
Investment income	857	3,674	3,935	15,513	
Interest expense	(581)	(1.772)	(581)	(7.457)	
Loss on early extinguishment of debt		(7)	***	(938)	
2000 on ourly examiguisminent or dest	276	1.895	3354	7.118	
Set loss before bucone tax expense	(1.015)	(16 005)	(31.341)	(46,541)	
Income tax expense		3,079		3,079	
Net loss	<u>\$ (1,015)</u>	\$ (19.084)	<u>\$ (31,341)</u>	\$ (49.620)	
Net loss per share, basic and diluted	\$ (0.01)	\$ (0.24)	\$ (0.39)	\$ (0.63)	
Weighted average shares dutstanding, basic	40.040	to over	70.070	90.70	
and diluted	79.866	78,937	79.663	78,796	

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENT OF STOCKHOLDERS' EQUITY (Unaudited) For the nine months ended September 30, 2009 (In thousands)

							Accumulated		
					Additional		Other	Total	
	Class A	Stock	Commo	n Stock	Paid-in	Accumulated	Comprehensive	Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance. December 31. Bion (Revised see Note 9)	2.249	1 2	77.542	; 78	\$ 1,294,613	\$ 1873,265 <u>)</u>	\$ (334)	\$ 421514	
Issuance of									
Common Stock									
in									
connection									
with exercise of									
stock									
options, net of									
shares									
tendered Issuance of Common Stock IT CHRECTION With Company 401(1) Savings Plant contribution Conversion of			518 518		4,626			4,626	
Class A Stock to									
Common									
Stock Sitick based compensation expense Net loss Change in net innesized gain (foss) on marketable securines Balance, September	(2)		2		22,802	(31,341)	ssa	22.862 (31.341) 3.663	\$ (31,341) \$ (31,341)
30, 2009	2,247	\$ 2	78,243	\$ 78	\$ 1,323,432	\$ (904,606)	\$ 3,537	\$ 422,443	\$ (27,690)

The accompanying notes are an integral part of the financial statements.

	Nine months ende	d September 30,
	2009	2008
		(Revised -
		see Note 9)
Cash flows from operating activities Net loss	\$ (31,341)	\$ (49,620)
Adjustments to reconcile net loss to net cash used in operating activities Depreciation and amortization	9,312	8,661
Non-cash compensation expense	22,602	24,716
Loss on early extinguishment of debt Net realized (gain) luss on marketable securities	(56)	938 1.166
Changes in assets and liabilities Increase in accounts receivable	(32,554)	(23.886)
Increase in prepaid expenses and other assets Decrease in deferred revenue	(370) (11.379)	(5,279) (10.076)
Increase in accounts payable, accrued expenses,		
and other liabilities	17,960	134
Total adjustments	5,515	(3.626)
Net cash used in operating activities	(25,826)	(53,246)
Cash flows from investing activities		
Purchases of marketable securities	(190,666)	(478,276)
Sales or majurities of marketable securities	284.934	443.587
Capital expenditures	(75,002)	(19,117)
Decrease (increase) in restricted cash	19,316	(53,856)
Net cash provided by (used in) investing activities	19,510	(55,650)
Cash flows from financing activities		(92.204)
Extinguishment of long-term debt Proceeds in connection with facility lease obligation	5.182	(83,304)
Payments in connection with facility lease obligation Net proceeds from the issuance of Common Stock	(773) 4 coe	etes
Net cash provided by (used in) financing activities	9,035	(77,139)
Net increase (decrease) in cash and cash equivalents	2,525	(184,241)
Cash and cash equivalents at beginning of period	2 47.795	498.925
Cash and cash equivalents at end of period	\$ 2 50.321	\$ 314.684
The accompanying notes are an integral part of the finance	ial statements.	
6		

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2008 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2008. In addition, the previously issued balance sheet of the Company at December 31, 2008 contained in the Company's Annual Report on Form 10-K for the year ended December 30, 2008, and the previously issued condensed statement of operations for the three and nine months ended September 30, 2008 and condensed statement of cash flows for the nine months ended September 30, 2008, contained in the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2008, have been revised in this Quarterly Report on Form 10-Q with respect to the Company's December 2006 lease of office and laboratory facilities in Tarrytown, New York by applying authoritative guidance issued by the Financial Accounting Standards Board (FASB). See Note 9b below.

Included in research and development expenses is the Company's share of VEGF Trap-Eye development expenses incurred by Bayer HealthCare LLC, including the Company's share of Bayer HealthCare's estimated VEGF Trap-Eye development expenses for the most recent interim fiscal quarter. The Bayer HealthCare estimate each quarter is adjusted to agree with actual expenses for such quarter in the subsequent interim fiscal quarter.

Effective in the first quarter of 2009, the estimated useful lives of laboratory and other equipment, which is a component of property, plant, and equipment, has been extended from 3 – 5 years to 3 – 10 years. The effect of this change in estimate was to lower depreciation expense by \$0.2 million and \$0.7 million for the three and nine months ended September 30, 2009. The impact on the net loss per share as a result of this change in estimate was not material.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company recognizes ARCALYST net product sales as revenue when the right of return no longer exists and rebates can be reasonably estimated. ARCALYST net product sales revenue totaled \$5.0 million and \$13.4 million for the three and nine months ended September 30, 2009, respectively, and \$2.7 million for both the three and nine months ended September 30, 2008. At September 30, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled \$5.0 million and \$3.8 million, respectively.

Cost of goods sold related to ARCALYST sales, which consisted primarily of royalties, totaled \$0.5 million and \$1.3 million for the three and nine months ended September 30, 2009, respectively, and \$0.3 million for both the three and nine months ended September 30, 2008. To date, ARCALYST shipments to the Company's customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST; therefore, the costs of these supplies were not included in costs of goods sold. At September 30, 2009, the Company had \$0.4 million of inventoried work-in-process costs related to ARCALYST, which is included in prepaid expenses and other current assets. There were no capitalized inventory costs at December 31, 2008.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and nine months ended September 30, 2009 and 2008, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months Ended September			
	2009	2008		
Net loss (Numerator)	\$ (1.015)	\$ (19,084)		
Weighted-average shares in thousands (Denominator)	79.866	78,937		
Basic and diluted net loss per share	\$ (0.01)	\$ (0.24)		
	Nine Months En	ded September 30,		
	2009	2008		
Net loss (Numerator)	\$ (31,341)	\$ (49,620)		
Weighted-average shares in thousands (Denominator)	79.663	78,706		
Basic and diluted net loss per share	\$ (0.39)	\$ (0.63)		

Shares issuable upon the exercise of stock options, vesting of restricted stock awards, and conversion of convertible debt, which have been excluded from the September 30, 2009 and 2008 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months ended September			
	2009	2008		
Stock Options Weighted average number, in thousands Weighted average exercise price	19,860 \$ 17.6 5	17,454 \$ 17,31		
Restricted Stock Weighted average number, in thousands	500	500		
Convertible Debt: Weighted average number, in thousands Conversion price		3,890 \$ 30.25		
		ed September 30,		
	2009	2008		
Stock Options Weighted average number, in thousands	20,059	17,572		
Weighted average exercise price	3 17.59	\$ 17.24		
Restricted Stock: Weighted average number, in thousands	500	500		
Convertible Debt				

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2009 and December 31, 2008 were \$10.5 million and \$7.0 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2008 and December 31, 2007 were \$5.1 million and \$1.7 million, respectively, of accrued capital expenditures.

In connection with the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities in Tarrytown, New York (see Note 9b), the Company recognized a facility lease obligation of \$4.0 million and \$23.0 million for the nine months ended September 30, 2009 and 2008, respectively, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in accounts payable and accrued expenses at December 31, 2008 and 2007 were \$1.5 million and \$1.1 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2009 and 2008, the Company contributed 81,086 and 58,575 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in marketable securities at September 30, 2009 and December 31, 2008 were \$1.0 million and \$1.7 million, respectively, of accrued interest income. Included in marketable securities at both September 30, 2008 and December 31, 2007 was \$2.2 million of accrued interest income.

5. Marketable Securities

Marketable securities at September 30, 2009 and December 31, 2008 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was \$7.1 million and \$3.7 million at September 30, 2009 and December 31, 2008, respectively, and the aggregate cost basis of which was \$4.0 million and \$4.1 million at September 30, 2009 and December 31, 2008. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at September 30, 2009 and December 31, 2008. The Company classifies its debt securities, other than mortgage-backed and other asset-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed and other asset-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair			
At September 30, 2009	Cost Basis	Value	Gains	(Losses)	Net
Maturities within one year					
U.S. government obligations	\$ 105,253	\$105,353	\$ 100		\$ 100
Corporate bonds	15,819	16.109	290		290
Mortgage-backed securities	3,417	3,211		\$ (206)	(206)
U.S. government guaranteed					
collateralized mortgage obligations	4,717	4.802	85		85
	129,206	129,475	475	(206)	269
Maturities between one and three years					
U.S. government guaranteed corporate bonds	48,608	49,086	478		478
Mortgage backed securities	1.278	999		(279)	(279)
	49,886	50,085	478	(279)	199
	\$ 179,092	\$179,560	\$ 953	\$ (485)	\$ 468
	****	·····			

	Amortized	Fair			
At December 31, 2008	Cost Basis	Value	Gains	(Losses)	Net
Maturities within one year					
U.S. government obligations	\$ 170,993	\$172,253	\$1,260		\$1,260
Corporate bonds	26,894	26.662	25	\$ (257)	(232)
Mortgage-backed securities	9,098	8,420		(678)	(678)
Other asset-backed securities	7.842	7.829		(13)	(13)
U.S. government guaranteed					
collateralized mortgage obligations	11,742	11,792	50		50
	226,569	226.956	1.335	(948)	387
Maturities between one and three years					
U.S. government guaranteed corporate bonds	29,853	29,811	82	(124)	(42)
Corperate bends	10.446	10.414	77	(109)	(92)
Mortgage-backed securities	1,821	1,556	******************	(265)	(265)
U.S. government guaranteed					
collateralized mortgage obligations	5,297	5,570	273		273
	47,417	47,351	432	(498)	(66)
	\$ 273,986	\$274,307	\$1,767	\$(1.446)	<u>\$ 321</u>

At September 30, 2009 and December 31, 2008, marketable securities included an additional unrealized gain of \$3.1 million and an additional unrealized loss of \$0.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at September 30, 2009 and December 31, 2008. The debt securities listed at September 30, 2009 mature at various dates through December 2011.

	Less than 12 Months		ss than 12 Months 12 Months or Greater			tal	
		Unrealized		Unrealized		Unrealized	
At September 30, 2009	<u>Fair Value</u>	Loss	Fair Value	Loss	Fair Value	Loss	
Mortgage-backed securities			<u>\$ 4,210</u>	<u>\$ (485)</u>	<u>\$ 4210</u>	<u>\$ (485)</u>	
At December 31, 2008 Corporate bonds Government guaranteed	\$ 15.559	\$ (287)	\$ 2,933	\$ (79)	\$ 18492	\$ (366)	
corporate bonds	11,300	(124)			11,300	(124)	
Mortgage: backed securities	871	(74)	9.104	(869)	9.975	(943)	
Other asset-backed securities	7,829	(13)			7,829	(13)	
Equity securities	3,608	(436)			3,608	(436)	
	\$ 39,167	\$ (934)	\$ 12,037	\$ (948)	\$ 51,204	\$ (1,882)	

Realized gains and losses are included as a component of investment income. For both the three and nine months ended September 30, 2009, realized gains on sales of marketable securities totaled \$0.2 million and realized losses on sales of marketable securities were not significant. For the three and nine months ended September 30, 2008, realized gains on sales of marketable securities totaled \$1.0 million and \$1.1 million, respectively, and realized losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at September 30, 2009 and December 31, 2008, were as follows:

		Fair Value Measurements at Reporting Date Using					
		Quoted Prices in					
		Active Markets	Significant Other	Significant			
	Fair Value at	for Identical	Observable	Unobservable			
	September 30,	Assets	Inputs	Inputs			
Description	2009	(Level 1)	(Level 2)	(Level 3)			
Available-for-sale marketable securities							
U.S. government obligations	\$ 105,353		\$ 105,353				
U.S. government guaranteed corporate bonds	49,086		49,086				
Corporate bonds	16,109		16,109				
Mortgage-backed securities	4,210		4.210				
U.S. government guaranteed							
collateralized mortgage obligations	4,802		4,802				
Equity securities	7,115	7,115					
Total	\$ 186,675	\$ 7,115	\$ 179,560	\$			
		Fair Value Meas	urements at Reporti	ng Date Using			
		Quoted Prices in					
		Active Markets	Significant Other	Significant			
	Fair Value at	for Identical	Observable	Unobservable			
	December 31,	Assets	Inputs	Inputs			
Description	2008	(Level 1)	(Level 2)	(Level 3)			
Available-for-sale marketable securities							
U.S. government obligations	\$ 172,253		\$ 172,253				
U.S. government guaranteed corporate bonds	29,811		29.811				
Corporate bonds	37,076		37,076				
Mortgage backed securities	9,976		9,976				
Other asset backed securities	7,829		7,829				
U.S. government guaranteed							
collateralized mortgage obligations	4 T 19/19		17,362				
	17,362			***************************************			
Equity securities	3,708	\$ 3,608		\$ 100			

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the best price for these securities. During the three and nine months ended September 30, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities. During the third quarter of 2008, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the security's \$2.0 million carrying value. As a result, the Company recognized a \$1.7 million charge related to this Level 2 marketable security, which the Company considered to be other than temporarily impaired.

Marketable securities included in Level 3 were valued using information provided by the Company's investment advisors, including quoted bid prices which take into consideration the securities' current lack of liquidity. During the nine months ended September 30, 2009 and 2008, deterioration in the credit quality of a marketable security included in Level 3 subjected the Company to the risk of not being able to recover the carrying value of the investment. As such, the Company recorded charges for other-than-temporary impairment of this Level 3 marketable security totaling \$0.1 million for both the three and nine months ended September 30, 2009, and \$0.5 million for the nine months ended September 30, 2008.

There were no unrealized gains or losses related to the Company's Level 3 marketable securities for the three or nine months ended September 30, 2009 and 2008. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities, and no transfers of marketable securities between the Level 2 and Level 3 classifications, during the three and nine months ended September 30, 2009 and 2008.

Changes in marketable securities included in Level 3 during the three months ended September 30, 2009 and 2008 were as follows:

	Level 3 marketable securi			
	2009	2008		
Balance, July I	\$ 100	\$ 4,995		
Settlements		(5,665)		
Realized gain		940		
Impairments	(100)			
Balance: September 30	\$	\$ 270		

Changes in marketable securities included in Level 3 during the nine months ended September 30, 2009 and 2008 were as follows:

	Level 3 marketa	ble securities
	2009	2008
Balance January I	\$ 100	\$ 7,950
Settlements		(8,090)
Realized gain		940
Impairments	(100)	(530)
Balance: September 30	\$	\$ 270

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

The current economic environment, the deterioration in the credit quality of some of the issuers of securities that the Company holds, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in the Company's investment portfolio and that such declines could result in charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2009 and December 31, 2008 consist of the following:

	September 30,	December 31,
	2009	2008
Accounts payable	\$ 13.855	\$ 6,268
Payable to Bayer HealthCare	2,753	9,799
Accrued payroll and related costs	15.706	5.948
Accrued clinical trial expense	11,637	4,273
Accrued property, plant, and equipment expenses	5,838	5,994
Accrued expenses, other	5,502	3,886
	\$ 55,291	\$ 36,168

7. Research Progress Payment from Bayer HealthCare LLC

In connection with the Company's license and collaboration agreement with Bayer HealthCare LLC to globally develop and commercialize outside the United States the Company's VEGF Trap-Eye for the treatment of eye disease by local administration, the Company received a \$20.0 million substantive milestone payment in July 2009 in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in Central Retinal Vein Occlusion ("CRVO"). The \$20.0 million payment was recognized in revenues as a research progress payment for the three and nine months ended September 30, 2009.

8. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities. For the three and nine months ended September 30, 2009 and 2008, the components of comprehensive loss are:

	Three months ended September			
	2009	2008		
Net loss	\$ (1,015)	\$ (19.084)		
Change in net unrealized gain (loss) on marketable securities	2,523	(3,645)		
Total comprehensive income (loss)	\$ 1,508	\$ (22,729)		
	Nine months ende	ed September 30,		
	2009	2008		
Net loss	\$ (31,341)	\$ (49,620)		
Change in net unrealized gain (loss) on marketable securities	3,651	(4,130)		
Total comprehensive loss	\$ (27,690)	\$ (53.750)		

9. Lease - Tarrytown, New York Facilities

a. Lease Amendment

The Company leases laboratory and office facilities in Tarrytown, New York. In December 2006, the Company entered into an agreement (which was amended in October 2007 and September 2008) to lease laboratory and office space at the Company's Tarrytown location, including newly constructed space that was completed during the third quarter of 2009 (the "new facilities"). The term of the lease commenced effective June 2008 and will expire in June 2024. In April 2009, the Company amended the lease agreement to increase the amount of space the Company will lease. As amended, the lease contains early termination options for the portion of the space that excludes the new facilities. Other terms and conditions, as previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, remain unchanged. In connection with the lease amendment, in April 2009, the Company terminated an April 2008 sublease for space in Tarrytown, New York.

In connection with the April 2009 lease amendment, the Company's total estimated future minimum noncancelable lease commitments, previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2008, will increase to \$9.4 million, \$14.5 million, \$14.7 million, \$13.7 million, and \$15.1 million for the years ended December 31, 2009, 2010, 2011, 2012, and 2013, respectively, and increase to an aggregate amount of \$182.5 million for the eleven-year period commencing on January 1, 2014.

b. Revisions of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, the Company became aware that certain of these conditions were applicable to its December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, the Company is deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

The Company revised its previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which the Company is leasing and to adjust the Company's previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability) at each balance sheet date. The Company also revised its statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of its lease, with a corresponding adjustment to other long-term liabilities. In addition, the Company's statement of cash flows for the quarter ended March 31, 2009 was revised to reclassify, from an operating activity to a financing activity, a \$5.2 million reimbursement received from the Company's landlord for tenant improvement costs that the Company incurred. Under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation.

As previously disclosed, the above described revisions consisted entirely of non-cash adjustments. They had no impact on the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs, including the preclinical and clinical development of its product candidates. The revisions also had no impact on the Company's previously reported net increases or decreases in cash and cash equivalents in any period and, except for the quarter ended March 31, 2009 (as described above), had no impact on the Company's previously reported net cash flows from operating activities, investing activities, and financing activities. In addition, these revisions had no impact on the Company's previously reported current assets, current liabilities, and operating revenues. We have not amended previously issued financial statements because, after considering both qualitative and quantitative factors, the Company determined that the judgment of a reasonable person relying on the Company's previously issued financial statements would not have been changed or influenced by these revisions.

Balance Sheet Impact at December 31, 2007 and 2008, and March 31, 2009 (in millions)

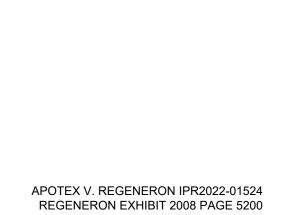
For comparative purposes, the impact of the above described revisions to the Company's balance sheets as of the dates set forth below is as follows:

	December 31,	December 31,	March 31,
	2007	2008	200 9
As originally reported Property, plant, and equipment, net Total assets	\$ 58.3	\$ 87.9	\$ 109.8
	936.3	670.0	681.4
Other long-term liabilities	476.0	5.1	13.2
Total liabilities		251.2	271.1
Accumulated deficit Total stockholders' equity Total liabilities and stockholders' equity	(793 2)	(875.9)	(893.4)
	460.3	418.8	410.3
	936.3	670.0	681.4
As revised Property, plant, and equipment, net Total assets	\$ 79.9	\$ 142.0	\$ 164.6
	957.9	72 4.2	736.2
Facility lease obligation Other long-term liabilities Total liabilities	21.6	54.2	60.0
	0.9	2.4	3.2
	498. 5	302.7	321.1
Accumulated deficit Total stockholders' equity Fotal habilities and stockholders equity	(794.1)	(873.3)	(888.7)
	459.4	421.5	415.1
	957.9	724.2	73 6.2

For comparative purposes, the impact of the above described revisions to the Company's statements of operations and statement of cash flows for the period(s) set forth below is as follows:

Statements of Operations Impact for the three, six, and nine month periods ended March 31, June 30, and September 30, 2008, the years ended December 31, 2007 and 2008, and the three months ended March 31, 2009 (in millions, except per share data)

	Ma	rch 31,	n 31, June 30, September 30,		June 30, September 30, December		December 31,		Ma	rch 31,
		2008		8002	 2008	200)7_	2008		2009
As originally reported										
Research and development expenses	\$	61.3	\$	127.8	\$ 201.7	\$ 20	1.6	\$278.0	\$	82.1
Selling, general, and administrative expenses		11.0		24.5	35.9	3	7.9	49.3		11.7
Total expenses		72.3		152.3	237.9	239	9.5	328.3		94.2
Net lass		(11.6)		(30.1)	(51.2)	(10)	i.G)	(82.7)		(17.5)
Net loss per share, basic and diluted	\$	(0.15)	\$	(0.38)	\$ (0.65)	\$ (1.	59)	\$ (1.05)	\$	(0.22)
As revised										
Research and development expenses	\$	61.5	\$	128.2	\$ 200.3	\$ 202	2.5	\$274.9	\$	80.3
Selling general and administrative expenses		11.1		24.6	35.7	3	7.9	48.9		11.4
Total expenses		72.5		152.8	 236.3	240	0.4	324.7		92.1
Net loss		(11.8)		(30.5)	(49.6)	(10)	5.51	(79.1)		(15.4)
Net loss per share, basic and diluted	\$	(0.15)	\$	(0.39)	\$ (0.63)	\$ (1.	61)	\$ (1.00)	\$	(0.19)



Statement of Cash Flows Impact for the three months ended March 31, 2009 (in millions)

	As Originally	
	Reported	As Re v ised
Net cash used in operating activities	\$ (10.2)	\$ (15.4)
Net cash used in investing activities	(39.5)	(39.5)
Net cash provided by financing activities	1.0	6.2
Net decrease in cash and cash equivalents	\$ (48.7)	\$ (48.7)

These revised amounts, as applicable, are reflected in the Company's financial statements included in this Quarterly Report on Form 10-Q for the period ended September 30, 2009, and will be reflected in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2009 and the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2010.

c. Facility Lease Obligation

As described above in Note 9b, in connection with the application of FASB authoritative guidance to the Company's lease of office and laboratory facilities constructed in Tarrytown, New York by the Company's landlord, the Company capitalized the landlord's costs of constructing the new facilities, which totaled \$58.2 million as of September 30, 2009, and recognized a corresponding facility lease obligation of \$58.2 million. The Company also recognized, as an additional facility lease obligation, a \$5.2 million reimbursement received from the Company's landlord for tenant improvement costs that the Company incurred since, under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. The new facilities were placed in service by the Company in September 2009. For the three and nine months ended September 30, 2009, the Company recognized \$0.6 million of interest expense in connection with the facility lease obligation in the Company's statement of operations. At September 30, 2009, the facility lease obligation balance was \$62.6 million.

10. Royalty Agreements with Novartis Pharma AG

In June 2009, the Company entered into two royalty agreements with Novartis Pharma AG ("Novartis") that replaced a previous collaboration and license agreement. Under the first royalty agreement, the Company is entitled to receive royalties on worldwide sales of Novartis' canakinumab (ACZ885), a fully human anti-interleukin-IL1ß antibody approved to treat CAPS and in development for a number of other inflammatory diseases. On the basis of the same agreement, the Company waived its rights to opt-in to the development and commercialization of canakinumab. Under the second royalty agreement, Novartis is entitled to receive royalties on worldwide sales of a second-generation interleukin-1 Trap, should the Company decide to proceed in the development of, and ultimately commercialize, this Trap. The financial terms of both agreements are identical in relation to stepped royalties to be paid on the basis of future sales, which start at 4% and reach 15% when annual sales exceed \$1.5 billion. The agreements do not provide for any upfront or milestone payments or any sharing of development expenses.

The royalty agreements replace a 2003 collaboration and license agreement under which the Company had the right to opt in to the development and commercialization of Novartis' interleukin-1 antibody and Novartis had the right to opt in to the development and commercialization of the Company's second-generation interleukin-1 Trap. That collaboration and license agreement has been terminated.

11. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

12. Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate arrangement consideration in a multiple element revenue arrangement by requiring the use of estimated selling price to allocate arrangement consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. The Company will be required to adopt this amended guidance effective for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management is currently evaluating the impact that this guidance will have on the Company's financial statements.

13. Subsequent Events

The Company has evaluated subsequent events through November 3, 2009, the date on which the financial statements were issued, and has determined that there are no subsequent events that require adjustments to the financial statements for the quarter ended September 30, 2009.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, stockholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We also have six product candidates currently in clinical development, including three in late-stage clinical development. Our late stage programs are aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group, VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC, and ARCALYST, which is being developed for the treatment of gout. Our earlier stage clinical programs are REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis, REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology, and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All three of these antibodies are being developed in collaboration with sanofi-aventis.

We expect that our next generation of product candidates will be based on our proprietary technologies for developing human monoclonal antibodies. Our antibody program is being conducted primarily in collaboration with sanofi-aventis. Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technology and combine that foundation with our clinical development and manufacturing capabilities to build a successful, integrated biopharmaceutical company. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*TM technology platforms. Our discovery platforms are designed to identify specific genes of therapeutic interest for a particular disease or cell type and validate targets through high-throughput production of mammalian models. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*TM) may then be utilized to design and produce new product candidates directed against the disease target. Our first three antibody product candidates currently in clinical trials were developed using *VelocImmune*. Over the course of the next several years, we plan to advance an average of two to three new antibody product candidates into clinical development each year. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, and commercialize new product candidates.

Commercial Product:

ARCALYST® (rilonacept) - Cryopyrin-Associated Periodic Syndromes (CAPS)

In February 2008, we received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older. We shipped \$5.3 million and \$15.0 million of ARCALYST to our distributors during the third quarter and first nine months of 2009, respectively, compared to \$4.3 million and \$6.7 million in the same periods of 2008. We expect to ship approximately \$20 million of ARCALYST to our U.S. distributors in 2009, compared to \$10.7 million in 2008.

In October 2009, rilonacept was approved under exceptional circumstances by the European Medicines Agency (EMEA) for the treatment of CAPS with severe symptoms in adults and children aged 12 years and older. Such authorizations are permissible for products for which a company can demonstrate that comprehensive data cannot be provided, for example, because of the rarity of the condition. Each year, we will need to provide for review by the EMEA any new or follow-up information that may become available. We own worldwide rights to ARCALYST (rilonacept).

ARCALYST is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST is approved in the United States for patients with CAPS, a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli. CAPS is caused by a range of mutations in the gene NLRP3 (formerly known as *CIAS1*) which encodes a protein named cryopyrin. In addition to FCAS and MWS, CAPS includes Neonatal Onset Multisystem Inflammatory Disease (NOMID). ARCALYST has not been studied for the treatment of NOMID.

Clinical Programs:

1. Aflibercept (VEGF Trap) - Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF), VEGF-B and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, VEGF-B and PIGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are enrolling patients in three Phase 3 trials that are evaluating combinations of aflibercept with standard chemotherapy regimens for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel. The third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. All three trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. At the end of the third quarter of 2009, each of these trials was more than 80% enrolled. Analyses of the data from these studies will be conducted when a prespecified number of events have occurred in each trial. Based on current enrollment and event rates, an interim analysis of the Phase 3 study in colorectal cancer is expected to be conducted by an Independent Data Monitoring Committee (IDMC) in the second half of 2010. Complete results from this study in colorectal cancer and from the study in non-small cell lung cancer are anticipated in the first half of 2011. Based on current enrollment and event rates, an interim analysis of the prostate study is expected to be conducted by an IDMC in mid-2011, with complete results anticipated in 2012. In addition, we and sanofi-aventis are conducting a Phase 2 study (called AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin.

In September 2009, as previously reported, a fourth Phase 3 trial (VANILLA) that was evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC. As part of a planned interim efficacy analysis, the IDMC determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine in this study. The types and frequencies of adverse events reported on the combination arm with aflibercept were generally as anticipated.

In addition, multiple exploratory studies are being conducted in conjunction with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) evaluating aflibercept as a single agent or in combination with chemotherapy regimens in a variety of cancer indications.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) collaborate on the development and commercialization of aflibercept globally. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

2. VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare also are conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. We and Bayer HealthCare also initiated a Phase 3 program in Central Retinal Vein Occlusion (CRVO) in July 2009. In connection with the dosing of the first patient in a Phase 3 study in CRVO, we received a \$20.0 million milestone payment from Bayer HealthCare.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in \underline{W} et age-related macular degeneration), are comparing VEGF Trap-Eye and Lucentis® (ranibizumab injection), marketed by Genentech, Inc., an antiangiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with Lucentis dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies. VIEW 1 and VIEW 2 are now fully enrolled, and initial data are expected in late 2010.

We and Bayer HealthCare have conducted a Phase 2 study in wet AMD which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year. These one-year study results were reported at the 2008 annual meeting of the Retina Society. In this double-masked Phase 2 trial, known as CLEAR-IT 2, 157 patients were initially treated for three months with VEGF Trap-Eye: two groups received monthly doses of 0.5 or 2.0 mg (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg (at baseline and week 12). Following the initial three-month fixed-dosing phase, patients continued to receive VEGF Trap-Eye at the same dose on a PRN dosing schedule through one year, based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria.

Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg for 12 weeks followed by PRN dosing achieved mean improvements in visual acuity versus baseline of 9.0 letters (p<0.0001 versus baseline) and 5.4 letters (p<0.085 versus baseline), respectively, at the end of one year. The proportion of patients with vision of 20/40 or better (part of the legal minimum requirement for an unrestricted driver's license in the U.S.) increased from 23% at baseline to 45% at week 52 in patients initially treated with 2.0 mg monthly and from 16% at baseline to 47% at week 52 in patients initially treated with 0.5 mg monthly. Patients receiving monthly doses of VEGF Trap-Eye of either 2.0 or 0.5 mg also achieved mean decreases in retinal thickness versus baseline of 143 microns (p<0.0001 versus baseline) and 125 microns (p<0.0001 versus baseline) at week 52, respectively. After week 12 to week 52 in the PRN dosing period, patients initially dosed on a 2.0 mg monthly schedule received, on average, only 1.6 additional injections and those initially dosed on a 0.5 mg monthly schedule received, on average, 2.5 additional injections.

While PRN dosing following a fixed quarterly dosing regimen (with dosing at baseline and week 12) also yielded improvements in visual acuity and retinal thickness versus baseline at week 52, the results generally were not as robust as those obtained with initial fixed monthly dosing.

All patients who completed the one year CLEAR-IT 2 study were eligible to participate in an extension stage of the study. Twenty-four-month results of the extension stage were presented in October 2009 at the 2009 American Academy of Ophthalmology meeting. After receiving VEGF Trap-Eye for one year, the 117 patients who elected to enter the extension stage were dosed on a 2.0 mg PRN basis, irrespective of the dose at which they were treated earlier in the study. On a combined basis, for these 117 patients, the mean gain in visual acuity was 7.3 letters (p<0.0001 versus baseline) at the three-month primary endpoint of the original Phase 2 study, 8.4 letters (p<0.0001 versus baseline) at one year, and 6.1 letters (p<0.0001 versus baseline) at month 12 of the extension stage. Thus, after 24 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 4.6 injections over the 21-month PRN dosing phase that extended from month three to month 24. The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

The DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study began in December 2008 and completed enrollment of approximately 200 patients in the U.S., Canada, European Union, and Australia in July 2009. The patients in the study will be treated for 52 weeks followed by six additional months of safety evaluation. The primary efficacy endpoint is the change in best corrected visual acuity (BCVA) from baseline to week 24. These data are expected to be reported during the first half of 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of Central Retinal Vein Occlusion (CRVO), another cause of blindness. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated iNtravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting Infitration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. Enrollment in the COPERNICUS study began during the third quarter of 2009, and enrollment in the GALILEO study began in October 2009. Initial data are anticipated in early 2011.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We received an up-front payment of \$75.0 million from Bayer HealthCare. In 2007, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in wet AMD. In July 2009, we received a \$20.0 million milestone payment from Bayer HealthCare following dosing of the first patient in a Phase 3 study of VEGF Trap-Eye in CRVO. We can earn up to \$70 million in additional development and regulatory milestones related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135 million in sales milestones if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

3. ARCALYST® (rilonacept) - Inflammatory Diseases

We are evaluating ARCALYST in gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation. In September 2008, we announced the results of a Phase 2 study which evaluated the efficacy and safety of ARCALYST versus placebo in the prevention of gout flares induced by the initiation of urate-lowering drug therapy that is used to control gout. In this 83-patient, double-blind, placebo-controlled study, the mean number of flares per patient over the first 12 weeks of urate-lowering therapy was 0.79 with placebo and 0.15 with ARCALYST (p=0.0011), an 81% reduction. This was the primary endpoint of the study. All secondary endpoints also were met with statistical significance. In the first 12 weeks of treatment, 45.2% of patients treated with placebo experienced a gout flare and, of those, 47.4% had more than one flare. Among patients treated with ARCALYST, only 14.6% experienced a gout flare (p=0.0037 versus placebo) and none had more than one flare. Injection-site reaction was the most commonly reported adverse event with ARCALYST and no serious drug-related adverse events were reported.

Results from this study after the first 16 weeks of urate-lowering therapy were reported at the annual meeting of the European League Against Rheumatism (EULAR) in June 2009. Through 16 weeks, the mean number of flares per patient was 0.93 with placebo and 0.22 with ARCALYST (p=0.0036). In the first 16 weeks of treatment, 47.6% of patients treated with placebo experienced a gout flare and, of those, 55.0% had more than one flare. Among patients treated with ARCALYST, 22.0% experienced a gout flare (p=0.0209 versus placebo) and none had more than one flare. Adverse events after 16 weeks of treatment were similar to those reported after 12 weeks with the most frequently reported categories being infection and musculoskeletal complaints.

Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The uric acid can form crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the uric acid crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the uric acid crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

During the first quarter of 2009, we initiated a Phase 3 clinical development program with ARCALYST for the treatment of gout. The program includes four clinical trials, all of which are currently enrolling patients. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating ARCALYST versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) is evaluating treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a placebo-controlled safety study (RE-SURGE). We expect to report initial data from the Phase 3 program during the first half of 2010.

In June 2009, we announced that we had entered into two royalty agreements with Novartis Pharma AG that replaced a previous collaboration and license agreement. Under the first royalty agreement, we are entitled to receive royalties on worldwide sales of Novartis' canakinumab (ACZ885), a fully human anti-interleukin-IL1ß antibody. Under this agreement, we also waived our rights to opt-in to the development and commercialization of canakinumab. Canakinumab is approved to treat Cryopyrin-Associated Periodic Syndrome (CAPS) and is in development for chronic gout and a number of other inflammatory diseases. On October 20, 2009, Novartis announced positive Phase 2 results showing that canakinumab is significantly more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout.

Under the second royalty agreement, Novartis is entitled to receive royalties on worldwide sales of a second-generation interleukin-1 Trap, should we decide to proceed in the development of this Trap. The financial terms of both agreements are identical in relation to stepped royalties, to be paid on the basis of future sales, which start at 4% and reach 15%, when annual sales exceed \$1.5 billion. The agreements do not provide for any upfront or milestone payments or any sharing of development expenses.

The royalty agreements replace a 2003 collaboration and license agreement under which we had the right to opt in to the development and commercialization of Novartis' interleukin-1 antibody and Novartis had the right to opt in to the development and commercialization of our second-generation interleukin-1 Trap. That collaboration and license agreement has been terminated.

4. Monoclonal Antibodies

We and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated using our *VelocImmune®* technology. The first therapeutic antibody product candidates to enter clinical development under the collaboration are REGN88, REGN475, and REGN421. During the third quarter of 2009, REGN475, an antibody to Nerve Growth Factor (NGF), a novel target for pain, began a dose ranging study in osteoarthritis of the knee. Trial results are expected during the first half of 2010. A Phase 1 study of REGN475 in healthy volunteers is also continuing, and Phase 1 studies are in progress with REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis, and REGN421, an antibody to Delta-like ligand-4 (Dll4) that is being studied in patients with advanced malignancies. We and sanofiaventis expect to enter two more human monoclonal antibodies into clinical development this year and to advance an average of two to three into clinical development each year thereafter over the course of the next several years.

Research and Development Technologies:

One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST® (rilonacept), as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite* is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies.

$VelociSuite^{TM}$

VelociSuite consists of $VelociMmune^{\circledast}$, $VelociGene^{\$}$, $VelociMouse^{\$}$, and $VelociMab^{TM}$. The VelociMmune mouse platform is utilized to produce fully human monoclonal antibodies. VelociMmune was generated by exploiting our VelociGene technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. Velocimmune mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. Velocimmune and our entire VelociSuite offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the Velocimmune technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene®* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body, during normal body functioning, as well as in disease processes. For the optimization of preclinical development and toxicology programs, *VelociGene* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

The *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, the VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMabTM* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *Velocimmune®* human monoclonal antibodies.

Antibody Collaboration with sanofi-aventis

In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$75 million of research from the collaboration's inception through December 31, 2008 and will fund up to \$100 million per year in 2009 through 2012. Sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/45% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of \$21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

License Agreement with AstraZeneca

In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made \$20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, and 2009. AstraZeneca is required to make up to three additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the next additional payment. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune* technology.

License Agreement with Astellas

In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made \$20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, and 2009. Astellas is required to make up to three additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the next additional payment. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune* technology.

Academic VelocImmune® Investigators' Program

In September 2008, we entered into an agreement that will provide researchers at Columbia University Medical Center with access to our *VelocImmune* technology platform. In March 2009, we entered into a similar agreement with The University of Texas Southwestern Medical Center at Dallas. Under the agreements, scientists at these academic institutions will use *VelocImmune* mice to generate antibodies against their research targets and will conduct research to discover potential human therapeutics based on the antibodies. We have an exclusive option to license the antibodies for development and commercialization as therapeutic or diagnostic products and will pay to the appropriate institution a low single-digit royalty on ensuing product sales.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. We are using our *VelociGene®* technology to take aim at 3,500 of the most difficult genes to target and which are not currently the focus of other large-scale knockout mouse programs. We also agreed to grant a limited license to a consortium of research institutions, the other major participants in the Knockout Mouse Project, to use components of our *VelociGene* technology in the Knockout Mouse Project. We are generating a collection of targeting vectors and targeted mouse ES cells which can be used to produce knockout mice. These materials are available to academic researchers without charge. We will receive a fee for each targeted ES cell line or targeting construct made by us or the research consortium and transferred to commercial entities.

Under the NIH grant, as amended, we are entitled to receive a minimum of \$25.3 million over the five-year period beginning September 2006, including \$1.5 million to optimize our existing C57BL/6 ES cell line and its proprietary growth medium, both of which are being supplied to the research consortium for its use in the Knockout Mouse Project. We have the right to use, for any purpose, all materials generated by us and the research consortium.

Research Programs:

Oncology and Angiogenesis

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor specifically expressed on blood vessel cells. In 1994, we discovered a second family of angiogenic growth factors, termed angiopoietins, and we have received patents covering members of this family. Angiopoietins include naturally occurring positive and negative regulators of angiogenesis, as described in numerous scientific manuscripts published by our scientists and their collaborators. Angiopoietins are being evaluated in preclinical research by us and our academic collaborators. Our preclinical studies have revealed that VEGF and angiopoietins normally function in a coordinated and collaborative manner during blood vessel growth. Manipulation of both VEGF and angiopoietins seems to be of value in either promoting or blocking vessel growth. We have research programs focusing on several targets in the areas of oncology and angiogenesis.

Tumors depend on the growth of new blood vessels (a process called "angiogenesis") to support their continued growth. Therapies that block tumor angiogenesis, specifically those that block VEGF, the key initiator of tumor angiogenesis, recently have been validated in human cancer patients. However, anti-VEGF approaches do not work in all patients, and many tumors can become resistant to such therapies.

In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. A fully human monoclonal antibody to Dll4 that was discovered using our *VelocImmune*® technology is being studied in a Phase 1 clinical trial in patients with advanced malignancies.

Metabolic and Related Diseases

Food intake and metabolism are regulated by complex interactions between diverse neural and hormonal signals that serve to maintain an optimal balance between energy intake, storage, and utilization. The hypothalamus, a small area at the base of the brain, is critically involved in integrating peripheral signals which reflect nutritional status and neural outputs which regulate appetite, food seeking behaviors, and energy expenditure. Metabolic disorders, such as type 2 diabetes, reflect a dysregulation in the systems which ordinarily tightly couple energy intake to energy expenditure. Our preclinical research program in this area encompasses the study of peripheral (hormonal) regulators of food intake and metabolism in health and disease. We have identified several targets in these therapeutic areas and are evaluating lead monoclonal antibodies in relevant preclinical models.

Muscle Diseases and Disorders

Muscle atrophy occurs in many neuromuscular diseases and also when muscle is unused, as often occurs during prolonged hospital stays and during convalescence. Currently, physicians have few options to treat subjects with muscle atrophy or other muscle conditions which afflict millions of people globally. Thus, a treatment that has beneficial effects on skeletal muscle could have significant clinical benefit. Our muscle research program is currently focused on conducting *in vivo* and *in vitro* experiments with the objective of demonstrating and further understanding the molecular pathways involved in muscle atrophy and hypertrophy, and discovering therapeutic candidates that can modulate these pathways. We have several molecules in late stage research and are evaluating them for possible further development.

Other Therapeutic Areas

We also have research programs focusing on ophthalmology, inflammatory and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® (rilonacept) or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2009, we had a cumulative loss of \$904.6 million. In the absence of significant revenues from the commercialization of ARCALYST or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST in other indications; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2009 and plans over the next 12 months are as follows:

Clinical Program ARCALYST® (rilonacept; also known as IL-1 Trap)	 2009 Events to Date Initiated patient enrollment in the Phase 3 program evaluating ARCALYST in the prevention of gout flares associated with the initiation of urate-lowering drug therapy and in the treatment of acute gout attacks 	 2009-10 Plans (next 12 months) Continue enrollment in the Phase 3 program in gout Report initial data from Phase 3 gout program during the first half of 2010
Aflibercept (VEGF Trap - Oncology)	 Initiated a Phase 2 1st line study in metastatic colorectal cancer in combination with chemotherapy Achieved more than 80% enrollment in each of the Phase 3 studies Reported results of a Phase 2 singleagent study in symptomatic malignant ascites (SMA) Discontinued a Phase 3 study in metastatic pancreatic cancer in combination with chemotherapy 	 Continue enrollment of the Phase 3 studies in colorectal cancer, non-small cell lung cancer, and prostate cancer During the second half of 2010, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study in colorectal cancer
VEGF Trap-Eye (intravitreal injection)	 Completed enrollment of patients in the Phase 3 wet AMD program (VIEW 1 and VIEW 2) Completed enrollment of patients in the Phase 2 DME trial Initiated a Phase 3 CRVO program 	 Continue enrollment in Phase 3 CRVO trials Report data from Phase 2 DME trial during the first half of 2010 Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010
Monoclonal Antibodies	 Initiated a Phase 1 trial for REGN475 (anti-NGF) in healthy volunteers Initiated a Phase 1 trial for REGN421 (anti-Dll4) in oncology Initiated a dose ranging study for REGN475 in osteoarthritis of the knee 	 Report data from a Phase 1 trial of REGN88 (anti-IL-6R) in rheumatoid arthritis Initiate a dose-ranging study for REGN88 in rheumatoid arthritis Initiate additional Phase 2 trials for REGN475 in pain indications Report data from the study of REGN475 in osteoarthritis of the knee during the first half of 2010 Advance additional antibody candidate(s) into clinical development

Results of Operations

Three Months Ended September 30, 2009 and 2008

Net Loss:

Regeneron reported a net loss of \$1.0 million, or \$0.01 per share (basic and diluted), for the third quarter of 2009 compared to a net loss of \$19.1 million, or \$0.24 per share (basic and diluted), for the third quarter of 2008. The decrease in our net loss was principally due to higher contract research and development revenue in connection with our antibody collaboration with sanofiaventis, and receipt of a \$20.0 million research progress payment from Bayer HealthCare, partially offset by higher research and development expenses, as detailed below.

Revenues:

Revenues for the three months ended September 30, 2009 and 2008 consist of the following:

(In millions)	200 9	2008
Contract research & development revenue		
Sanofi-aventis	\$ 68.5	\$42.0
Bayer HealthCare	12.2	9.0
Other	1.8	1.9
Total contract research & development revenue	82.5	529
Research progress payment	20.0	
Technology licensing revenue	10.0	10.0
Net product sales	5.0	2.7
Total revenue	\$117.5	\$65.6

The contract research and development revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

	Three mor	nths ended
Sanofi-aventis Contract Research & Development Revenue	Septem	ber 30,
(In millions)	2009	2008
Affibercept		
Regeneron expense reimbursement	\$ 7.0	\$ 7.3
Recognition of deferred revenue related to up-front payments	2.5	2.1
Total aflibercept	9.5	9.4
Antibody		
Regeneron expense reimbursement	55.7	29.5
Recognition of deferred revenue related to up-front payment	2.6	2.6
Recognition of revenue related to $VelociGene$ agreement	0.7	0.5
Total antibody	59.0	32.6
Total sanofi-aventis contract research & development revenue	\$ 68.5	\$ 42.0

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in the third quarter of 2009, compared to the same period in 2008, primarily due to lower costs related to internal research activities, partially offset by higher costs related to manufacturing aflibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments increased in the third quarter of 2009 compared to the same period in 2008 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of September 30, 2009, \$45.0 million of the original \$105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In the third quarter of 2009, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of \$25.7 million under the discovery agreement and \$30.0 million of development costs under the license agreement, compared to \$24.1 million and \$5.4 million, respectively, in the third quarter of 2008. The higher reimbursement amounts in the third quarter of 2009 compared to the same period in 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates, including REGN88, REGN421, and REGN475, under the license agreement.

Recognition of deferred revenue under the antibody collaboration related to sanofi-aventis' \$85.0 million up-front payment. As of September 30, 2009, \$65.7 million of this up-front payment was deferred and will be recognized as revenue in future periods.

As described above, in August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the three months ended September 30, 2009, we recognized \$0.7 million of revenue related to this agreement.

The contract research and development revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of deferred revenue related to a non-refundable \$75.0 million up-front payment and \$20.0 million non-substantive milestone payment.

	Three mon	iths ended
Bayer HealthCare Contract Research & Development Revenue	Septem	ber 30,
(In millions)	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eve development expenses	§ 9.7	\$ 5.7
Recognition of deferred revenue related to up-front and non-substantive milestone payments	2.5	3.3
Total Bayer HealthCare contract research & development revenue	\$ 12.2	\$ 90

In the third quarter of 2009, cost-sharing of Regeneron VEGF Trap-Eye development expenses increased, compared to the same period in 2008, primarily due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO. Recognition of deferred revenue related to Bayer's up-front and milestone payments decreased in the third quarter of 2009 compared to the same period in 2008 due to an extension of the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008. As of September 30, 2009, \$59.3 million of the up-front licensing and non-substantive milestone payments was deferred and will be recognized as revenue in future periods.

Other contract research and development revenue in the third quarter of 2009 and 2008 includes \$1.4 million and \$1.2 million, respectively, in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

In July 2009, we received a \$20.0 million substantive milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO. The payment was recognized in revenues as a research progress payment for the three months ended September 30, 2009.

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the third quarter of both 2009 and 2008, we recognized \$10.0 million of technology licensing revenue related to these agreements.

For the three months ended September 30, 2009, we recognized as revenue \$5.0 million of ARCALYST® (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated, compared to \$2.7 million for the same period in 2008. At September 30, 2009, deferred revenue related to ARCALYST net product sales totaled \$5.0 million.

Expenses:

Total operating expenses increased to \$118.7 million in the third quarter of 2009 from \$83.5 million in the same period of 2008. Our average headcount increased to 998 in the third quarter of 2009 from 851 in the same period of 2008, principally as a result of our expanding research and development activities that are primarily attributable to the sanofi-aventis antibody collaboration.

Operating expenses in the third quarter of 2009 and 2008 include a total of \$7.5 million and \$8.2 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended September 30, 2009			
	Expenses before			
	inclusion of Non-cash	Non-cash		
Expenses	Compensation	Compensation	Expenses as	
(In millions)	Expense	Expense	Reported	
Research and development	\$ 100.8	\$ 46	\$ 105.4	
Selling, general, and administrative	9.9	2.9	12.8	
Cost of goods sold	0.5		0.5	
Total operating expenses	\$ 111.2	\$ 7.5	\$ 118.7	
	For the three months ended September 30, 2008			
	Expenses before			
	inclusion of Non-cash	Non-cash		
Expenses	Compensation	Compensation	Expenses as	
(In millions)	Expense	Expense	Reported	
Research and development	\$ 67.1	\$ 50	\$ 72.1	
Selling, general, and administrative	7.9	3.2	11.1	
Cost of goods sold	0.3		0.3	

Research and Development Expenses:

Total operating expenses

Research and development expenses increased to \$105.4 million in the third quarter of 2009 from \$72.1 million in the same period of 2008. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2009 and 2008:

75.3

83.5

	For the three	months ended	
Research and Development Expenses	September 30,		
(In millions)	2009	2008	Increase
Payroll and benefits (1)	\$ 24.5	\$ 22.5	\$ 20
Clinical trial expenses	29.4	14.7	14.7
Clinical manufacturing costs (2)	18.0	13.8	4.2
Research and preclinical development costs	11.1	8.7	2.4
Occupancy and other operating costs	10.5	8.8	1.7
Cost-sharing of Bayer HealthCare VEGF			
Trap: Eye development expenses (3)	11.9	36	8.3
Total research and development	\$ 105.4	\$ 72.1	\$ 33.3

- (1) Includes \$3.9 million and \$4.3 million of Non-cash Compensation Expense for the three months ended September 30, 2009 and 2008, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.7 million of Non-cash Compensation Expense for both the three months ended September 30, 2009 and 2008.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent interim fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent interim quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and recently initiated Phase 3 trial in CRVO, (ii) ARCALYST, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibodies, primarily related to REGN475 for the treatment of pain. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of monoclonal antibodies. Research and preclinical development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount and expanded research and development activities. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD, which is being conducted by Bayer HealthCare.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	For the three months ended		
Project Costs	September 30,		Increase
(In millions)	2009	2008	(Decr ea s e)
ARCALYST® (rilonacept)	\$ 15.5	\$ 9.7	\$ 5.8
Aflibercept	6.1	6.6	(0.5)
VEGF Trap-Eye	29.9	18.7	11.2
REGN88	10.0	5.4	4.6
REGN421 and REGN475	9.5		9.5
Other research programs & unallocated costs	34.4	31.7	2.7
Total research and development expenses	\$ 105.4	\$ 72.1	\$ 33.3

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We project to ship approximately \$20 million of ARCALYST to our U.S. distributors in 2009.

Selling, General, and Administrative Expenses:

Selling, general, and administrative expenses increased to \$12.8 million in the third quarter of 2009 from \$11.1 million in the same period of 2008 due primarily to (i) higher compensation and facility-related expenses due primarily to increases in administrative headcount to support our expanded research and development activities, (ii) higher patent-related costs, (iii) higher professional fees related to various corporate matters, and (iv) higher patient assistance costs related to ARCALYST,. These increases were partially offset by lower market research costs related to various programs and a decrease in recruitment costs for administrative headcount.

Cost of Goods Sold:

In the third quarter of 2008, we began recognizing revenue and cost of goods sold from product sales of ARCALYST. We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not being included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold for the third quarter of 2009 was \$0.5 million, compared to \$0.3 million for the same period of 2008, and consisted primarily of royalty and other period costs related to ARCALYST commercial supplies.

Other Income and Expense:

Investment income decreased to \$0.9 million in the third quarter of 2009 from \$3.7 million in the comparable quarter of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in the first quarter of 2009 compared to the same quarter of 2008. Interest expense decreased to \$0.6 million in the third quarter of 2009 from \$1.8 million in the comparable quarter of 2008. Interest expense in 2009 was attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. Interest expense in the third quarter of 2008 related to \$200.0 million of formerly outstanding 5.5% Convertible Senior Subordinated Notes which we either repurchased or repaid in full during 2008. During the second and third quarters of 2008, we repurchased a total of \$82.5 million in principal amount of these convertible notes for \$83.3 million. In connection with the repurchases, we recognized a \$7 thousand loss on early extinguishment of debt in the third quarter of 2008.

Income Tax Expense:

In the third quarter of 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards for tax purposes that would otherwise have expired over the next several years. As a result, we incurred income tax expense of \$3.1 million, which relates to U.S. Federal and New York State alternative minimum tax and includes \$0.2 million of interest and penalties.

Nine Months Ended September 30, 2009 and 2008

Net Loss:

Regeneron reported a net loss of \$31.3 million, or \$0.39 per share (basic and diluted), for the first nine months of 2009 compared to a net loss of \$49.6 million, or \$0.63 per share (basic and diluted), for the same period of 2008. The decrease in our net loss was principally due to higher contract research and development revenue in connection with our antibody collaboration with sanofiaventis, receipt of a \$20.0 million research progress payment from Bayer HealthCare, and higher ARCALYST® (rilonacept) sales, partially offset by higher research and development expenses, as detailed below.

Revenues:

Revenues for the nine months ended September 30, 2009 and 2008 consist of the following:

(In millions)	2009	2008
Contract research & development revenue		
Sanofi-aventis	\$178.9	\$116.3
Bayer HealthCare	34.9	28.2
Other	5.3	5.4
Total contract research & development revenue	219.1	149.9
Research progress payment	20.0	
Technology licensing revenue	30.0	30.0
Net product sales	13.4	2.7
Total revenue	\$282.5	\$182.6

The contract and research development revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and partly of the recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

	Nine mor	nths ended
Sanofi-aventis Contract Research & Development Revenue	Septer	mber 30,
(In millions)	2009	2008
Affiberrept		
Regeneron expense reimbursement	\$ 21.6	\$ 29.3
Recognition of deferred revenue related to up-front payments	7.4	6.2
Total aflibercept	29.0	35.5
Antibody		
Regeneron expense reimbursement	139.8	72.4
Recognition of deferred revenue related to up-front payment	7.9	7.9
Recognition of revenue related to <i>VelociGene®</i> agreement	2.2	0.5
Total antibody	149.9	80.8
Total sanofi-aventis contract research & development revenue	\$ 178.9	\$ 116.3

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in the first nine months of 2009, compared to the same period in 2008, primarily due to lower costs related to internal research activities and manufacturing aflibercept clinical supplies. Recognition of deferred revenue related to sanofi-aventis' up-front aflibercept payments increased in the first nine months of 2009 compared to the same period in 2008 due to shortening the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008.

In the first nine months of 2009, sanofi-aventis' reimbursement of Regeneron's antibody expenses consisted of \$76.7 million under the discovery agreement and \$63.1 million of development costs under the license agreement, compared to \$56.5 million and \$15.9 million, respectively, in the first nine months of 2008. The higher reimbursement amounts in the first nine months of 2009 compared to the same period in 2008 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates, including REGN88, REGN421, and REGN475, under the license agreement.

As described above, in August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the nine months ended September 30, 2009, we recognized \$2.2 million of revenue related to this agreement, compared to \$0.5 million for the same period in 2008.

The contract research and development revenue we earn from Bayer HealthCare, as detailed below, consists partly of cost sharing of Regeneron VEGF Trap-Eye development expenses and partly of recognition of deferred revenue related to a non-refundable \$75.0 million up-front payment and \$20.0 million non-substantive milestone payment.

	Nine mont	hs e nd ed
Bayer HealthCare Contract Research & Development Revenue	Septemb	oer 30,
(In millions)	2009	2008
Cost-sharing of Regeneron VEGT Trap-Eye development expenses	\$ 27.5	\$ 18.3
Recognition of deferred revenue related to up-front and non-substantive milestone payments	7.4	9.9
Total Bayer HealthCare contract research & development revenue	\$ 34.9	\$ 28.2

In the first nine months of 2009, cost-sharing of Regeneron VEGF Trap-Eye development expenses increased, compared to the same period in 2008, primarily due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO. Recognition of deferred revenue related to Bayer's up-front and non-substantive milestone payments decreased in the first nine months of 2009 compared to the same period in 2008 due to an extension of the estimated performance period over which this deferred revenue is being recognized, effective in the fourth quarter of 2008.

Other contract research and development revenue in the first nine months of 2009 and 2008 includes \$4.4 million and \$3.6 million, respectively, in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

In July 2009, we received a \$20.0 million substantive milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO. The payment was recognized in revenues as a research progress payment for the nine months ended September 30, 2009.

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the first nine months of both 2009 and 2008, we recognized \$30.0 million of technology licensing revenue related to these agreements.

For the nine months ended September 30, 2009, we recognized as revenue \$13.4 million of ARCALYST® (rilonacept) net product sales for which both the right of return no longer exists and rebates can be reasonably estimated, compared to \$2.7 million for the same period in 2008.

Expenses:

Total operating expenses increased to \$317.2 million in the first nine months of 2009 from \$236.3 million in the same period of 2008. Our average headcount increased to 967 in the first nine months of 2009 from 778 in the same period of 2008 principally as a result of our expanding research and development activities that are primarily attributable to the sanofi-aventis antibody collaboration.

Operating expenses for the first nine months of 2009 and 2008 include a total of \$22.6 million and \$24.7 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the nine months ended September 30, 2009			
	Expenses before			
	inclusion of Non-cash	Non-cash		
Expenses	Compensation	Compensation	Expenses as	
(In millions)	Expense	Expense	Reported	
Research and development	\$ 256.0	\$ 14.0	\$ 280.0	
Selling, general, and administrative	27.3	8.6	35.9	
Cost of goods sold	1.3		1.3	
Total operating expenses	\$ 294.6	\$ 22.6	\$ 317.2	
	For the nine month Expenses before	s ended Septemb	er 30, 2008	
	inclusion of Non-cash	Non-cash		
Expenses	Compensation	Compensation	Expenses as	
(In millions)	Expense	Expense	Reported	
Research and development	\$ 185.5	\$ 14.8	\$ 200.3	
Selling, general, and administrative	25.8	9.9	35.7	
Cost of goods sold	0.3		0.3	
Total operating expenses	\$ 211.6	\$ 24.7	\$ 236.3	

Research and Development Expenses:

Research and development expenses increased to \$280.0 million in the first nine months of 2009 from \$200.3 million in the same period of 2008. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2009 and 2008:

	roi the line mo		
Research and Development Expenses	Septe m be		
(In millions)	2009	2008	Increase
Payroll and benefits (1)	\$ 71.D \$	61.4	\$ 96
Clinical trial expenses	78.9	35.2	43.7
Clinical manufacturing costs (2)	46.0	40.3	5.7
Research and preclinical development costs	29.5	21.6	7.9
Occupancy and other operating costs	27.9	22.8	5.1
Cost-sharing of Bayer HealthCare VEGF			
Trap-Eye development expenses (3)	26.7	19.0	7.7
Total research and development	\$ 280.0 \$	200.3	\$ 79.7

- (1) Includes \$11.8 million and \$12.6 million of Non-cash Compensation Expense for the nine months ended September 30, 2009 and 2008, respectively.
- (2)Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$2.2 million of Non-cash Compensation Expense for both
- the nine months ended September 30, 2009 and 2008.
 Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF (3)Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent interim fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent interim quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

For the nine menths anded

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO, (ii) ARCALYST, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibodies, primarily related to REGN88 in rheumatoid arthritis and REGN475 for the treatment of pain. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of ARCALYST and monoclonal antibodies, partially offset by lower costs related to manufacturing aflibercept clinical supplies. Research and preclinical development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount and expanded research and development activities. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD, which is being conducted by Bayer HealthCare.

We budget our research and development costs by expense category, rather than by project. We also prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs (including ARCALYST for the treatment of CAPS prior to receipt of marketing approval from the FDA in February 2008) are shown below:

	For the nine months ended			
Project Costs	Septemb	Increase		
(In millions)	2009	2009 2008		
ARCALYST® (rilonacept)	\$ 49.1	\$ 24.9	\$ 24.2	
Aflibercept	17.7	25.4	(7.7)	
VEGE Trap-Eye	77.7	57.6	20.1	
REGN88	27.5	14.7	12.8	
REGN421 and REGN475	19,4		19.4	
Other research programs & unallocated costs	88.6	77.7	10.9	
Total research and development expenses	\$ 280.0	\$ 200.3	\$ 79.7	

For the reasons described above under "Research and Development Expenses" for the three months ended September 30, 2009 and 2008, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We project to ship approximately \$20 million of ARCALYST to our U.S. distributors in 2009.

 $Selling,\ General,\ and\ Administrative\ Expenses:$

Selling, general, and administrative expenses increased slightly to \$35.9 million from \$35.7 million for the first nine months of 2009 compared to 2008. In 2009, we incurred (i) higher compensation expense and facility-related expenses, due primarily to increases in administrative headcount to support our expanded research and development activities, (ii) higher selling expenses and patient assistance costs related to ARCALYST, and (iii) higher patent-related costs. These increases were offset by (i) lower market research costs related to various programs, (ii) a decrease in recruitment costs for administrative headcount, and (iii) lower professional fees related to various corporate matters.

Cost of Goods Sold:

In the third quarter of 2008, we began recognizing revenue and cost of goods sold from product sales of ARCALYST® (rilonacept). We began capitalizing inventory costs associated with commercial supplies of ARCALYST subsequent to receipt of marketing approval from the FDA in February 2008. Costs for manufacturing supplies of ARCALYST prior to receipt of FDA approval were recognized as research and development expenses in the period that the costs were incurred. Therefore, these costs are not included in cost of goods sold when revenue is recognized from the sale of those supplies of ARCALYST. Cost of goods sold for the first nine months of 2009 was \$1.3 million, compared to \$0.3 million for the same period in 2008, and consisted primarily of royalty and other period costs related to ARCALYST commercial supplies.

Other Income and Expense:

Investment income decreased to \$3.9 million in the first nine months of 2009 from \$15.5 million in the comparable period of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in the first nine months of 2009 compared to the same period in 2008. Interest expense decreased to \$0.6 million in the first nine months of 2009 from \$7.5 million in the comparable period of 2008. Interest expense in 2009 was attributable to the imputed interest portion of the payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown. Interest expense in the first nine months of 2008 related to \$200.0 million of formerly outstanding 5.5% Convertible Senior Subordinated Notes which we either repurchased or repaid in full during 2008. In the first nine months of 2008, we repurchased a total of \$82.5 million in principal amount of these convertible notes for \$83.3 million. In connection with the repurchases, we recognized a \$0.9 million loss on early extinguishment of debt, representing the premium paid on the notes plus related unamortized debt issuance costs.

Income Tax Expense:

In the third quarter of 2008, we implemented a tax planning strategy which resulted in the utilization of certain net operating loss carry-forwards for tax purposes that would otherwise have expired over the next several years. As a result, we incurred income tax expense of \$3.1 million, which relates to U.S. Federal and New York State alternative minimum tax and includes \$0.2 million of interest and penalties.

Revision of Previously Issued Financial Statements

The application of authoritative guidance issued by the Financial Accounting Standards Board (FASB), under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, we became aware that certain of these conditions were applicable to our December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, we are deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

We revised our previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which we are leasing and to adjust our previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability) at each balance sheet date. We also revised our statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of our lease, with a corresponding adjustment to other long-term liabilities. In addition, we revised our statement of cash flows for the quarter ended March 31, 2009 to reclassify, from an operating activity to a financing activity, a \$5.2 million reimbursement received from our landlord for tenant improvement costs we incurred. Under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation.

As previously disclosed, the above described revisions consisted entirely of non-cash adjustments. They had no impact on our business operations, existing capital resources, or our ability to fund our operating needs, including the preclinical and clinical development of our product candidates. The revisions also had no impact on our previously reported net increases or decreases in cash and cash equivalents in any period and, except for the quarter ended March 31, 2009 (as described above), had no impact on our previously reported net cash flows from operating activities, investing activities, and financing activities. In addition, these revisions had no impact on our previously reported current assets, current liabilities, and operating revenues. We have not amended previously issued financial statements because, after considering both qualitative and quantitative factors, we determined that the judgment of a reasonable person relying on our previously issued financial statements would not have been changed or influenced by these revisions.

For comparative purposes, the impact of the above described revisions to our balance sheets as of the dates set forth below is as follows:

Balance Sheet Impact at December 31, 2007 and 2008, and March 31, 2009 (in millions)

	December 31,	December 31,	March 31,		
	2007	2008	2009		
As originally reported Property, plant, and equipment, net Total assets	\$ 58.3	\$ 87.9	\$ 109.8		
	936.3	670.0	681.4		
Other long-term liabilities	476.0	5.1	13.2		
Total liabilities		251.2	271.1		
Accumulated deficit Total stockholders' equity Total liabilities and stockholders, equity	(793.2)	(875.9)	(893.4)		
	460.3	418.8	410.3		
	936.3	670.0	681.4		
<u>As revised</u> Property, plant, and equipment, net Total assets	\$ 79.9 957.9	\$ 142.0 724. 2	\$ 164.6 736.2		
Facility lease obligation	21.6	54.2	60.0		
Other long-term liabilities	0.9	2.4	3.2		
Foral liabilities	498.5	302.7	321.1		
Accumulated deficit	(794 1)	(873.3)	(888.7)		
Total stockholders' equity	459.4	421.5	415.1		
Total liabilities and stockholders' equity	957.9	724.2	73 6.2		

For comparative purposes, the impact of the above described revisions to our statements of operations and statement of cash flows for the period(s) set forth below is as follows:

Statements of Operations Impact for the three, six, and nine month periods ended March 31, June 30 and September 30, 2008, the years ended December 31, 2007 and 2008, and the three months ended March 31, 2009 (in millions, except per share data)

	M	arch 31,	J	une 30,	S€	eptember 30,		December 31,		March 31,	
		2008		2008		2008		2007	2 0 08		2009
As originally reported											
Research and development expenses	\$	61.3	\$	127.8	\$	201.7	\$	201.6	\$278.0	\$	82.1
Selling, general, and administrative expenses		11.0		24.5		35.9		37.9	49.3		11.7
Total expenses		72.3		152.3		237.9		239.5	328.3		94.2
Net Inss		(11.6)		(30.1)		(51.2)		(105.6)	(82.7)		(17.5)
Net loss per share, basic and diluted	\$	(0.15)	\$	(0.38)	\$	(0.65)	\$	(1.59)	\$ (1.05)	\$	(0.22)
As revised											
Research and development expenses	\$	61.5	\$	128.2	\$	200.3	******* }	202.5	\$274.9	\$	80.3
Selling, general, and administrative expenses		11.1		24.6		35.7		37.9	48.9		11.4
Total expenses		72.5		152.8		236.3		240.4	324.7		92.1
Net loss		(11.8)		(30.5)		(49.6)		(106.5)	(79.1)		(15.4)
Net loss per share, basic and diluted	\$	(0.15)	\$	(0.39)	\$	(0.63)	\$	(1.61)	\$ (1.00)	\$	(0.19)

Statement of Cash Flows Impact for the three months ended March 31, 2009 (in millions)

	As Original	lly	
	Reported	l As	s Revised
Net cash used in operating activities	\$ (10.2)	8	(15.4)
Net cash used in investing activities	(39.5)		(39.5)
Net cash provided by financing activities	1.0		6.2
Net decrease in cash and cash equivalents	\$ (48.7)	\$	(48.7)

These revised amounts, as applicable, are reflected in this Quarterly Report on Form 10-Q for the period ended September 30, 2009, and will be included in our Annual Report on Form 10-K for the year ended December 31, 2009 and our Quarterly Report on Form 10-Q for the period ended March 31, 2010.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, and our technology licensing agreements, ARCALYST® (rilonacept) product revenue, and investment income.

Nine months ended September 30, 2009 and 2008

At September 30, 2009, we had \$438.6 million in cash, cash equivalents, restricted cash, and marketable securities compared with \$527.5 million at December 31, 2008. In February 2009, we received a \$20.0 million annual, non-refundable payment in connection with our non-exclusive license agreement with AstraZeneca. In May 2009, we received a \$20.0 million annual, non-refundable payment in connection with our non-exclusive license agreement with Astellas. In July 2009, we received a \$20.0 million milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO.

Cash Used in Operations:

Net cash used in operations was \$25.8 million in the first nine months of 2009 compared to \$53.2 million in the first nine months of 2008. Our net losses of \$31.3 million in the first nine months of 2009 and \$49.6 million in the first nine months of 2008 included \$22.6 million and \$24.7 million, respectively, of Non-cash Compensation Expense.

At September 30, 2009, accounts receivable increased by \$32.6 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at September 30, 2009 decreased by \$11.4 million, compared to end-of-year 2008, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by the receipt of the \$20.0 million payments from AstraZeneca and Astella, as described above, which were deferred and are being recognized ratably over the ensuing year. At September 30, 2009, accounts payable, accrued expenses, and other liabilities increased by \$18.0 million compared to end-of-year 2008. The increase was due primarily to higher liabilities for clinical trial and payroll-related costs, partially offset by a \$7.0 million decrease in the cost-sharing payment due to Bayer HealthCare at September 30, 2009 compared to December 31, 2008 in connection with the companies' VEGF Trap-Eye collaboration.

At September 30, 2008, accounts receivable increased by \$23.9 million, compared to end-of-year 2007, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at September 30, 2008 decreased by \$10.1 million, compared to end-of-year 2007, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by (i) the receipt of \$20.0 million payments from AstraZeneca in February 2008 and Astellas in June 2008, which were deferred and recognized ratably over the ensuing year, and (ii) deferral of \$3.8 million of ARCALYST® (rilonacept) net product sales at September 30, 2008.

Cash Provided by (Used in) Investing Activities:

Net cash provided by investing activities was \$19.3 million in the first nine months of 2009 compared to net cash used in investing activities of \$53.9 million in the same period of 2008, due primarily to a decrease in purchases of marketable securities net of sales or maturities. In the first nine months of 2009, sales or maturities of marketable securities exceeded purchases by \$94.3 million, whereas in the first nine months of 2008, purchases of marketable securities exceeded sales or maturities by \$34.7 million. In addition, cash used for capital expenditures totaled \$75.0 million in the first nine months of 2009, primarily for tenant improvements and related costs in connection with our new leased facilities in Tarrytown.

Cash Provided by (Used in) Financing Activities:

Net cash provided by financing activities was \$9.0 million in the first nine months of 2009 compared to net cash used in financing activities of \$77.1 million in the same period in 2008. In the first nine months of 2009, we received a \$5.2 million reimbursement of tenant improvements from our landlord in connection with our new Tarrytown facilities, which we are deemed to own in accordance with FASB authoritative guidance. In the first nine months of 2008, we repurchased \$82.5 million in principal amount of our convertible senior subordinated notes for \$83.3 million. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were \$4.6 million and \$6.2 million in the first nine months of 2009 and 2008, respectively.

Fair Value of Marketable Securities:

At September 30, 2009 and December 31, 2008, we held marketable securities whose aggregate fair value totaled \$186.7 million and \$278.0 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	September	30, 2 0 09	December 31, 2008		
Investment type	Fair Value	Percent	Fair Value	Percent	
U.S. Treasury securities	\$ 80.5	43%	\$ 113.9	41%	
U.S. government agency securities	24.9	13%	58.3	21%	
U.S. government-guaranteed corporate bonds	49.1	26%	29.8	11%	
U.S. government guaranteed collateralized mortgage obligations	4.8	3%	17.4	6%	
Corporate bonds	16.1	9%	37.1	13%	
Mortgage-backed securities	4.2	2%	10.0	4%	
Other asset-backed securities			7.8	39.	
Other	7.1	4%	3.7	1%	
Total marketable securities	\$ 186.7	100%	\$ 278.0	100%	

In addition, at September 30, 2009 and December 31, 2008, we had \$251.9 million and \$249.5 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During the first nine months of 2009, as marketable securities in our portfolio matured or paid down, we purchased primarily U.S. Treasury securities, U.S. government agency obligations, and U.S. government-guaranteed debt. This shift toward higher quality securities, which we initiated in 2008, continues to reduce the risk profile, as well as the overall yield, of our portfolio. In particular, we continue to reduce the proportion of asset-backed securities and corporate bonds in our portfolio.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled \$75.0 million and \$19.1 million for the first nine months of 2009 and 2008, respectively. During the remainder of 2009, we expect to incur approximately \$10 to \$15 million in capital expenditures, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our new leased Tarrytown facilities, which will be funded by our existing capital resources. In October 2009, we received \$16.9 million from our landlord as partial reimbursement of tenant improvement costs we incurred in Tarrytown. An additional \$33 million is reimbursable at our option at any time through June 2010 under the terms of our Tarrytown lease.

Amendment to Lease - Tarrytown, New York Facilities:

We currently lease approximately 248,000 square feet of laboratory and office facilities in Tarrytown, New York. In December 2006, we entered into a new lease agreement (as amended in October 2007 and September 2008) to lease approximately 348,000 square feet of laboratory and office space at our current Tarrytown location, including approximately 230,000 square feet in newly constructed facilities that were completed during the third quarter of 2009. The term of the lease commenced effective June 2008 and will expire in June 2024. In April 2009, we amended the lease agreement to increase the amount of space we will lease to approximately 389,500 square feet. As amended, the lease contains early termination options on approximately 159,500 square feet of space. Other terms and conditions, as previously described in our Annual Report on Form 10-K for the year ended December 31, 2008, remain unchanged. In connection with the lease amendment, in April 2009, we terminated a sublease for 16,200 square feet of space in Tarrytown, New York.

Facility Lease Obligation:

As described above, in connection with the application of FASB authoritative guidance to our lease of office and laboratory facilities constructed in Tarrytown, New York by our landlord, we capitalized the landlord's costs of constructing the new facilities, which totaled \$58.2 million as of September 30, 2009, and recognized a corresponding facility lease obligation of \$58.2 million. We also recognized, as an additional facility lease obligation, a \$5.2 million reimbursement received from our landlord for tenant improvement costs that we incurred since, under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation. Monthly lease payments on these facilities are allocated between the land element of the lease (which is accounted for as an operating lease) and the facility lease obligation, based on the estimated relative fair values of the land and buildings. The imputed interest rate applicable to the facility lease obligation is approximately 11%. The new facilities were placed in service in September 2009. For the three and nine months ended September 30, 2009, we recognized \$0.6 million of interest expense in connection with the facility lease obligation in our statement of operations. At September 30, 2009, the facility lease obligation balance was \$62.6 million.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from collaborators, we currently anticipate that approximately 50-60% of our expenditures for 2009 will be directed toward the preclinical and clinical development of product candidates, including ARCALYST® (rilonacept), aflibercept, VEGF Trap-Eye, and monoclonal antibodies (including REGN88, REGN421, and REGN475); approximately 20-30% of our expenditures for 2009 will be applied to our basic research and early preclinical activities and the remainder of our expenditures for 2009 will be used for the continued development of our novel technology platforms, capital expenditures, and general corporate purposes.

We currently anticipate that in 2009 sales of ARCALYST® (rilonacept) for the treatment of CAPS will not materially enhance or otherwise materially impact our cash flows.

In connection with the April 2009 amendment to our lease agreement for facilities in Tarrytown, New York, as described above, our total estimated future minimum noncancelable lease commitments, previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008, will increase (i) from \$9.1 million to \$9.4 million for the year ending December 31, 2009, (ii) from \$26.8 million to \$29.2 million for the two-year period beginning January 1, 2010, (iii) from \$27.2 million to \$28.8 million for the two-year period beginning January 1, 2012, and (iv) from \$167.0 million to \$182.5 million for the eleven-year period beginning January 1, 2014.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs.

Other than a \$1.6 million letter of credit issued to our landlord in connection with our lease for facilities in Tarrytown, New York, as described above, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of September 30, 2009, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scaleback, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In October 2009, the FASB amended its authoritative guidance on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate arrangement consideration in a multiple element revenue arrangement by requiring the use of estimated selling price to allocate arrangement consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple deliverable revenue arrangements. This guidance may be applied retrospectively or prospectively for new or materially modified arrangements. We are required to adopt this amended guidance effective for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. We are currently evaluating the impact that this guidance will have on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates primarily from our investment of available cash balances in investment grade corporate, asset-backed, and U.S. government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimated that a one percent unfavorable change in interest rates would result in approximately a \$0.9 million and \$1.7 million decrease in the fair value of our investment portfolio at September 30, 2009 and 2008, respectively.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of \$5.9 million, \$2.5 million and \$0.1 million in 2007, 2008, and the first nine months of 2009, respectively.

The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that there could be further declines in the market value of marketable securities in our investment portfolio and that such declines could result in charges against income in future periods for other-than-temporary impairments, and such amounts could be material.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in applicable rules and forms of the Securities and Exchange Commission, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15 (f) under the Exchange Act) during the quarter ended September 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2009, we had a cumulative loss of \$904.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of September 30, 2009, cash, cash equivalents, restricted cash, and marketable securities totaled \$438.6 million and represented 59% of our total assets. We have invested available cash balances primarily in money market funds and U.S. Treasury, U.S. government agency, corporate, and to a lesser extent, asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled \$186.7 million at September 30, 2009, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of \$5.9 million, \$2.5 million and \$0.1 million in 2007, 2008, and the first nine months of 2009, respectively. The current volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and ARCALYST in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd line metastatic colorectal cancer, 1st line androgen independent prostate cancer, and 2nd line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In September 2009, we announced the discontinuation of a Phase 3 clinical trial that evaluated aflibercept plus gemcitabine versus placebo plus gemcitabine for the first-line treatment of metastatic pancreatic cancer after an Independent Data Monitoring Committee for the trial determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of Central Retinal Vein Occlusion (CRVO). Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis® (ranibizumab injection), marketed by Genentech, Inc. A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

ARCALYST is in Phase 3 clinical trials for two different gout indications – the prevention of gout flares in patients initiating urate-lowering drug therapy and acute gout. We do not have proof of concept data from Phase 2 clinical trials that ARCALYST will be safe or effective in the acute gout setting. Although we reported positive Phase 2 proof of concept data from a small number of patients initiating urate-lowering drug therapy, there is a risk that the results of the larger Phase 3 trials of ARCALYST in patients initiating urate-lowering drug therapy will differ from the previously reported Phase 2 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors and other consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating aflibercept as a 1st line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could harm the future development of our product candidate(s) and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval and large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® (rilonacept) in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), marketed by Biovitrum, Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor Ortho Biotech, Inc., ARCALYST affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST may interfere with the body's ability to fight infections. Treatment with Kineret, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST in new disease settings. These side effects may also result in a reduction, or even the elimination, of sales of ARCALYST in approved indications.

ARCALYST® (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST. Nineteen of 55 subjects (35%) who received ARCALYST for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have patent applications that are being opposed and it is likely that we will need to defend additional patent applications in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptor compositions. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST® (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® (rilonacept) for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST and the EMEA approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of rilonacept or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with current Good Manufacturing Practice, or cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar legislation is being considered in other states and also at the federal level. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

Changes in the securities laws and regulations have increased, and are likely to continue to increase, our costs.

The Sarbanes-Oxley Act of 2002, which became law in July 2002, has required changes in some of our corporate governance, securities disclosure, and compliance practices. In response to the requirements of that Act, the SEC and the NASDAQ Stock Market have promulgated rules and listing standards covering a variety of subjects. Compliance with these rules and listing standards has increased our legal costs, and significantly increased our accounting and auditing costs, and we expect these costs to continue. These developments may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance. Likewise, these developments may make it more difficult for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2008, which report is included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates:
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies; and
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business.
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the United States of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and current pending legislation which would ease the entry of competing follow-on biologics into the marketplace are examples of changes and possible changes in laws that could adversely affect our business.

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on the funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to \$400 million between 2009 and 2012 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, and REGN475, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody pro

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business, operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® (rilonacept) and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable Good Manufacturing Practices (GMPs) or good clinical practices, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST and many other related activities in connection with the commercialization of ARCALYST for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST® (rilonacept) and our product candidates at our manufacturing facilities in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for manufacturing and formulation of ARCALYST and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we currently rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize $ARCALYST^{\circledast}$ (rilonacept) in this indication.

Our only approved product is ARCALYST for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In June 2009, Novartis received marketing approval from the FDA for its IL-1 antibody product for the treatment of CAPS. In October 2009 we received European marketing authorization for rilonacept for CAPS and Novartis received European marketing authorization for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin® (bevacizumab), on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline plc. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis® (ranibizumab injection), marketed by Genentech, Inc., for the treatment of age-related macular degeneration (wet AMD) and other eye indications. Lucentis was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF, VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin® (bevacizumab), with success for the treatment of wet AMD. The National Eye Institute is conducting a Phase 3 trial comparing Lucentis to Avastin in the treatment of wet AMD. The marketing approval of Lucentis and the potential off-label use of Avastin make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis, because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin in patients with wet AMD presents a further competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., Remicade® (infliximab), marketed by Centocor Ortho Biotech, Inc., Humira® (adalimumab), marketed by Abbott Laboratories, and SimponiTM (golimumab), marketed by Centocor Ortho Biotech, Inc., and the IL-1 receptor antagonist Kineret® (anakinra) marketed by Biovitrum, and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® (rilonacept). This is one of the reasons we discontinued the development of ARCALYST in adult rheumatoid arthritis. In addition, even if ARCALYST is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma, and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing its IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST. For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST. The successful development of these competing molecules could impair our ability to successfully commercialize ARCALYST.

We have plans to develop ARCALYST for the treatment of certain gout indications. As noted above, Novartis is testing its IL-1 antibody in gout. Novartis' product candidate is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST in that disease.

Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST in these diseases.

The successful commercialization of ARCALYST® (rilonacept) and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have announced plans to initiate a Phase 3 program studying the use of ARCALYST for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payer more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST in the United States for the treatment of a group of rare genetic disorders called CAPS. We recently received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST. Physicians may not prescribe ARCALYST, and CAPS patients may not be able to afford ARCALYST, if third party payers do not agree to reimburse the cost of ARCALYST therapy and this would adversely affect our ability to commercialize ARCALYST profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. In the United States, there have been, and we expect will continue to be, actions and proposals to control and reduce healthcare costs. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs.

Since ARCALYST and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of September 30, 2009, our five largest shareholders beneficially owned 42.0% of our outstanding shares of Common Stock, assuming, in the case of our Leonard S. Schleifer, M.D. Ph.D., our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2009. As of September 30, 2009, sanofiaventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.9% of the shares of Common Stock then outstanding. Under our investor agreement with sanofiaventis, sanofiaventis may not sell these shares until December 20, 2012 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofiaventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofiaventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2009, holders of Class A Stock held 22.3% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, plus any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in us taking corporate actions that you may not consider to be in your best interest and may affect the price of our Common Stock. As of September 30, 2009:

- our current executive officers and directors beneficially owned 13.2% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2009, and 28.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2009; and
- our five largest shareholders beneficially owned 42.0% of our outstanding shares of Common Stock, assuming, in the case of Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2009. In addition, these five shareholders held 48.8% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30, 2009.

Pursuant to an investor agreement, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for you and other shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan.

ITEM 6. EXHIBITS

(a) Exhibits

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EXMIDIT	
Number	Description
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: November 3, 2009

By: /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

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Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Leonard S. Schleifer, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2009 /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2009 /s/ Murray A. Goldberg

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer November 3, 2009

/s/ MURRAY A. GOLDBERG Murray A. Goldberg Chief Financial Officer November 3, 2009

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 4/29/2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 10-Q

(X)	(Mark One) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURI EXCHANGE ACT OF 1934	TIES
	For the quarterly period ended March 31, 2010	
		OR
()	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURI EXCHANGE ACT OF 1934	
	For the transition period from to	
	Commission File	e Number <u>0-19034</u>
		RMACEUTICALS, INC. t as specified in its charter)
	New York (State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
	777 Old Saw Mill River Road <u>Tarrytown, New York</u> (Address of principal executive offices)	10591-6707 (Zip Code)
		347-7000 umber, including area code)
Indic prec	cate by check mark whether the registrant (1) has filed all reports required techniques 12 months (or for such shorter period that the registrant was required	to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the d to file such reports), and (2) has been subject to such filing requirements for the
past	90 days. Yes <u>X</u>	No
Indic subn	cate by check mark whether the registrant has submitted electronically and mitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this charequired to submit and post such files).	posted on its corporate Web site, if any, every Interactive Data File required to be apter) during the preceding 12 months (or for such shorter period that the registran
was	Yes	No
Indic defir	cate by check mark whether the registrant is a large accelerated filer, an nitions of "large accelerated filer", "accelerated filer", and "smaller reporting of the control	a accelerated filer, a non-accelerated filer, or a smaller reporting company. See company" in Rule 12b-2 of the Exchange Act.
	ge accelerated filer <u>X</u> -accelerated filer (Do not check if a smaller reporting company)	Accelerated filer Smaller reporting company
Indic	cate by check mark whether the registrant is a shell company (as defined in Ru Yes	
Num	nber of shares outstanding of each of the registrant's classes of common stoc	k as of April 14, 2010:
	Class of Common Stock Class A Stock, \$0.001 par value Common Stock, \$0.001 par value	<u>Number of Shares</u> 2,182,036 79,730,517

REGENERON PHARMACEUTICALS, INC. Table of Contents March 31, 2010

Page Numbers PART I FINANCIAL INFORMATION ttem t Financial Statements Condensed balance sheets (unaudited) at March 31, 2010 and December 31, 2009. Condensed statements of operations (unaudited) for the three months ended March 31, 2010 and 2009 Condensed statements of stockholders, equity (unandited) for the three months ended March 31, 2010 and 2009 Condensed statements of cash flows (unaudited) for the three mouths ended March 31, 2010 and 2009 Notes to condensed financial statements (urandited) Hem 2 Management's Discussion and Analysis of Financial Condition and Results of Operations 15-33 Ben 3 Obstitutive and Qualitative Disclosures About Warket Risk 33 Item 4 Controls and Procedures 33-34 PART II OTHER INFORMATION tem 1 Legal Proceedings Item IA RISK Factors 34-50 Rem 6 Exhibits 50 SIGNATURE PAGE

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AT MARCH 31, 2010 AND DECEMBER 31, 2009 (Unaudited) (In thousands, except share data)

	March 31,	December 31,
ASSETS Current abouts	2010	2009
Cash and cash equivalents	\$ 117,311	\$ 207,075
Marketable securities	186.328	134.255
Accounts receivable from the sanofi-aventis Group Accounts receivable—mae:	68,838 3.020	62,703 2.865
Prepaid expenses and other current assets	19,947	18,610
Total current assets	395.444	425 508
Restricted cash	1 500	1 600
Marketable securities	108,278	47,080
Property, plant, and equipment, at cost, net of accumulated depreciation and amortization	274,621	259.676
Other assets	7,213	7,338
Total assets	3 787 196	\$ 741,202
LEARLETTES and STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable and accrued expenses Deferred revenue from sanofi-aventis, current portion	\$ 53.905 17,784	9 49.031 17,523
Deferred revenue other, current partion	31.969	27.021
Facility lease obligations, current portion Total success Habilines	435 104 093	93.575
Deferred revenue from saneti aventis Deferred revenue - other	91.684 44.504	90 933 46,951
Facility lease obligations	156.464	40,531 109.022
Other long term liabilities	4,140	3,959
Total liabilities	400.885	344.440
Commissions and contingencies		
Stackheiders equity		
Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and	***************************************	
outstanding - none Class A Stock convertede 3:001 par value: 40:000:000 shares authorized;		
shares issued and outstanding 2.211 698 in 2010 and 2.244 698 in 2008		
Common Stock, \$.001 par value; 160,000,000 shares authorized;		5 0
shares issued and outstanding - 79,690,055 in 2010 and 78,860,862 in 2009 Adminial part in capital	80 1.337.089	79 1 336 732
Accumulated deficit	(971,617)	(941,095)
Acrumulared other comprehensive income Total stockholders' equity	717 386.271	396,762
Total stockholders equity Total liabilities and stockholders equity	380,271 \$ 787,156	\$ 741.202
***	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	<u> </u>

The accompanying notes are an integral part of the financial statements.

	Three months e	nded March 31, 2009
	2010	(Revised -
		see Note 8)
Resenues Sanofi-aventis collaboration revenue	\$ 68,671	\$ 49,660
Other collaboration revenue	\$ 00,071 13.087	\$ 49,000 9,948
Technology licensing	10,038	10,000
Net product sales Contract research and other	9.852 1,886	3.891 1,482
Contract research and other	1,886	74.981
Expenses	117.171	00.007
Research and development Selling, general, and administrative	117,471 14 005	80,307 11.420
Cost of goods sold	717_	392
	132 [93	92.119
Loss from operations	(28.659)	[17 138]
Other tecome (expense)		
Investment income	439 (2.084)	1,750
Interest expense	(1,645)	1,750
Net loss before income tax expense	(30,304)	(15,388)
licome tax expense	218	
Not lose	(30,522)	11.388
Net loss per share, basic and dilined	\$ (0.38)	\$ (0.19)
Weighted average shares outstanding, basic and diluted	81 169	79.498
The accompanying notes are an integral part of the financial statements.		

							Accumulated	m t	
	61		0	0. 1	Additional		Other	Total	
		A Stock		n Stock	Paid-in	Accumulated	Comprehensive	Stockholders	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance December 31, 2003	2,245		78,861	\$ 79	8 1 336 732	\$ (041 005)	\$ 1,044	\$ 356,762	
Issuance of Common Stock in connection with									
exercise of stock options, net of shares tendered			685	1	8,656			8,657	***************************************
Issuance of Common Stack in connection with									
Company 401(k) Savings Francontribution			191		2.697			2,867	
Conversion of Class A Stock to Common Stock	(33)		33						
Stock-trains companience expense					8.934			8,834	
Net loss						(30,522)		(30,522)	\$ (30,522)
Change in her unrealized gain on marketable securities									
ner of tax benefit of \$0.2 motion		<u></u>	<u></u>	<u></u>				(327)	
								***************************************	500000000000000000000000000000000000000
Balance March 31, 2010	<u> </u>	<u>* </u>	79.690	8 80	\$ 1,357,089	\$ 6971,617		\$ 386,271	(30.849)
Balance December 31, 2008	2,249		77,042	\$ 78	8 1,294,813	3 (873,265)	\$ 1014	3 481,514	
Issuance of Common Stock in connection with									
exercise of stock options, net of shares tendered			117		1,038			1,038	
issuance of Common Stock in connection with									
Company 401 (k) Savings Francontribution			81		1,391			1,391	
Conversion of Class A Stock to Common Stock	(2)		2						
Stock-based compensation expansio					7,654			7.664	
Net loss						(15,388)		(15,388)	\$ (15,388)
Change in that attained settings off									
marketable-securities							(1,134)	(1,134)	(1,134)
	~ <u>~~~~~~</u>	···· <u>······</u> ···	<u></u>	··· <u>·</u> ····	··· <u>·······</u> ···				
Balance March 31, 2009 (Fevised - see Note 8)	9.247		77.842	\$ 78	\$ 1,304,896	1 1888 653	\$ 11,248)	\$ 415,075	\$ 016.5223
	· <u>······</u>	::: <u>:::::::::::</u> :::	<u></u> :::	<u></u>	::: <u>::::::::::::::::::::::::::::::::::</u>	<u></u>	<u></u>	<u></u>	<u></u>

The accompanying notes are an integral part of the financial statements.

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	Three months en	ded March 31,	
	2010	2009	
		(Revised -	
		see Note 8)	
Cash flows from operating activities			
Net loss	\$ (30,522)	\$ (15,388)	
Adjustments to reconcile net loss to net cash			
used in operating activities			
Depreciation and amortization	4,183	2,724	
Non-cash compensation expense	8.834	7.654	
Other non-cash charges and expenses	470	***************************************	
Changes in assets and liabilities			
Increase in accounts receivable	(6,290)	(12,997)	
increase in prepaid expenses and other assers	(2,483)	(8.611)	
Increase in deferred revenue	3,513	3,194	
Increase in accounts payable, accrued expenses			
and other liabilities	12 294	8 043	
Total adjustments	20,521	7	
Ner eash used in operating activities	(10.001)	(15,381)	
Cash flows from investing activities			
Purchases of marketable securities	(177,594)	(100,315)	
Seles or manuffles of marketable securities	64,359	82.694	
Capital expenditures	(22,743)	(21,917)	
Net cash used in investing activities	(135,978)	(39,528)	
Cash flows from financing activities			
Proceeds in connection with facility lease obligations	47,544	5,182	
Payments in connection with facility lease driligations	(555)		
Net proceeds from the issuance of Common Stock	9,226	1,038	
Net cash provided by Ithancing activities	56.215	6.220	
Net decrease in cash and cash equivalents	(89.764)	(48.699)	
	207077	89.	
Cash and cash equivalents at beginning of period	207.075	247.796	
	3 117 311	\$ 199.097	
Cash and cash equivalents at end of period		***************************************	

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2009 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009, la addition, the previously issued condensed statements of operations, stockholders' equity, and cash flows for the three months ended March 31, 2009, contained in the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2009, have been revised in this Quarterly Report on Form 10-Q with respect to the Company's December 2006 lease of office and laboratory facilities in Tarrytown, New York by applying authoritative guidance issued by the Financial Accounting Standards Board (FASB). See Note 8 below.

Effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, was extended. The effect of this change in estimate was to lower depreciation expense by \$1.0 million and to lower the Company's net loss per share by \$0.01 for the three months ended March 31, 2010.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® (rilonacept) Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® (rilonacept) beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® (rilonacept) net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST® (rilonacept). As a result, for the three months ended March 31, 2010, the Company recognized as revenue \$9.9 million of ARCALYST® (rilonacept) net product sales, which included \$5.1 million of ARCALYST® (rilonacept) net product sales made during the quarter and \$4.8 million of previously deferred net product sales. For the three months ended March 31, 2009, the Company recognized as revenue \$3.9 million of ARCALYST® (rilonacept) net product sales. There was no deferred ARCALYST® (rilonacept) net product sales revenue at March 31, 2010. At March 31, 2009, deferred ARCALYST® (rilonacept) net product sales revenue was \$4.2 million. The effect of this change in estimate related to ARCALYST® (rilonacept) net product sales revenue was to lower the Company's net loss per share by \$0.06 for the three months ended March 31, 2010.

Cost of goods sold related to ARCALYST® (rilonacept) sales, which consisted primarily of royalties, totaled \$0.7 million and \$0.4 million for the three months ended March 31, 2010 and 2009, respectively. To date, ARCALYST® (rilonacept) shipments to the Company's customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® (rilonacept); therefore, the costs of these supplies were not included in costs of goods sold. At both March 31, 2010 and December 31, 2009, the Company had \$0.4 million of inventoried work-in-process costs related to ARCALYST® (rilonacept), which is included in prepaid expenses and other current assets.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three months ended March 31, 2010 and 2009, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months En	ided March 31,
	20 10	2009
Net loss (Numerator)	\$ (30,522)	5 (15,388)
Weighted average shares, in thousands (Denominator)	81.169	79.198
Basic and dilitred net loss per share	\$ (0.38)	5 (0.19)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the March 31, 2010 and 2009 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months en	nded March 31,
	2010	2009
Stack Options		
Weighted average number, in thousands	21,400	20,216
Weighted average exercise price	\$ 18.59	8 1755
Restricted Stock		
Weighted average number, in thousands	501	500

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2010 and December 31, 2009 were \$5.4 million and \$9.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2009 and December 31, 2008 were \$9.8 million and \$7.0 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2009 and 2008 were \$2.6 million and \$1.5 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2010 and 2009, the Company contributed 111,419 and 81,086 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Pursuant to the application of authoritative guidance issued by the Financial Accounting Standards Board ("FASB") to the Company's lease of office and laboratory facilities in Tarrytown, New York (see Note 8), the Company recognized a facility lease obligation of \$0.6 million for the three months ended March 31, 2009, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in facility lease obligations and property, plant, and equipment at March 31, 2010 was \$0.8 million of capitalized and deferred interest for the quarter ended March 31, 2010, as the related facilities being leased by the Company are currently under construction and lease payments on these facilities do not commence until January 2011.

Included in other assets at March 31, 2010 and December 31, 2009 were \$0.1 million and \$0.7 million, respectively, due to the Company in connection with employee exercises of stock options.

Included in marketable securities at March 31, 2010 and December 31, 2009 were \$1.3 million and \$0.6 million, respectively, of accrued interest income. Included in marketable securities at March 31, 2009 and December 31, 2008 were \$2.5 million and \$1.7 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at March 31, 2010 and December 31, 2009 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was \$4.8 million and \$5.5 million at March 31, 2010 and December 31, 2009, respectively, and the aggregate cost basis of which was \$4.0 million at both March 31, 2010 and December 31, 2009. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at March 31, 2010 and December 31, 2009. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair Unrealized			
At March 31, 2010	Cost Basis	Value	Gains	(Losses)	Net
Manufes within one year					
U.S. government obligations	\$ 149,697	\$149,688	\$ 33	\$ (42)	\$ (9)
U.S. government guaranteed corporate					
bants	23822	23 956	136	(2)	134
Corporate bonds	8,152	8,248	96		96
Mongage backed securities	1.255	1.134		(121)	(121)
U.S. government guaranteed					
collateralized mortgage obligations	3,170	3,302	132		132
	186,096	186,328	397	(165)	232
Maturities between one and three years					
U.S. government obligations	59,524	59,487	13	(50)	(37)
U.S. government guaranteed corporate					
bonds	40.001	40,376	390	(15)	373
Mortgage-backed securities	1,517	1,439		(78)	(78)
Municipal bonds	2,217	2,208		(9)	(9)
	103,259	103,510	403	(152)	251
	\$ 289,355	\$289.838	\$ 800	\$ (317)	\$ 483
At December 31, 2009					
Maturities within one year					
U.S. government obligations	\$ 100,491	\$100,573	\$ 82		\$ 82
U.S. government guaranteed corporate					
bonds	17 176	17.340	164		164
Corporate bonds	10,142	10,342	200		200
Mongage backed securities	2 471	2.338		\$ (133)	(133)
U.S. government guaranteed					
collateralized mortgage obligations	3,612	3,662	50		50
	133,892	134,255	496	(133)	363

	Amortized	Fair		Unrealized	
At December 31, 2009 (continued)	Cost Basis	Value	Gains	(Losses)	Net
Maturities between one and two years					
U.S. government obligations	9,413	9,367		(46)	(46)
U.S. government guaranteed corporate bonds	31.064	31 344	280		280
Mortgage-backed securities	1,168	900		(268)	(268)
	41,545	41.511	280	(314)	(34)
	\$ 175.537	\$175,866	<u>\$ 776</u>	<u>1 (11)</u>	5 329

At March 31, 2010 and December 31, 2009, marketable securities included an additional unrealized gain of \$0.7 million and \$1.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at March 31, 2010 and December 31, 2009. The debt securities listed at March 31, 2010 mature at various dates through December 2011.

	Less than 12 Months		12 Months or Greater		To	tal
		Unrealized		Unrealized		Unrealized
At March 31, 2010	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss
U.S. government obligations	\$ 121,293	5 (92)			\$ 121,293	\$ (92)
U.S. government guaranteed						
corporate bond	12,362	(17)			12,362	(17)
Mortgage backed securities			2,572	(199)	2.572	(199)
Municipal bonds	2,209	(9)			2,209	(9)
	\$ 135,864	\$ (118)	\$ 2,572	\$ (199)	\$ 138,436	\$ (317)
		···	···	··		×
At December 31, 2009						
U.S. government obligations	\$ 9,367	\$ (46)			\$ 9,367	\$ (46)
Mortgage backed securities			\$ 3,238	\$ (401)	3 2 3 8	(401)
	\$ 9,367	\$ (46)	\$ 3,238	\$ (401)	\$ 12,605	\$ (447)

Realized gains and losses are included as a component of investment income. For the three months ended March 31, 2010 and 2009, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at March 31, 2010 and December 31, 2009, were as follows:

		Fair Value Meas	urements at Repo	rting Date Using
		Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
	Fair Value	(Level 1)	(Level 2)	(Level 3)
At March 31, 2010 Available-for-sale marketable securities				
U.S. government characterises U.S. government guaranteed corporate	\$ 209.175		3 209.175	
bonds	64,332		64,332	
Corporate bonds	8 248		8,248	
Mortgage-backed securities	2,573		2,573	
U.S. government guaranteed collateralized mortgage obligations	3,302		3.302	
Municipal bonds	2,208		2,208	
Equity securities	\$ 294,606	\$ 4,768 \$ 4,768	\$ 289,838	
At December 31, 2009				
Available-for-sale marketable securities				
U.S. government obligations	\$ 109,940		\$ 109.940	
U.S. government guaranteed corporate	48,684		48,684	
bonds Carperate bands	10.342		10 342	
Mortgage-backed securities	3,238		3,238	
US government guaranteed collaterised mortgage obligations	3.662		3.662	
Equity securities	5,469	\$ 5,469		
	\$ 181,335	\$ 5,469	\$ 175.866	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the three months ended March 31, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the securities \$1.1 million carrying value. As a result, the Company recognized a \$0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three months ended March 31, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

At March 31, 2009 and December 31, 2008, the Company held one Level 3 marketable security whose fair value was \$0.1 million. This Level 3 security was valued using information provided by the Company's investment advisors, including quoted bid prices which take into consideration the securities' current lack of liquidity. During the three months ended March 31, 2009, the Company did not record any settlements, realized gains or losses, or charges for other-than-temporary impairment related to this Level 3 marketable security. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three months ended March 31, 2009. The Company held no Level 3 marketable securities at March 31, 2010 and December 31, 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three months ended March 31, 2010 and 2009.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

The current economic environment and the deterioration in the credit quality of issuers of securities that the Company holds increase the risk of potential declines in the current market value of marketable securities in the Company's investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2010 and December 31, 2009 consist of the following:

	March 31,	December 31,
	2010	2009
Accounts payable	3 14315	\$ 18,638
Accrued payroll and related costs	11,026	9,444
Arcmed clinical trial expense	14.880	11.673
Accrued property, plant, and equipment expenditures	4,181	1,883
Accrued expanses, other	7 629	6,207
Payable to Bayer HealthCare	1,874	1,186
	5 53905	\$ 49.031

7. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three months ended March 31, 2010 and 2009, the components of comprehensive loss are:

	Th	Three months ended March 31,		
		2010		2009
Net Joss		(30,522)	•	(15.388)
Change in net unrealized gain (loss) on marketable securities		(545)		(1,134)
Tax benefit of decrease to ner incealized gain on markerable securities		218		
Total comprehensive loss	\$	(30,849)	\$	(16,522)

8. Revisions of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, the Company became aware that certain of these conditions were applicable to its December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, the Company is deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on the Company's books as a non-cash transaction, offset by a corresponding lease obligation on the Company's balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

REGENERON PHARMACEUTICALS, INC. Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

As previously disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2009, the Company revised its previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which the Company is leasing and to adjust the Company's previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability). The Company also revised its statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of its lease, with a corresponding adjustment to other long-term liabilities. In addition, the Company's statement of cash flows for the quarter ended March 31, 2009 was revised to reclassify, from an operating activity to a financing activity, a \$5.2 million reimbursement received from the Company's landlord for tenant improvement costs that the Company incurred. Under FASB authoritative guidance, such payments that the Company receives from its landlord are deemed to be a financing obligation.

The above described revisions consisted entirely of non-cash adjustments. They had no impact on the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs. The revisions also had no impact on the Company's previously reported net increases or decreases in cash and cash equivalents. In addition, these revisions had no impact on the Company's previously reported current assets, current liabilities, and operating revenues. The Company did not amend previously issued financial statements because, after considering both qualitative and quantitative factors, the Company determined that the judgment of a reasonable person relying on the Company's previously issued financial statements would not have been changed or influenced by these revisions.

For comparative purposes, the impact of the above described revisions to the Company's statement of operations, statement of stockholders' equity, and statement of cash flows for the three months ended March 31, 2009 is as follows:

Statement of Operations Impact for the three months ended March 31, 2009 (In millions, except per share data)

	As Originally	
	Reported	As Revised
Research and development expenses	\$ 821	\$ 80.3
Selling, general, and administrative expenses	11.7	11.4
Total expenses	94.2	92.1
Net loss	(17.5)	(15.4)
Net loss per share, basic and dilitted	\$ (0.22)	\$ (0.19)

Statement of Stockholders' Equity Impact for the three months ended March 31, 2009 (In millions)

	As C	riginally	
	Re	ported	 Revised
Accumulated deficit		(893.4)	\$ (887.7)
Total stockholders' equity	\$	410.3	\$ 415.1

Statement of Cash Flows Impact for the three months ended March 31, 2009 (In millions)

	As Originally		
	Reported	As	Revised
Net eash used in operating activities	\$ 110.2	. 5	(15.4)
Net cash used in investing activities	(39.5)	(39.5)
Net cash provided by financing activities	1.0		6.2
Net decrease in cash and cash equivalents	\$ (48.7) \$	(48.7)

These revised amounts are reflected in the Company's financial statements included in this Quarterly Report on Form 10-Q for the period ended March 31, 2010.

9. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

REGENERON PHARMACEUTICALS, INC. Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

10. Future Impact of Recently Issued Accounting Standards

In March 2009, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. The Company will be required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are rilonacept, which is being developed for the prevention and treatment of gout-related flares; VEGF Trap-Eye, which is being developed in eye diseases using intraocular delivery in collaboration with Bayer HealthCare LLC; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology; REGN727, an antibody to PCSK9, which is being developed for low density lipoprotein (LDL) cholesterol reduction; and REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed for certain allergic and immune conditions. All five of our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our $VelociSuite^{TM}$ technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our $VelociGene^{\oplus}$ technology to understand the role of these proteins in normal physiology as well as in models of disease. Our human monoclonal antibody technology ($Velocimmune^{\oplus}$) and cell line expression technologies ($VelociMab^{\#}$) may then be utilized to design and produce new product candidates directed against the disease target. Our five antibody product candidates currently in clinical trials were developed using $Velocimmune^{\oplus}$. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® (rilonacept) - Cryopyrin-Associated Periodic Syndromes (CAPS)

We recognized \$9.9 million of net product sales of ARCALYST® (rilonacept) Injection for Subcutaneous Use in the first quarter of 2010, which included \$5.1 million of ARCALYST® (rilonacept) net product sales made during the quarter and \$4.8 million of previously deferred net product sales, as described below under "Results of Operations." In the same quarter of 2009, we recognized \$3.9 million of ARCALYST® (rilonacept) net product sales. ARCALYST® (rilonacept) is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

ARCALYST® (rilonacept) is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. CAPS is a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

In October 2009, rilonacept was approved under exceptional circumstances by the European Medicines Agency for the treatment of CAPS with severe symptoms in adults and children 12 and older. Rilonacept is not currently marketed in the European Union. We own worldwide rights to ARCALYST® (rilonacept).

Clinical Programs:

1. Rilonacept - Inflammatory Diseases

We are evaluating rilonacept in gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation. Gout is characterized by high blood levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Chronic treatment with uric acid-lowering medicines, such as allopurinol, is prescribed to eliminate the urate crystals and prevent reformation. During the first months of allopurinol therapy, while uric acid blood levels are being reduced, the break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

During the first quarter of 2009, we initiated a Phase 3 clinical development program with rilonacept for the treatment of gout. The program includes four clinical trials. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating rilonacept versus placebo for the prevention of gout flares in patients initiating urate-lowering drug therapy. A third Phase 3 trial in acute gout (SURGE) is evaluating treatment with rilonacept alone versus rilonacept in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a placebo-controlled safety study (RE-SURGE) of rilonacept in patients receiving urate-lowering therapy. SURGE and PRE-SURGE 1 are fully enrolled. We expect to report initial data from SURGE and PRE-SURGE 1 during the second quarter of 2010 and from PRE-SURGE 2 and RE-SURGE during the first half of 2011. We own worldwide rights to rilonacept.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis Pharma AG (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. Canakinumab is approved to treat Cryopyrin-Associated Periodic Syndrome (CAPS) and is in development for gout, type 2 diabetes, and other inflammatory diseases.

2. VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in a Phase 3 program in patients with the neovascular form of age-related macular degeneration (wet AMD). We and Bayer HealthCare are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation. We and Bayer HealthCare are also conducting a Phase 3 program in central retinal vein occlusion (CRVO).

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and Lucentis® (ranibizumab injection), owned by Genentech, Inc., an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with Lucentis (Genentech) dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. Asneeded dosing (PRN) with both agents will be evaluated in the second year of the studies. VIEW 1 and VIEW 2 were fully enrolled in 2009, and initial data are expected in late 2010.

The Phase 2 DME study, known as the DA VINCI study, is a double-masked, randomized, controlled trial that is evaluating four different VEGF Trap-Eye dosing regimens versus laser treatment. In February 2010, we and Bayer HealthCare announced that treatment with VEGF Trap-Eye demonstrated a statistically significant improvement in visual acuity compared to focal laser therapy, the primary endpoint of the study. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 (p< 0.01 for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported in the study. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results will be available later in 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of central retinal vein occlusion (CRVO), another cause of blindness. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting Inflictration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. The COPERNICUS study was initiated during the third quarter of 2009 and is fully enrolled. The GALILEO study was initiated in October 2009 and is approximately half enrolled. Initial data are anticipated in early 2011.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We can earn up to \$70 million in future development and regulatory milestone payments related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

3. Aflibercept (VEGF Trap) - Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A, also known as Vascular Permeability Factor or VPF), VEGF-B, and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a less validated degree, PIGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow and is a potent regulator of vascular permeability and leakage.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are conducting three randomized, double-blind Phase 3 trials, all of which are fully enrolled, that are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid (leucovorin), 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen independent prostate cancer in combination with docetaxel/prednisone. In addition, a Phase 2 study (called AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with FOLFOX (folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin) is also fully enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a prespecified number of events have occurred in each trial. Based on projected event rates, (i) an interim analysis of VELOUR is expected to be conducted by an independent statistician and reviewed by an IDMC in the second half of 2010, (ii) final results are anticipated in the first half of 2011 from the VITAL study and (iii) an interim analysis of VENICE is expected to be reviewed by an IDMC in mid-2011, with final results anticipated in 2012. Initial data from the AFFIRM study are anticipated in the second half of 2011.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

4. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

REGN475 is a fully human monoclonal antibody to NGF generated using our *VelocImmune*® technology. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4/5, or BDNF.

In the third quarter of 2009, we began a Phase 2 double-blind, placebo-controlled, dose-ranging, proof-of-concept study of REGN475 in persons with osteoarthritis of the knee. Preliminary data from that study are expected in the second quarter of 2010. Additionally, four Phase 2 proof-of-concept studies in other pain indications were initiated in late 2009 and early 2010. One of these studies, in patients with thermal injuries, is being discontinued because of difficulty enrolling patients. REGN475 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), tocilizumab, developed by Roche, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune*® technology that is in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN421 (Anti-Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dlt4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune*® technology. REGN421 is being developed in collaboration with sanofiaventis and is in Phase 1 clinical development.

7. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) cholesterol levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase substilisin/kexin type 9) is a protein that binds to LDLR, which prevents LDLR from binding to and removing LDL from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. We used our *VelocImmune*® technology to derive a fully human monoclonal antibody called REGN727 that is designed to bind to PCSK9 and prevent it from inhibiting LDLR. REGN727 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

8. REGN668 (Anti-IL-4R Antibody) for allergic and immune conditions

Interleukin-4 receptor (IL-4R) is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis. REGN668 is a fully human *VelocImmune*® antibody that is designed to bind to IL-4R. REGN668 is being developed in collaboration with sanofi-aventis and is in Phase 1 clinical development.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST® (rilonacept), as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite*TM is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuiteTM

VelociSuiteTM consists of Velocimmune[®], VelociGene[®], VelociMouse[®], and VelociMouse[®]. The Velocimmune[®] mouse platform is utilized to produce fully human monoclonal antibodies. Velocimmune[®] was generated by exploiting our VelociGene[®] technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. Velocimmune[®] mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. Velocimmune[®] and our entire VelociSuiteTM offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the Velocimmune[®] technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene*® platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of pre-clinical development and pharmacology programs, *VelociGene*® offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene*® allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, the VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab®* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *Velocimmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$175 million of research from the collaboration's inception through December 31, 2009.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to \$160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In addition, sanofi-aventis will fund up to \$30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities. As under the original 2007 agreement, sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate will be shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of \$21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

AstraZeneca UK Limited. In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made \$20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, 2009, and 2010. AstraZeneca is required to make up to two additional annual payments of \$20.0 million, subject to its ability to terminate the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune*® technology.

Astellas Pharma Inc. In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made \$20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, and 2009. Astellas is required to make up to three additional annual payments of \$20.0 million, subject to its ability to terminate the agreement after making the next annual payment in the second quarter of 2010. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune®* technology.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received \$17.0 million through March 31, 2010 and are entitled to receive an additional \$8.3 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® (rilonacept) or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® (rilonacept) or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the U.S. Food and Drug Administration (FDA) and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2010, we had a cumulative loss of \$971.6 million. In the absence of significant revenues from the commercialization of ARCALYST® (rilonacept) or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and rilonacept; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2010 and plans over the next 12 months are as follows:

2010-11 Plans

Clinical Program	2010 Events to Date	(next 12 months)
Rilonacepi	Completed patient enrollment in the first of two Phase 3	Report data from SURGE and PRE_SURGE I during the
(also known as II I. Trap)	mais (PRE-SURGE 1) evaluating ritinaceur in the prevention of good flares associated with the burnation of	second quarter of 2010 • Complete patient enrollment of the remaining Phase 3
	urate fewering drug therapy	Complete parent entitlinent of the remaining thase of studies in cont.
	 Completed parient enrollment in a Phase 3 study (SURGE) evaluating rifouscept in the treatment of scare goal flares 	
VEGE Trap Eye	 Reported positive 24-week primary endpoint results from 	Report data from VIEW Land VIEW 2 trials in the fourth
fintravitreal injection)	the Phase 2 DME trial • Completed patient enrollment in the first of two Phase 3	quarter of 2010 • Considere patient enrollment in the second Phase 3 CKVO
	CPVC mais (COPERSICUS)	rnal (CALILEO) and report mutat data from both trials
		Report one year results from the Phase 2 DMF trial
Aflibercept	Completed patient enrollment in the Phase 3 studies in	During the second half of 2010, an independent Data
VEGF Trap -	non-small cell-lung cancer prostate cancer, and	Monitoring Committee is expected to conduct an intentil
Oncology)	colorectal cancer • Completed patient enrollment to a Phase 2 Lst line study	enetysis of the Phase 3 study in colorectal cancer
	in metastatic colorectal cancer in combination with	
	chemotherapy	
Menoclonal	RECN88: Initiated a Phase 2/3 dose ranging study in	 RECN475: Report data from the study in osteoarthritis of
Antibodies	chemicated arthritis and a Phase 2 dose, ranging study in ankylosing spondylins.	the knee during the second quarter of 2010 and from another study in a pain indication during the second half
	and the constitution of th	of 2040
		 REGN727 Report proof of concept data from the Phase I program and initiate a Phase 2 program for LDI.
		chelesterol reduction
		 RECN668 Initiate a Phase 2 program in the treatment of a
		curonic allergic condition • REGNES: Report data from a Phase 1 trial in rieumatoid
		arthritis
		 Advance additional analody candidates and clinical development
		ARE VELLEPORTELIAL

Results of Operations

Three Months Ended March 31, 2010 and 2009

Net Loss

Regeneron reported a net loss of \$30.5 million, or \$0.38 per share (basic and diluted), for the first quarter of 2010, compared to a net loss of \$15.4 million, or \$0.19 per share (basic and diluted) for the first quarter of 2009. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher contract research and development revenue primarily in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the three months ended March 31, 2010 and 2009 consist of the following:

(In millions)	2010	2 00 9
Callaboranon revenue		
Sanofi-aventis	\$ 68.7	\$49.6
Bayer Health Gre	13.1	10.0
Total collaboration revenue	81.8	59.6
Technology licensing revenue	100	10.0
Net product sales	9.9	3.9
Contract research and other revenue	1.8	<u></u>
Total revenue	\$103.5	\$75.0
· · · · · · · · · · · · · · · · · · ·		

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue	Thre	e mo n	ths	ended
(In millions)		Marc	h 31,	
	20	10	2	:009
Affibercept				
Regeneron expense reimbursement	\$	4.9	\$	5.4
Recognition of deferred revenue related to up from payments		25		2.5
Total aflibercept		7.4		7.9
Antifody				
Regeneron expense reimbursement		59.3		38.4
Recognition of deferred revenue related to up from and other payments		1.6		2.6
*	**********	0.4	*******	**************************************
Recognition of revenue related to VelociGene® agreement		U.4		U.7
Tetal antibody		61.3		41.7
Total sanofi-aventis collaboration revenue	\$	68.7	\$	49.6

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the first quarter of 2010 compared to same period in 2009, primarily due to lower costs related to internal research activities. As of March 31, 2010, \$40.0 million of the original \$105.0 million of up-front payments related to aflibercept was deferred and will be recognized as revenue in future periods.

In the first quarter of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of \$26.7 million under the discovery agreement and \$32.6 million of development costs under the license agreement, compared to \$22.7 million and \$15.7 million, respectively, in the first quarter of 2009. The higher reimbursement amounts in the first quarter of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenues related primarily to sanofi-aventis' \$85.0 million up-front payments decreased during the first quarter of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to \$30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which \$5.1 million was received or receivable from sanofi-aventis as of March 31, 2010. Payments for such funding from sanofi-aventis are deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the original \$85.0 million up-front payment. As of March 31, 2010, \$67.2 million of the original up-front payment and subsequent payments to fund expansion of our Rensselaer facilities was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the three months ended March 31, 2010 and 2009, we recognized \$0.4 million and \$0.7 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable \$75.0 million up-front payment and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	Three mon	ths ended
(In millions)	March	1 31,
	2010	2009
Cost sharing of Regeneron VBCs. Frap. Eve disvelopment expenses Recognition of deferred revenue related to up-front and milestone	\$ 10.6	7.5
payments	2.5	2.5
Total Bayer HealthCare collaboration revenue	5 131	10.0

In periods when we recognize VEGF Trap-Eye development expenses that we incur under our collaboration with Bayer HealthCare, we also recognize, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the first quarter of 2010, compared to the same period in 2009, due to higher clinical development costs in connection with our VIEW 1 trial in wet AMD, Phase 2 trial in DME, and Phase 3 trial in CRVO. In 2010 and 2009, development expenses incurred by Regeneron and Bayer HealthCare under the VEGF Trap-Eye global development plan were shared equally. As of March 31, 2010, \$54.4 million of the \$75.0 million up-front licensing and \$20.0 million milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the first quarter of both 2010 and 2009, we recognized \$10.0 million of technology licensing revenue related to these agreements.

Net Product Sales

In February 2008, we received marketing approval from the FDA for ARCALYST® (rilonacept) for the treatment of CAPS. We had limited historical return experience for ARCALYST® (rilonacept) beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® (rilonacept) net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST® (rilonacept). As a result, for the three months ended March 31, 2010, we recognized as revenue \$9.9 million of ARCALYST® (rilonacept) net product sales, which included \$5.1 million of ARCALYST® (rilonacept) net product sales made during the quarter and \$4.8 million of previously deferred net product sales. For the three months ended March 31, 2009, we recognized as revenue \$3.9 million of ARCALYST® (rilonacept) net product sales. There was no deferred ARCALYST® (rilonacept) net product sales revenue at March 31, 2010. At March 31, 2009, deferred ARCALYST® (rilonacept) net product sales revenue was \$4.2 million.

Contract research and other revenue for the three months ended March 31, 2010 and 2009 included \$1.1 million and \$1.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to \$132.2 million in the first quarter of 2010 from \$92.1 million in the first quarter of 2009. Our average headcount increased to 1,087 in the first quarter of 2010 from 938 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the first quarter of 2010 and 2009 include a total of \$8.8 million and \$7.7 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three mor	nths ended March	31, 2010
	Expenses before		
	inclusion of Non-cash	Non-cash	
Expenses	Compensation	Compensation	Expenses as
(In millions)	E xp ense	Expense	Reported
Research and developmen:	\$ 112.5	\$ 5.0	\$ 117.5
Selling, general, and administrative	10.2	3.8	14.0
Cost of goods sold	0.7		0.7
Total operating expenses	\$ 123.4	\$ 8.8	\$ 132.2
	For the three mor	nths anded March	21 2000
		itiis chaca march	31, 2009
	Expenses before	itiis ciided maren	31, 2009
		Non-cash	31, 2009
Expenses	Expenses before		Expenses as
Expenses (In millions)	Expenses before inclusion of Non-cash	Non-cash	
	Expenses before inclusion of Non-cash Compensation	Non-cash Compensation	Expenses as
(In millions)	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported
(In millions) Research and development	Expenses before inclusion of Non-cash Compensation Expense \$ 75.6	Non-cash Compensation Expense \$ 4.7	Expenses as Reported \$ 863
(In millions) Research and development Selling, general, and administrative	Expenses before inclusion of Non-cash Compensation Expense 5. 6.84	Non-cash Compensation Expense \$ 4.7	Expenses as Reported 8 86.3

Research and development expenses increased to \$117.5 million in the first quarter of 2010 from \$80.3 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2010 and 2009:

	For the three mo	mins ended	
Research and Development Expenses	March 3	1,	
(In millions)	2010	2009	Increase
Payroll and benefits (i)	\$ 27.7	5 22.9	\$ 4.8
Clinical trial expenses	32.2	19.3	12.9
Clinical manufacturing costs (2)	20.0	14.1	5.9
Research and other development costs	12.8	8.4	4.4
Occupancy and other operating costs Cost-sharing of Bayer HealthCare VEGF Trap-	12.0	8.6	3.4
Eye development expenses (3)	12.8	7.0	5.8
Fotal research and development	12.0	80.3	3.0

Includes \$4.3 million and \$4.0 million of Non-cash Compensation Expense for the three months ended March 31, 2010 and 2009, respectively. Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.7 million of Non-cash Compensation Expense for both the three months ended March 31, 2010 and 2009.

Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, including our VIEW 1 trial in wet AMD, DA VINCI trial in DME, and COPERNICUS trial in CRVO, (ii) rilonacept, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibody candidates, which are in earlier stage clinical development. Clinical manufacturing costs increased due to higher costs related to manufacturing clinical supplies of monoclonal antibodies and rilonacept. Research and other development costs increased primarily due to higher costs associated with VEGF Trap-Eye and our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare. We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	For the thr	ee months	
Project Costs	ended M	arch 31,	Increase
(In millions)	2010	2009	(Decrease)
Rilonacept	\$ 201	\$ 179	3.00
VEGF Trap-Eye	33.6	20.8	12.8
Affibercept	49	42	(0.3)
REGN88	4.9	9.0	(4.1)
Other ambody candidates in clinical development	24.1	49	19.2
Other research programs & unallocated costs	30.9	23.5	7.4
Total research and development expenses	\$ 117.5	\$ 80.3	37.2

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug, Clinical development typically involves three phases of study. Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of rilonacept, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST* (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® (rilonacept) for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$14.0 million in the first quarter of 2010 from \$11.4 million in the same period of 2009. In the first quarter of 2010, we incurred (i) higher compensation expense due primarily to higher Non-cash Compensation Expense and increases in headcount, (ii) higher recruitment costs, and (iii) higher facility-related costs due primarily to our new and expanded leased facilities in Tarrytown, New York and higher headcount.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® (rilonacept) sales, which consisted primarily of royalties and other period costs, totaled \$0.7 million and \$0.4 million for the quarters ended March 31, 2010 and 2009, respectively. To date, ARCALYST® (rilonacept) shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® (rilonacept) in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to \$0.4 million in the first quarter of 2010 from \$1.8 million in the comparable quarter of 2009, primarily due to lower yields on, and lower balances of, cash and marketable securities and a \$0.1 million other-than-temporary impairment charge. Interest expense of \$2.1 million in the first quarter of 2010 was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Income Tax Expense

In accordance with authoritative guidance issued by the Financial Accounting Standards Board (FASB), changes in our unrealized gain on marketable securities, which is included in Accumulated Other Comprehensive Income in the Stockholders' Equity section of our condensed balance sheet, are recognized net of their tax effect. In the first quarter of 2010, we recognized an income tax benefit of \$0.2 million in Accumulated Other Comprehensive Income in connection with a decrease in our unrealized gain on marketable securities for the three months ended March 31, 2010. As a result, we recognized \$0.2 million of income tax expense in our condensed statement of operations.

Revision of Previously Issued Financial Statements

The application of FASB authoritative guidance, under certain conditions, can result in the capitalization on a lessee's books of a lessor's costs of constructing facilities to be leased to the lessee. In mid-2009, we became aware that certain of these conditions were applicable to our December 2006 lease, as amended, of new laboratory and office facilities in Tarrytown, New York. As a result, we are deemed, in substance, to be the owner of the landlord's buildings, and the landlord's costs of constructing these new facilities were required to be capitalized on our books as a non-cash transaction, offset by a corresponding lease obligation on our balance sheet. In addition, the land element of the lease should have been accounted for as an operating lease; therefore, adjustments to non-cash rent expense previously recognized in connection with these new facilities were also required. Lease payments on these facilities commenced in August 2009.

As previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2009, we revised our previously issued financial statements to capitalize the landlord's costs of constructing the new Tarrytown facilities which we are leasing and to adjust our previously recognized rent expense in connection with these facilities, as described above. These revisions primarily resulted in an increase to property, plant, and equipment and a corresponding increase in facility lease obligation (a long-term liability). We also revised our statements of operations and statements of cash flows to reflect rent expense in connection with only the land element of its lease, with a corresponding adjustment to other long-term liabilities. In addition, our statement of cash flows for the quarter ended March 31, 2009 was revised to reclassify, from an operating activity to a financing activity, a \$5.2 million reimbursement received from our landlord for tenant improvement costs that we incurred. Under FASB authoritative guidance, such payments that we receive from our landlord are deemed to be a financing obligation.

The above described revisions consisted entirely of non-cash adjustments. They had no impact on our business operations, existing capital resources, or our ability to fund our operating needs. The revisions also had no impact on our previously reported net increases or decreases in cash and cash equivalents. In addition, these revisions had no impact on our previously reported current assets, current liabilities, and operating revenues. We did not amend previously issued financial statements because, after considering both qualitative and quantitative factors, we determined that the judgment of a reasonable person relying on our previously issued financial statements would not have been changed or influenced by these revisions.

For comparative purposes, the impact of the above described revisions to the statement of operations, statement of stockholders' equity, and statement of cash flows for the three months ended March 31, 2009 is as follows:

Statement of Operations Impact for the three months ended March 31, 2009 (In millions, except per share data)

	As Originally	
	Reported	As Revised
Research and development expenses	\$ 82.1	\$ 803
Selling, general, and administrative	11.7	11.4
Total expenses	94.2	92.1
Net loss	(17.5)	(15.4)
Net loss per share, basic and diluted	\$ (0.22)	\$ (0.19)

Statement of Stockholders' Equity Impact for the three months ended March 31, 2009 (In millions)

	As C	Priginally		
		ported		Revised
Accumulated deficit	8	(893.4)	8	(887.7)
Total stockholders' equity	\$	410.3	\$	415.1

Statement of Cash Flows Impact for the three months ended March 31, 2009 (In millions)

	As O	riginally		
	Re	ported	As I	Revised
Vet cash used in operating activities	4	(10.2)	4	(15.4)
Net cash used in investing activities		(39.5)		(39.5)
Net cash provided by financing activities		1.0		6.2
Net decrease in cash and cash equivalents	\$	(48.7)	\$	(48.7)

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® (rilonacept) product revenue, and investment income.

Three months ended March 31, 2010 and 2009

At March 31, 2010, we had \$413.5 million in cash, cash equivalents, restricted cash, and marketable securities compared with \$390.0 million at December 31, 2009. In February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs for the new laboratory and office facilities that we lease in Tarrytown, New York, and a \$20.0 million annual technology licensing payment from AstraZeneca.

Cash Used in Operations:

Net cash used in operations was \$10.0 million in the first quarter of 2010 and \$15.4 million in the first quarter of 2009. Our net losses of \$30.5 million in the first quarter of 2010 and \$15.4 million in the first quarter of 2009 included \$8.8 million and \$7.7 million, respectively, of Non-cash Compensation Expense, and \$4.2 million and \$2.7 million, respectively, of depreciation and amortization.

At March 31, 2010, accounts receivable increased by \$6.3 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. At March 31, 2010, accounts payable, accrued expenses, and other liabilities increased by \$12.3 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for clinical-related expenses and payroll and related costs.

At March 31, 2009, accounts receivable increased by \$13.0 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, prepaid expenses and other assets increased by \$8.6 million at March 31, 2009, compared to end-of-year 2008, due primarily to higher prepaid clinical trial costs. At March 31, 2009, accounts payable, accrued expenses, and other liabilities increased by \$8.0 million, compared to end-of-year 2008, primarily due to higher liabilities for clinical-related expenses and payroll and related costs, which were partially offset by a lower cost-sharing payment due to Bayer HealthCare in connection with the companies' VEGF Trap-Eye collaboration.

Cash Used in Investing Activities:

Net cash used in investing activities was \$136.0 million in the first quarter of 2010 and \$39.5 million in the first quarter of 2009. In the first quarter of 2010 and 2009, purchases of marketable securities exceeded sales or maturities by \$113.2 million and 17.6 million, respectively. Capital expenditures in the first quarter of 2010 and 2009 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased office and laboratory facilities in Tarrytown, New York.

Cash Provided by Financing Activities:

Net cash provided by financing activities was \$56.2 million in the first quarter of 2010 and \$6.2 million in the first quarter of 2009. In the first quarter of 2010 and 2009, we received \$47.5 million and \$5.2 million, respectively, from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with FASB authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were \$9.2 million in the first quarter of 2010 and \$1.0 million in the first quarter of 2009.

Fair Value of Marketable Securities:

At March 31, 2010 and December 31, 2009, we held marketable securities whose aggregate fair value totaled \$294.6 million and \$181.3 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	March 31, 2010		December 31, 2009	
Investment type	F air V al ue	Percent	Fair Value	Percent
S. Treasury securities	\$ 59.2	20%	S 804	44%
U.S. government agency securities	150.0	51%	29.6	16%
U.S. government guaranteed corporate bonds	54.3	22%	48.7	27%
U.S. government guaranteed collateralized mortgage				
obligations	3.3	1%	3.7	2%
Carparate bands	8.2	3%	103	6%
Mortgage-backed securities	2.6	1%	3.2	2%
Equity security	4.8	1%	5.4	304
Other	2.2	1%		
Foral marketable securities	\$ 294.5	100%	\$ 1813	100%

In addition, at March 31, 2010 and December 31, 2009, we had \$118.9 million and \$208.7 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2009 and 2010 to date, as marketable securities in our portfolio matured or paid down, we purchased higher quality securities such as U.S. Treasury securities, U.S. government agency obligations and U.S. government-guaranteed debt. This shift in our investment portfolio, which we initiated in 2008, has reduced the risk profile, as well as the overall yield, of our portfolio.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled \$22.7 million and \$21.9 million for the first three months of 2010 and 2009, respectively. We expect to incur capital expenditures of approximately \$60 to \$90 million during the remainder of 2010 and approximately \$40 to \$60 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our leased Tarrytown facilities. As described above, in February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. We also expect to be reimbursed for a portion of the capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the clinical development of product candidates, including rilonacept, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our amended and expanded antibody collaboration with sanofi-aventis.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST® (rilonacept) for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® (rilonacept) for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, if we choose to commercialize products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than a \$1.6 million letter of credit issued to our landlord in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of March 31, 2010, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In March 2009, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We are required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates principally in connection with our investment of excess cash in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a \$1.6 million decrease in the fair value of our investment portfolio at both March 31, 2010 and 2009.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of \$2.5 million, \$0.1 million in 2008, 2009, and the first three months of 2010, respectively.

The current economic environment and the deterioration in the credit quality of issuers of securities that we hold increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2010, we had a cumulative loss of \$971.6 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2012; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. Our expenses may increase for many reasons, including for expenses in connection with the commercial launch of our products, for expenses related to new clinical trials testing rilonacept or VEGF Trap-Eye, or for the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of March 31, 2010, cash, cash equivalents, restricted cash, and marketable securities totaled \$413.5 million and represented 53% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled \$294.6 million at March 31, 2010, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of \$2.5 million, \$0.1 million in 2008, 2009, and the first three months of 2010, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and rilonacept in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd line metastatic colorectal cancer, 1st line androgen independent prostate cancer, and 2nd line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (bevacizumab), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of aflibercept in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of CRVO. Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis (Genentech). A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

Rilonacept is in Phase 3 clinical trials for two different gout indications - the prevention of gout flares in patients initiating urate-lowering drug therapy and acute gout. We do not have proof of concept data from Phase 2 clinical trials that rilonacept will be safe or effective in the acute gout setting. Although we reported positive Phase 2 proof of concept data from a small number of patients initiating urate-lowering drug therapy, there is a risk that the results of the larger Phase 3 trials of rilonacept in patients initiating urate-lowering drug therapy will differ from the previously reported Phase 2 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating affibercept as a 1st line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could harm the future development of our product candidate(s) and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large number of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® (rilonacept) in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST® (rilonacept) may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), marketed by Biovitrum, Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor Ortho Biotech, Inc., ARCALYST® (rilonacept) affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® (rilonacept) may interfere with the body's ability to fight infections. Treatment with Kineret (Biovitrum), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST® (rilonacept). These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® (rilonacept), we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® (rilonacept) in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® (rilonacept) in approved indications.

 $ARCALYST^*$ (rilonacept) and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of rilonacept were detected in patients with CAPS after treatment with ARCALYST® (rilonacept). Nineteen of 55 subjects (35%) who received ARCALYST® (rilonacept) for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our VelocImmune® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye or uses thereof. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing RECN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST® (rilonacept), aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® (rilonacept) for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST® (rilonacept) and the Europeans Medicines Agency approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST® (rilonacept) or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with current Good Manufacturing Practice, or cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST® (rilonacept) that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST $^{\circ}$ (rilonacept) in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states and were included in health care reform legislation recently enacted by the federal government. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2009, which report is included in our Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could
 materially increase our costs of doing business; and
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical
 candidates in accordance with cGMPs.

The enactment in the U.S. of health care reform, potential regulations easing the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to \$1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, REGN475, REGN727, and REGN668 we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of affibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the affibercept program. If the affibercept program continues, we will rely on sanofi-aventis to assist with funding the affibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of affibercept. While we cannot assure you that affibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize affibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of affibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for affibercept would create substantial new and additional risks to the successful development and commercialization of affibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of $ARCALYST^*$ (rilonacept) and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST® (rilonacept) and many other related activities in connection with the commercialization of ARCALYST® (rilonacept) for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST® (rilonacept) for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of $ARCALYST^{\oplus}$ (rilonacept) and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST® (rilonacept) and our product candidates at our manufacturing facilities in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for manufacturing and formulation of ARCALYST® (rilonacept) and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® (rilonacept) or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST® (rilonacept) for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on affibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept) in this indication.

Our only approved product is ARCALYST® (rilonacept) for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009 we received European marketing authorization for rilonacept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST® (rilonacept) in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone/Eli Lilly, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis, for the treatment of age-related macular degeneration (wet AMD), DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin. The National Eye Institute and others are conducting long-term, controlled clinical trials comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using the medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel (Amgen and Wyeth), Remicade (Centocor), Humira® (adalimumab), marketed by Abbott, and SimponiTM (golimumab), marketed by Centocor, and the IL-1 receptor antagonist Kineret (Biovitrum), and other marketed therapies makes it more difficult to successfully develop and commercialize rilonacept in other indications and this is one of the reasons we discontinued the development of rilonacept in adult rheumatoid arthritis. In addition, even if rilonacept is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over rilonacept, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST® (rilonacept). For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST® (rilonacept). The successful development and/or commercialization of these competing molecules could impair our ability to successfully commercialize ARCALYST® (rilonacept).

We have plans to develop rilonacept for the treatment of certain gout indications. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. Novartis' IL-1 antibody is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over rilonacept in gout by some physicians, which would make it difficult for us to successfully commercialize rilonacept in that disease.

Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of these gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize rilonacept in these diseases.

The successful commercialization of ARCALYST® (rilonacept) and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we have initiated a Phase 3 program studying the use of rilonacept for the treatment of certain gout indications. Patients suffering from these gout indications are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® (rilonacept) in the United States for the treatment of a group of rare genetic disorders called CAPS. We recently received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST® (rilonacept). Physicians may not prescribe ARCALYST® (rilonacept), and CAPS patients may not be able to afford ARCALYST® (rilonacept), if third party payers do not agree to reimburse the cost of ARCALYST® (rilonacept) therapy and this would adversely affect our ability to commercialize ARCALYST® (rilonacept) profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. The U.S. Congress recently enacted legislation to reform the health care system. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® (rilonacept) and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® (rilonacept) or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- · arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 14, 2010, our six largest shareholders plus Leonard Schleifer, M.D. Ph.D., our Chief Executive Officer, beneficially owned 51.1% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2010. As of April 14, 2010, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18,6% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 14, 2010, holders of Class A Stock held 21.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, including any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 14, 2010:

- our current executive officers and directors beneficially owned 13.7% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2010, and 28.1% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2010; and
- our six largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 51.1% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2010. In addition, these seven shareholders held 56.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 14, 2010.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders
 consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an
 "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to
 vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring
 shareholder approval."

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, as amended, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 6. EXHIBITS

(a) Exhibits

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Number	Description
10.1(a)	- Fifth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of February 11, 2010.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.

Description:

(a) Incorporated by reference from the Form 8-K for Regeneron Pharmaceuticals, Inc., filed February 16, 2010.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: April 29, 2010

By: /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

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Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 29, 2010 /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 29, 2010 /s/ Murray A. Goldberg

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

<u>/s/ Leonard S. Schleifer</u> Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer April 29, 2010

/s/ Murray A. Goldberg Murray A. Goldberg Chief Financial Officer April 29, 2010

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 7/28/2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 10-Q

	(Mark One)	
(X)	(X) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURI EXCHANGE ACT OF 1934	ITIES
	For the quarterly period ended June 30, 2010	
		OR
()	() TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURI EXCHANGE ACT OF 1934	ITIES
	For the transition period from to	
	Commission Fil	le Number <u>0-19034</u>
		RMACEUTICALS, INC. nt as specified in its charter)
	New York (State or other jurisdiction of incorporation or organization)	13-3444607 (I.R.S. Employer Identification No.)
	777 Old Saw Mill River Road <u>Tarrytown, New York</u> (Address of principal executive offices)	10591-6707 (Zip Code)
	(<u>914)</u> (Registrant's telephone n	347-7000 number, including area code)
Indic	Indicate by check mark whether the registrant: (1) has filed all reports required preceding 12 months (or for such shorter period that the registrant was required past 90 days.	to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the d to file such reports), and (2) has been subject to such filing requirements for the
pasc	Yes X	No
Indic subn was	Indicate by check mark whether the registrant has submitted electronically and submitted and posted pursuant to Rule 405 of Regulation S-T ($\S 232.405$ of this check was required to submit and post such files).	posted on its corporate Web site, if any, every Interactive Data File required to bapter) during the preceding 12 months (or for such shorter period that the registran
	Yes X	No
Indic defir	Indicate by check mark whether the registrant is a large accelerated filer, an definitions of "large accelerated filer", "accelerated filer" and "smaller reporting of "large" accelerated filer."	accelerated filer, a non-accelerated filer, or a smaller reporting company. See the company" in Rule 12b-2 of the Exchange Act.
Larg	Large accelerated filer \underline{X}	Accelerated filer
Non	Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
Indic	Indicate by check mark whether the registrant is a shell company (as defined in R $$\operatorname{Yes}$$	tule 12b-2 of the Exchange Act). No X
Num	Number of shares outstanding of each of the registrant's classes of common stock	ck as of July 15, 2010:
	<u>Class of Common Stock</u> Class A Stock, \$0.001 par value Common Stock, \$0.001 par value	Number of Shares 2,182,036 79,931,305

REGENERON PHARMACEUTICALS, INC. Table of Contents June 30, 2010

Page Numbers PART I FINANCIAL INFORMATION <u>Financial Statements</u> Condensed balance sheets (unaudited) at June 30, 2010 and December 31, 2009. Condensed statements of operations unsedired) for the three and six ments ended June 30, 2010 and 2009 Condensed statements of stockholders, equity (unaudited) for the six months ended june 30, 2010 and 2009 5 Condensed statements of cash flows funantified) for the six months ended time 30, 2010 and 2009. 6 Notes to condensed financial statements funaudited: 7-13 Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations 14:37 <u>ltem 3</u> Quantitative and Qualitative Disclosures About Market Kisk 37 Controls and Procedures 37-38 <u>ltem 4</u> PART II OTHER INFORMATION Item 1 Legal Proceedings 38 Ben IA Risk Factors 38-54 Item 6 Exhibits SIGNATURE PAGE

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AT JUNE 30, 2010 AND DECEMBER 31, 2009 (Unaudited) (In thousands, except share data)

	June 30,	December 31,
ASSETS	2010	2009
Current essets Cash and cash equivalents	\$ 112,000	\$ 207,075
Marketable securities Accounts receivable from the sanofi-aventis Group	194.337 91.126	134.255 62,703
Accounts receivable ather	4 070	2.865
Prepaid expenses and other current assets Foral current assets	16,217 417,750	18,610 425,50 8
Restricted cash Marketable securities	3.40 0 70,465	1.600 47,080
Property, plant, and equipment, at cost, net of accumulated		
depreciation and amortization Other assets	292 329 6,697	239.676 7,338
Total assets	790.611	<u>\$ 711.202</u>
LIABILITIES and STOCKHOLDERS EQUITY Current liabilities		
Accounts payable and accrued expenses Deferred revenue from sanofi-aventis, current portion	58.25 6 19.126	\$ 49.031 17.523
Deferred revenue other, current portion Facility lease obligations, current portion	41.741 448	27.021
Total current liabilities	119.571	93,73
Beferred revenue from sanofi avenus Deferred revenue - other	96,168 42,009	90.933 46.951
Bacility lease obligations	157.359 4.318	109.022 3,959
Other long term liabilities Total habilities	419.423	344.440
Communeurs and contingencies		
Stockholders: equity Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and		
outstanding - none		
Class A Stock, convertible, \$ 001 par value: 40,000,000 shares authorized: shares issued and ourstanding: 2,182,036 in 2010 and 2,244,698 in 2009 Common Stock, \$,001 par value; 160,000,000 shares authorized;		2
shares issued and outstanding - 79,923,216 in 2010 and 78,860,862 in 2009	80	79
Additional paid: inceptial	1 368 531	1 336 732
Accumulated deficit Accumulated other comprehensive floss) income	(997,091) (306)	(941,095) 1.044
Total stockholders' equity	371,216	396,762
Total liabilities and stockholders, equity	790.641	\$ 741,202

The accompanying notes are an integral part of the financial statements.

3

	Three months e		Six months en	
	2010	2009	2010	2009
Revenues				
Sanofi-aventis collaboration revenue	\$ 84,941	\$ 60,732	\$ 153,612	\$ 110,392
Other collaboration revenue	13.635	12,846	26.722	22.794
Technology licensing	10,037	10,000	20,075	20,000
Net product sales	5.197	4,500	15 049	8,391
Contract research and other	2,076	1,954	3,962	3,436
	115,886	90.032	219,420	165.013
rxpenses				
Research and development	124,526	94,231	241,997	174,538
Selling, general, and administrative	14.679	11 632	28,902	23.062
Cost of goods sold	405	435	1,122	827
	139610	106,298	272.021	198.417

Loss from operations	(25 124)	[16,266]	(52,801)	(33.404)
Other income (expense)	=00			
Investment income	592	1,328	1,031	3,078
Interest expense	(1.750)	1.000	(9.925)	0.070
	(1,750)	1,328	(3,395)	3,078
Net loss	\$ (25,474)	\$ (14,938)	5 (0.033)	\$ (30,326)
	5 (0.31)		\$ (0.69)	
Net loss per share, basic and dilinted	3 (0.31)	5 (0.19)	a (0.03)	(0.38)
	64.0466	76.676		
Weighted average shares outstanding, basic and dillated	na viiz	759.020	31 330	737,201Z

					Additional		Accumulated Other	Total	
	Class A	Stock	Commo	on Stock	Paid-in	Accumulated	Comprehensive	St ockh olde rs '	Comprehe
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2003	2.745	5 2	78.861	\$ 79	\$ 1,006,732	\$ (941,095)	\$ 1,044	\$ 396,762	
Issuance of Common Stock in connection with									
exercise of stock options, net of shares tendered seasons of Common Stock in connection with Company 401 to Secretary Por common stock under			878 111	1	11,391 2,867			11,392 2 867	
Long-Term Incentive Plan Conversion of Cass A Stock to Common Stock	(63)		10 63						
Stock-based compensation expense					17,541	(53,996)		17,541 656,9 9 63	8
Change in net unrealized gain (loss) on									
marketable securities							(1,350)	(1,350)	
Balance: june 39, 2010			79,923	<u> 80</u>	8 1 368 531	s (Ser Del)	\$ (306)	371,216	<u> </u>
Balance Discension 31 ACCS Issuance of Common Stock in connection with	2,249		77.642	\$ 75	\$ 1,294,813	\$ (973,255)	3 118	\$ 421,514	
exercise of stock options, net of shares tendered			196		1,705			1,705	
Issued to DECompton Stock in contraction with Company 401(4) Sevenge Plan contribution Conversion of Class A Stock to Common Stock	(2)		81 2		1 961			1,091	
Stock based compensation expense	(2)				15494			15,094	
Net loss	***************	**************				(30,326)		(30,326)	\$ (3
Charge is tot uniselated gain liess; on mathematic securities							1,129	1.126	
Balonce June 40, 2003			<u> </u>		<u> </u>	9 (903.531)	<u> 1014</u>	\$ 41CL506	<u> </u>

	Six months e	nded June 30,
	20 10	2009
Cosh flows from operating activities		
Net loss	\$ (55,996)	\$ (30,326)
Adjustments to reconcile act loss to act cash used in operating activities		
Depreciation and amortization	8,707	5,722
Non-caste compensation expense	17,541	15,094
Other non-cash charges and expenses	225	
Net realized less on marketable securities	200	
Changes in assets and liabilities		
lacrease in accounts receivable	(29.628)	(24,834)
Decrease (increase) in prepaid expenses and other assets	1,604	(578)
Increase in defensed revenue Increase in accounts payable, accrued expenses,	16.616	5.873
and other liabilities	18,105	13,045
Total adjustments	33.370	14 322
Net cash used in operating activities	(22,626)	(16,004)
Cash flows from investing activities		
Purchases of marketable securities	(222,168)	(105,315)
Sales or maturities of marketable securities	137 909	190.723
Capital expenditures	(45,324)	(52,671)
Operage) decrease in restricted casti	(1800)	50
Net cash (used in) provided by investing activities	(131,383)	32,787
Cash flows from financing activities		
Proceeds in connection with facility lease obligations	47,544	5,182
Payments in connection with facility lease obligations	(674)	
Net proceeds from the issuance of Common Stock	12,064	1,705
Net cash provided by financing activities	58.934	6.887
Not (decrease) increase in cash and cash equivalents	(95,075)	23.670
Cash and cash equivalents at beginning of period	207.075	247 796
Cash and cash equivalents at end of period	\$ 112,000	\$ 271.466
	··· <u></u> /···	<u></u>

The accompanying notes are an integral part of the financial statements.

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2009 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

Effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, was extended. The effect of this change in estimate was to lower depreciation expense by \$1.0 million and \$2.0 million and to lower the Company's net loss per share by \$0.01 and \$0.02 for the three and six months ended June 30, 2010, respectively.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, \$4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010.

ARCALYST® net product sales totaled \$5.2 million and \$4.5 million for the three months ended June 30, 2010 and 2009, respectively, and \$15.0 million and \$8.4 million for the six months ended June 30, 2010 and 2009, respectively. ARCALYST® net product sales during the first six months of 2010 included \$10.2 million of net product sales made during this period and \$4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at June 30, 2010. At June 30, 2009, deferred ARCALYST® net product sales revenue was \$4.9 million. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by \$0.06 for the six months ended June 30, 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled \$0.4 million for both the three months ended June 30, 2010 and 2009, and \$1.1 million and \$0.8 million for the six months ended June 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to the Company's customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST®; therefore, the costs of these supplies were not included in costs of goods sold. At both June 30, 2010 and December 31, 2009, the Company had \$0.4 million of inventoried work-in-process costs related to ARCALYST®, which is included in prepaid expenses and other current assets.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and six months ended June 30, 2010 and 2009, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

		s Ended June 30,
Net loss (Numerator)	2010 \$ (25.174)	2009
Weighted average shares, in thousands (Denominator)	81,492	79.628
Basic and dilitted net loss per store	\$ (C.31)	(0.19)
	Six Months	Ended June 30,
Net loss (Numerator)	Six Months 2010 \$ (55.90ff	Ended June 30, 2009
Net loss (Sumeraco) Weighted: average shares, in thousands (Denominator)		

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the June 30, 2010 and 2009 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months en	ded June 30, 2009
Stork Options Weighted average number, in thousands Weighted average exercise price	21,288 \$ 1867 \$	20,106
Restricted Stock Weighted average number, in thousands	510	500
	Six months end	ed June 30,
Szort Conzens	Six months ender	ed June 30, 2009
Stock Options Weighted average number, in thousands Weighted average exercise price		

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at June 30, 2010 and December 31, 2009 were \$4.1 million and \$9.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at June 30, 2009 and December 31, 2008 were \$12.1 million and \$7.0 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2009 and 2008 were \$2.6 million and \$1.5 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2010 and 2009, the Company contributed 111,419 and 81,086 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Pursuant to the application of authoritative guidance issued by the Financial Accounting Standards Board ("FASB") to the Company's lease of office and laboratory facilities in Tarrytown, New York, the Company recognized a facility lease obligation of \$1.3 million for the six months ended June 30, 2009, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in facility lease obligations and property, plant, and equipment at June 30, 2010 was \$1.7 million of capitalized and deferred interest for the six months ended June 30, 2010, as the related facilities being leased by the Company are currently under construction and lease payments on these facilities do not commence until January 2011.

Included in other assets at December 31, 2009 was \$0.7 million due to the Company in connection with employee exercises of stock options.

Included in marketable securities at June 30, 2010 and December 31, 2009 were \$1.3 million and \$0.6 million, respectively, of accrued interest income. Included in marketable securities at June 30, 2009 and December 31, 2008 were \$1.3 million and \$1.7 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at June 30, 2010 and December 31, 2009 consisted of debt securities, as detailed below, and an equity security, the aggregate fair value of which was \$3.8 million and \$5.5 million at June 30, 2010 and December 31, 2009, respectively, and the aggregate cost basis of which was \$4.0 million at both June 30, 2010 and December 31, 2009. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at June 30, 2010 and December 31, 2009. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair		Unrealized	
At June 30, 2010	Cost Basis	Value	Gains	(Losses)	Net
Manufires within one year U.S. government obligations	\$ 156,142	\$156,208	\$ 70	\$ (4)	\$ 66
U.S. government guaranteed corporate	φ 150,142	\$130,206	\$ 10	φ (4)	\$ 00
bands	31.216	31,362	146		146
Corporate bonds	3,053	3,067	14		14
Mortgage backed securities U.S. government guaranteed	773	707		(G6)	(66)
collateralized mortgage obligations	2,803	2,993	190		190
	193,987	194.337	420	(70)	350
Maturities between one and four years					
U.S. government obligations U.S. government guaranteed corporate	30 476	30,536	60		60
bonds	32,240	32.648	408		408
Mortgage backed securines	1.450	1313		(137)	(137)
Municipal bonds	2,196	2,192	3	(7)	(4)
	66,362	66,689	471	(144)	327
	\$ 260,349	\$261.026	\$ 891	\$ (214)	\$ 677
<u>At December 31, 2009</u>			····		<u></u>
Materiales within one year					
U.S. government obligations U.S. government guaranteed corporate	\$ 100,491	\$100,573	\$ 82		\$ 82
tronds	17.176	17.340	164		164
Corporate bonds	10,142	10,342	200	***************************************	200
Mortgage-backed securities	2.471	2,338		\$ (133)	(133)
U.S. government guaranteed	2.612	2.002	50		50
collateralized mortgage obligations	3,612 133,892	3,662 134.255	50 496	183	50 363
Maturities between one and two years					***********
L.S. government obligations	9.419	9.367		(46)	(46)
U.S. government guaranteed corporate					
bonds Mortgage backed securities	31,064 1,168	31,344 900	280	1982	280
WWW.80.64. WWW.7044-975-04.7145-9	41,645	41,611	280	(314)	(34)
	\$ 175,537	\$175,866	\$ 776	\$ (447)	5 329

At June 30, 2010 and December 31, 2009, marketable securities included an additional unrealized loss of \$0.3 million and an additional unrealized gain of \$1.4 million, respectively, related to the equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at June 30, 2010 and December 31, 2009. The debt securities listed at June 30, 2010 mature at various dates through July 2013.

	Less tha	n 12 Months	12 Month	s or Greater	To	tal
		Unrealized		Unrealized		Unrealized
<u>At June 30, 2010</u>	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss
U.S. government obligations	\$ 23.417	\$ (4)			3 23.417	\$ (4)
Mortgage-backed securities			\$ 2,020	\$ (203)	2,020	(203)
Municipal bonds	1,188	(7)			1.188	(7)
Equity security	3,776	(268)			3,776	(268)
	<u> </u>		1 2020	2031	30.401	14823
At December 31, 2009						
U.S. government obligations	\$ 9,367	\$ (46)			\$ 9,367	\$ (46)
Mortgage backed securities			\$ 3,238	\$ (401)	3.238	(401)
	\$ 9,367	\$ (46)	\$ 3,238	\$ (401)	\$ 12,605	\$ (447)

Realized gains and losses are included as a component of investment income. For the three and six months ended June 30, 2010 and 2009, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at June 30, 2010 and December 31, 2009, were as follows:

		Fair Value Measurements at Reporting Date Usi			
		Quoted Prices	Significant		
		in Active	Other	Significant	
		Markets for	Observable	Unobservable	
		Identical Assets	Inputs	Inputs	
	Fair Value	(Level 1)	(Level 2)	(Level 3)	
<u>At June 36, 2010</u>					
Available-for-sale marketable securities					
U.S. government obligations	\$ 186.744		\$ 188.744		
U.S. government guaranteed corporate					
bonds	64,010		64,010		
Corporate bonds	3.067		3.067		
Mortgage-backed securities	2,020		2,020		
U.S. government guaranteed collateratized mortesse oblestions	2 993		2.993		
Municipal bonds	2,192		2,192		
Equity security	3,776	\$ 3,778			
	\$ 264,802	\$ 3,776	\$ 261,026	*******************************	
At December 31, 2009 Available-for-sale marketable securities					
US government chilipations	\$ 109.940		\$ 109.940		
U.S. government guaranteed corporate	48,684		48,684	***************************************	
bonds					
Corporate boods	10.342		10,342		
Mortgage-backed securities	3,238		3,238		
U.S. government guaranteed	3,662		3,662		
collateralized morrgage obligations					
Equity security	5,469	\$ 5,469			
	\$ 181,335	\$ 5.469	175.866		

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the six months ended June 30, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the carrying value of the security. As a result, the Company recognized a \$0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three months ended June 30, 2010, and the three and six months ended June 30, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

At June 30, 2009 and December 31, 2008, the Company held one Level 3 marketable security whose fair value was \$0.1 million. This Level 3 security was valued using information provided by the Company's investment advisors, including quoted bid prices which took into consideration the securities' lack of liquidity. During the three and six months ended June 30, 2009, the Company did not record any settlements, realized gains or losses, or charges for other-than-temporary impairment related to this Level 3 marketable security. In addition, there were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and six months ended June 30, 2010 and 2009. The Company held no Level 3 marketable securities at June 30, 2010 and December 31, 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and six months ended June 30, 2010 and 2009.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

The current economic environment, the deterioration in the credit quality of issuers of securities that the Company holds, and the continuing volatility of securities markets increase the risk of potential declines in the current market value of marketable securities in the Company's investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of June 30, 2010 and December 31, 2009 consist of the following:

	June 30,	December 31,
	2010	2009
Accounts payable	3 15.525	3 18 638
Accrued payroll and related costs	19,469	9,444
Accrued clinical relativespense	16.141	11 673
Accrued property, plant, and equipment expenditures	2,041	1,883
Accraed expenses, other	5.080	0.207
Payable to Bayer HealthCare		1,186
	\$ 58.256	\$ 49,031

7. Comprehensive Loss

Comprehensive loss of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three and six months ended June 30, 2010 and 2009, the components of comprehensive loss are:

	Three months ended June 30,	
	2010	2009
Net loss	\$ (25,474)	\$ (14,938)
Change in net unrealized gain (loss) on marketable securities	(1,023)	2,262
Taral comprehensive loss	\$ (26.497)	\$ (12,676)
	··· <u></u> ····	···
	Six months er	ided June 30,
	Six months er	aded June 30, 2009
Not bee	2010	
Net loss Change in net unrealized gain (loss) on marketable securities	2010	

8. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

9. Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. The Company will be required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

10. Subsequent Event- Extension of Technology Licensing Agreement with Astellas

In March 2007, the Company entered into a six-year non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million annual, non-refundable payment to the Company in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas will make a \$130.0 million payment to the Company in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate this license agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as a material breach of the agreement by the Company. Astellas may terminate the agreement and receive a refund of a portion of its payment to the Company under the July 2010 amendment to the agreement. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's VelocImmune® technology.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment; VEGF Trap-Eye, which is being developed using intraocular delivery for the treatment of eye diseases in collaboration with Bayer HealthCare LLC; and affibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN727, an antibody to PCSK9, which is being developed for low density lipoprotein (LDL) cholesterol reduction; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and ankylosing spondilitis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in anotology; REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis; and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. All five of our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuiteTM* technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene®* technology to understand the role of these proteins in normal physiology as well as in models of disease. Our human monoclonal antibody technology (*Velocimmune®*) and cell line expression technologies (*VelociMab®*) may then be utilized to design and produce new product candidates directed against the disease target. Our five antibody product candidates currently in clinical trials were developed using *Velocimmune®*. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

We and Astellas Pharma Inc. announced in July 2010 that Astellas has extended through 2023 the non-exclusive license agreement that allows Astellas to utilize our VelocImmune® technology in its internal research programs to discover fully human monoclonal antibody product candidates. Astellas will pay \$165.0 million up-front and another \$130.0 million in June 2018 unless it terminates the agreement prior to that date. Upon commercialization of any antibody products discovered utilizing VelocImmune®, Astellas will pay us a mid-single-digit royalty on product sales.

Commercial Product:

ARCALYST® - Cryopyrin-Associated Periodic Syndromes (CAPS)

Net product sales of ARCALYST® Injection for Subcutaneous Use in the second quarter of 2010 were \$5.2 million, compared to \$4.5 million during the same period of 2009. We recognized \$15.0 million of net product sales during the first six months of 2010, which included \$10.2 million of ARCALYST® net product sales made during the first half of 2010 and \$4.8 million of previously deferred net product sales, as described below under "Results of Operations." In the first six months of 2009, we recognized \$8.4 million of ARCALYST® net product sales. ARCALYST® is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. CAPS is a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. ARCALYST®- Inflammatory Diseases

ARCALYST® is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly with allopurinol, is prescribed to eliminate the urate crystals and prevent reformation. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

During the first quarter of 2009, we initiated a Phase 3 clinical development program with ARCALYST® for the treatment of gout. The program included four clinical trials called PRE-SURGE 1 (\underline{PRE} vention \underline{S} tudy against \underline{UR} ate-lowering drug-induced \underline{G} out \underline{E} xacerbations), PRE-SURGE 2, SURGE (\underline{S} tudy \underline{U} tilizing \underline{R} ilonacept in \underline{G} out \underline{E} xacerbations), and RE-SURGE (\underline{RE} view of \underline{S} afety \underline{U} tilizing \underline{R} ilonacept in \underline{G} out \underline{E} xacerbations), each of which are described below.

In June 2010, we announced that our PRE-SURGE 1 study in gout patients initiating allopurinol therapy to lower their uric acid levels showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 milligrams (mg) had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, p<0.0001). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, p<0.0001).

All secondary endpoints of the study were highly positive (p<0.001 vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88% (3.7% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo, p<0.0001). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST® 160 mg, 18.8% with ARCALYST® 80 mg, and 46.8% with placebo, p<0.001).

A total of 241 patients were randomized in PRE-SURGE 1, a North America-based double-blind, placebo-controlled study. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Adverse events that occurred at a frequency of at least 5% in any study group were: injection site reaction (19.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 1.3% with placebo), upper respiratory tract infection (9.9% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 7.6% with placebo), lower respiratory tract infection (0% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 2.5% with placebo), musculoskeletal pain/ discomfort (6.2% with ARCALYST® 160 mg, 7.5% with ARCALYST® 80 mg, and 8.9% with placebo), and headache, (3.7% with ARCALYST® 160 mg, 6.3% with ARCALYST® 80 mg, and 1.3% with placebo).

In addition, in June 2010, we reported results from a placebo-controlled, Phase 3 study (called SURGE), evaluating pain in patients presenting with an acute gout flare. The results of this study showed that there was no significant benefit from combining ARCALYST® with indomethacin (a non-sterodial anti-inflammatory drug considered the standard of care), as measured by the primary study endpoint of the average intensity of gout pain from 24 to 72 hours after initiation of treatment. Patients treated with indomethacin alone experienced an average reduction in patient-reported pain scores (0 to 4 Likert scale where 0 represents no pain and 4 represents extreme pain) of 1.40 points from baseline compared to an average reduction of 1.55 points from baseline in patients treated with both indomethacin and ARCALYST® (p=0.33). Patients who received ARCALYST® alone experienced an average pain reduction of 0.69 points. Treatment with ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. The most commonly reported adverse event with ARCALYST® was headache.

There are two ongoing studies in the Phase 3 program with ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy. The global PRE-SURGE 2 study, which has a similar trial design as PRE-SURGE 1, is evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. In addition, the global RE-SURGE study is evaluating the safety of ARCALYST® versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. PRE-SURGE 2 is fully enrolled and RE-SURGE is over 90% enrolled. Data from both studies are expected in early 2011. We own worldwide rights to ARCALYST®.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis Pharma AG (that replaced a previous collaboration and license agreement), we receive tiered royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The multi-tiered royalty rates in the agreement start at 4% and reach 15% when annual sales exceed \$1.5 billion. Canakinumab is approved to treat Cryopyrin-Associated Periodic Syndrome (CAPS) and is in development for gout, type 2 diabetes, and other inflammatory diseases.

2. VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD) and central retinal vein occlusion (CRVO). We and Bayer HealthCare are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (\underline{V} EGF Trap: Investigation of \underline{E} fficacy and Safety in \underline{W} et age-related macular degeneration), are comparing VEGF Trap-Eye and Lucentis® (ranibizumab injection), owned by Genentech, Inc., an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with Lucentis (Genentech) dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. Asneeded dosing (PRN) with both agents will be evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks. VIEW 1 and VIEW 2 were fully enrolled in 2009, and initial data are expected in the fourth quarter of 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of central retinal vein occlusion (CRVO), another cause of visual impairment. The COPERNICUS (COntrolled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (Ceneral Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. COPERNICUS is fully enrolled and GALILEO is over 90% enrolled. Initial data from both studies are anticipated in early 2011.

The Phase 2 DME study, known as DA VINCI (DME And VEGF Trap-Eye: Nestigation of Clinical Impact), is a double-masked, randomized, controlled trial that is evaluating four different dosing regimens of VEGF Trap-Eye versus laser treatment. In February 2010, we and Bayer HealthCare announced that treatment with VEGF Trap-Eye demonstrated a statistically significant improvement in visual acuity compared to focal laser therapy, the primary endpoint of the study. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 (p< 0.01 for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results will be available later in 2010.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We can earn up to \$70 million in future development and regulatory milestone payments related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

3. Aflibercept (VEGF Trap) - Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A), VEGF-B, and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PIGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are conducting three randomized, double-blind Phase 3 trials, all of which are fully enrolled, that are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (called VELOUR) is evaluating aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd-line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st-line treatment for metastatic castration-resistant prostate cancer in combination with docetaxel/prednisone. In addition, a Phase 2 study (called AFFIRM) of aflibercept in 1st-line metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin) is also fully enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a pre-specified number of events have occurred in each trial. Based on projected event rates, (i) an interim analysis of VELOUR at 65% of the prespecified number of events required for the final analysis of overall survival is expected to be conducted by an independent statistician and reviewed by an IDMC in the second half of 2010, (ii) final results are anticipated in the first half of 2011 from the VITAL study and in the second half of 2011 from the VELOUR study, and (iii) an interim analysis of VENICE is expected to be reviewed by an IDMC in mid-2011, with final results anticipated in 2012. Initial data from the AFFIRM study are anticipated in the second half of 2011.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

4. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) cholesterol levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase substilisin/kexin type 9) is a protein that binds to LDLR and prevents LDLR from binding to and removing LDL from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. We used our *VelocImmune®* technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to robustly lower LDL cholesterol through a novel mechanism of action. REGN727 is targeted at inhibiting PCSK9, which results in prevention of the degradation of LDLRs in the liver, thereby facilitating LDL clearance from the systemic circulation leading to lower LDL levels in the blood.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL (bad) cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from the Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. No serious adverse events and no dose limiting toxicities have been reported. Dose escalation is ongoing in both studies.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested to-date, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities have been reported. Dose escalation in this study is ongoing. REGN727 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), tocilizumab, developed by Roche, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune®* technology that has completed Phase 1 studies, the results of which were presented at the annual meeting of the European League Against Rheumatism (EULAR) in June 2010. REGN88 was well tolerated by patients with rheumatoid arthritis, and no dose-limiting toxicities were reported. Treatment with REGN88 resulted in dose-related reductions in biomarkers of inflammation. REGN88 is currently in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. REGN88 is being developed in collaboration with sanofiaventis.

6. REGN421 (Anti-Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune®* technology. REGN421, which is being developed in collaboration with sanofi-aventis, is in Phase 1 clinical development.

7. REGN668 (Anti-IL-4R Antibody) for allergic and immune conditions

Interleukin-4 receptor (IL-4R) is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis. REGN668 is a fully human *VelocImmune®* antibody that is designed to bind to IL-4R. REGN668, which is being developed in collaboration with sanofiaventis, has completed a Phase 1 trial in healthy volunteers, and will be initiating a Phase 2 trial in atopic dermatitis in the second half of 2010.

8. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune®* technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF. REGN475 is being developed in collaboration with sanofi-aventis.

In May 2010, we announced an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks. The primary endpoint of this study is safety, and REGN475 was generally well tolerated. Serious treatment emergent adverse events were rare and balanced between placebo and drug arms with three events (5.5%) in the placebo group and four events (2.5%) in the combined REGN475 groups. The most frequent adverse events reported among patients receiving REGN475 included sensory abnormalities, arthralgias, hyper/hypo-reflexia, peripheral edema, and injection site reactions. The types and frequencies of adverse events reported were similar to those previously reported from other investigational studies involving an anti-NGF antibody.

In the first interim efficacy analysis, REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 8 weeks following a single intravenous infusion (p<0.01). In July 2010, we reported that REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 16 weeks following a second intravenous infusion at week 8 (p<0.01). Pain was measured by the Numeric Rating Scale (NRS), as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) pain and function subscales

Analysis of efficacy data from a Phase 2 trial in the acute setting of nerve root compression induced pain (acute sciatica) suggests that REGN475 therapy will not be effective in this setting.

At the request of the U.S. Food and Drug Administration (FDA), another pharmaceutical company has suspended its anti-NGF antibody clinical program in osteoarthritis and certain other chronic pain indications. We have responded to FDA requests for information about patients in our REGN475 clinical trials. REGN475 is currently not on clinical hold, and our Phase 2 trials in patients with vertebral fracture pain and chronic pancreatitis pain are ongoing. Our Phase 2 trial in osteoarthritis of the knee has been completed. We will update our plans for REGN475 following feedback from the FDA.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. *VelociSuite™* is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuiteTM

VelociSuiteTM consists of VelociMmune[®], VelociGene[®], VelociMouse[®], and VelociMab[®]. The Velocimmune[®] mouse platform is utilized to produce fully human monoclonal antibodies. Velocimmune[®] was generated by exploiting our VelociGene[®] technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. Velocimmune[®] mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. Velocimmune[®] and our entire VelociSuiteTM offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the Velocimmune[®] technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene®* platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of pre-clinical development and pharmacology programs, *VelociGene®* offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene®* allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, the VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab®* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *Velocimmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

Sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$175 million of research from the collaboration's inception through December 31, 2009.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to \$160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In addition, sanofi-aventis will fund up to \$30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities. In 2010, as we scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only \$130-\$140 million of antibody discovery costs, with the balance between that amount and \$160 million added to the funding otherwise available to us in 2011-2012. As under the original 2007 agreement, sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application, toxicology studies, and manufacture of preclinical and clinical supplies. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates over the next eight years.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial related costs for that drug candidate will be shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our *VelociGene®* platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of \$21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

AstraZeneca UK Limited. In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune®* technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made \$20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, 2009, and 2010. AstraZeneca is required to make up to two additional annual payments of \$20.0 million, subject to its ability to terminate the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune®* technology.

Astellas Pharma Inc. In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made \$20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas will make a \$165.0 million up-front payment to us. In addition, Astellas will make a \$130.0 million payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate this license agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its payment to us under the July 2010 amendment to the agreement. We are entitled to receive a midsingle-digit royalty on any future sales of antibody products discovered by Astellas using our VelocImmune® technology.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received \$18.1 million through June 30, 2010 and are entitled to receive an additional \$7.2 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

Regeneron plans to file an Investigational New Drug Application for REGN910, an antibody to Angiopoietin-2, a novel anti-angiogenesis target, by the end of 2010.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST * or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST * or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through June 30, 2010, we had a cumulative loss of \$997.1 million. In the absence of significant revenues from the commercialization of ARCALYST® or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST®; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2010 and plans over the next 12 months are as follows:

Clinical Program ARCALYST® (rilonacept)	2010 Events to Date Reported positive results from PRE-SURGE 1 and completed patient enrollment of PRE-SURGE 2. Both Phase 3 studies are evaluating ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy Reported results showing no significant improvement in pain relief from a Phase 3 study (SURGE) evaluating ARCALYST® in the treatment of acute gout flares	2010-11 Plans (next 12 months) Complete patient enrollment of an additional Phase 3 study (RE-SURGE) and report data from PRE-SURGE 2 and RE-SURGE in early 2011 If PRE-SURGE 2 and RE-SURGE are successful, file for regulatory approval of ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy by mid-2011
VEGF Trap - Eye	 Completed patient enrollment in the first of two Phase 3 CRVO trials (COPERNICUS) Reported positive 24-week primary endpoint results from the Phase 2 DME trial 	 Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010 Complete patient enrollment in the second Phase 3 CRVO trial (GALILEO) and report initial data from both trials Report one-year results from the Phase 2 DME trial
Aflibercept (VEGF Trap - Oncology)	Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer, prostate cancer, and colorectal cancer Completed patient enrollment in a Phase 2 1st-line study in metastatic colorectal cancer in combination with chemotherapy	 During the second half of 2010, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study (VELOUR) in colorectal cancer Report data from the Phase 3 study (VITAL) in non-small cell lung cancer. In mid-2011, an Independent Data Monitoring Committee is expected to conduct an interim analysis of the Phase 3 study (VENICE) in prostate cancer
Monoclonal Antibodies	 REGN727: Reported interim proof-of-concept data from a Phase 1 study for LDL cholesterol reduction REGN88: Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis and a Phase 2 dose-ranging study in ankylosing spondylitis REGN88: Reported data from the Phase 1 program in rheumatoid arthritis REGN475: Reported interim data from the Phase 2 studies in osteoarthritis of the knee and acute sciatica 	 REGN727: Report additional data from the Phase 1 program and initiate a Phase 2 program for LDL cholesterol reduction REGN668: Initiate a Phase 2 program in the treatment of atopic dermatitis REGN475: Report additional data from the Phase 2 study in osteoarthritis of the knee REGN475: Update clinical plans following feedback from the FDA Advance additional antibody candidates into clinical development, including REGN910

Results of Operations

Three Months Ended June 30, 2010 and 2009

Net Loss

Regeneron reported a net loss of \$25.5 million, or \$0.31 per share (basic and diluted), for the second quarter of 2010, compared to a net loss of \$14.9 million, or \$0.19 per share (basic and diluted) for the second quarter of 2009. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher collaboration revenue primarily in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the three months ended June 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis S	84.9	\$60.7
Bayer HastinCare	13.7	12.8
Total collaboration revenue	98.6	73.5
Technology licensing revenue	100	100
Net product sales	5.2	4.5
Contract research and other revenue	2.1	2.0
Total revenue	3115.9	\$90.0
-		

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

Sanofi-aventis Collaboration Revenue	Three r	nonth	ıs ended
(In millions)	J	une 3	0,
	2010		2009
Affibercept			
Regeneron expense reimbursement	\$ 3	.8 \$	9.2
Recognition of deferred revenue related to up strutt payments		.5	2.5
Total aflibercept	6	i.3	11.7
Antflody			
Regeneron expense reimbursement	76	.4	45.7
Recognition of deferred revenue related to up-front and other			4.6
payments			
Recognition of revenue related to $\mathit{VelociGene}^{\oplus}$ agreement	C	1.4	0.7
Total antibady	78		467.0
Total sanofi-aventis collaboration revenue	\$ 84	.9 \$	60.7

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the second quarter of 2010 compared to same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities. As of June 30, 2010, \$37.5 million of the original \$105.0 million of up-front payments related to our aflibercept collaboration with sanofi-aventis was deferred and will be recognized as revenue in future periods.

In the second quarter of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of \$36.6 million under the discovery agreement and \$39.8 million of development costs under the license agreement, compared to \$28.3 million and \$17.4 million, respectively, in the second quarter of 2009. The higher reimbursement amounts in the second quarter of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' \$85.0 million up-front payment, decreased during the second quarter of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to \$30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which \$14.3 million was received or receivable from sanofi-aventis as of June 30, 2010. Payments for such funding from sanofi-aventis are deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the original \$85.0 million up-front payment. As of June 30, 2010, \$74.6 million of the original up-front payment and subsequent payments to fund expansion of our Rensselaer facilities was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the three months ended June 30, 2010 and 2009, we recognized \$0.4 million and \$0.7 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable \$75.0 million up-front payment received in October 2006 and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	Three mon	ths ended
(In millions)	June	30,
	2010	2009
Cost Souring of Regeneron VPCF Trap Eye development expenses Recognition of deferred revenue related to up-front and milestone	\$ 11.2	\$ 103
payments	2.5	2.4
Total Dever HealthCare collaboration revenue	<u>137</u>	3 128

In periods when we recognize VEGF Trap-Eye development expenses that we incur under our collaboration with Bayer HealthCare, we also recognize, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the second quarter of 2010, compared to the same period in 2009, due to higher clinical development costs in connection with our Phase 3 trial in CRVO and Phase 2 trial in DME and higher costs related to VEGF Trap-Eye clinical drug supplies. In 2010 and 2009, development expenses incurred by Regeneron and Bayer HealthCare under the VEGF Trap-Eye global development plan were shared equally. As of June 30, 2010, \$51.9 million of the \$75.0 million up-front licensing and \$20.0 million milestone payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our *VelocImmune* license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the second quarter of both 2010 and 2009, we recognized \$10.0 million of technology licensing revenue related to these agreements.

Net Product Sales

For the three months ended June 30, 2010, ARCALYST® net product sales were \$5.2 million, compared to \$4.5 million during the same period in 2009. There was no deferred ARCALYST® net product sales revenue at June 30, 2010. At June 30, 2009, deferred ARCALYST® net product sales revenue was \$4.9 million.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended June 30, 2010 and 2009 included \$1.2 million and \$1.5 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to \$139.6 million in the second quarter of 2010 from \$106.3 million in the second quarter of 2009. Our average headcount increased to 1,214 in the second quarter of 2010 from 966 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the second quarter of 2010 and 2009 include a total of \$8.7 million and \$7.4 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended June 30, 2010			
	Expenses before			
	inclusion of Non-cash	Non-cash		
Expenses	Compensation	Compensation	Expenses as	
(In millions)	Expense	Expense	Reported	
Research and development	\$ 1195	3.0	1245	
Selling, general, and administrative	11.0	3.7	14.7	
Cost of goods sold	0.4		0.4	
Total operating expenses	\$ 130.9	\$ 8.7	\$ 139.6	
	For the three mor	nths e nd ed June	30, 2009	
	For the three more Expenses before	nths ended June	30, 2009	
		nths ended June Non-cash	30, 2009	
Expenses	Expenses before			
Expenses (In millions)	Expenses before inclusion of Non-cash	Non-cash		
	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation	Expenses as Reported	
(In millions)	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported	
(In millions) kessarch and development	Expenses before inclusion of Non-cash Compensation Expense	Non-cash Compensation Expense	Expenses as Reported	

Research and Development Expenses

Research and development expenses increased to \$124.5 million in the second quarter of 2010 from \$94.2 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the three months ended June 30, 2010 and 2009:

Research and Development Expenses	For the three month	s ended June 30,	I ncrea se
(In millions)	2010	2009	(Decrease)
Payroll and benefits (1)	31.9	\$ 24.6	8 83
Clinical trial expenses	28.5	30.2	(1.7)
Clinical manufacturing costs (2)	27.6	13.8	13.8
Research and other development costs	13.8	9.9	3.9
Occupancy and other operating costs	12.7	8.9	3.8
Cost-sharing of Bayer HealthCare VEGF			
Trap-Eye development expenses (3)	10.0	7.8	2.2
Total research and development	1245	3 94.2	1 10 1

- (1) Includes \$4.2 million and \$4.0 million of Non-cash Compensation Expense for the three months ended June 30, 2010 and 2009, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.8 million and \$0.7 million of Non-cash Compensation Expense for the three months ended June 30, 2010 and 2009, respectively.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our ARCALYST® clinical development program in gout. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing clinical supplies of monoclonal antibodies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	For the three months ended June 30,		Increase
(In millions)	2010	2009	(Decrease)
ARCALYST	\$ 11.6 \$	15.7	\$ (4.1)
VEGF Trap-Eye	31.2	27.0	4.2
Affibercept	3.0	7.4	(4.4)
REGN88	9.8	8.5	1.3
Other antibody candidates in clinical development	26.2	5.1	21.1
Other research programs & unallocated costs	42.7	30.5	12.2
Fotal research and development expenses	5 124.5 \$	94.2	\$ 30.3

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST* (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$14.7 million in the second quarter of 2010 from \$11.7 million in the same period of 2009. In the second quarter of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, and higher recruitment costs.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled \$0.4 million for both of the quarters ended June 30, 2010 and 2009. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to \$0.6 million in the second quarter of 2010 from \$1.3 million in the comparable quarter of 2009, primarily due to lower balances of, and lower yields on, cash and marketable securities and a \$0.1 million other-than-temporary impairment charge. Interest expense of \$2.3 million in the second quarter of 2010 was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Six Months Ended June 30, 2010 and 2009

Net Loss

Regeneron reported a net loss of \$56.0 million, or \$0.69 per share (basic and diluted), for the first half of 2010, compared to a net loss of \$30.3 million, or \$0.38 per share (basic and diluted) for the first half of 2009. The increase in our net loss was principally due to higher research and development expenses, as detailed below, partly offset by higher collaboration revenue primarily in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the six months ended June 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	\$153.6	\$110.4
Bayer HealthCare	26.7	22.8
Total collaboration revenue	180.3	133.2
Technology licensing revenue	20.1	2010
Net product sales	15.0	8.4
Contract research and other revenue	4.0	
Total revenue	\$219.4	\$165.0

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration

Sanofi-aventis Collaboration Revenue	Six mont	ths e nd ed
(In millions)	Jun	e 30 ,
	2010	2009
Affibercept		
Regeneron expense reimbursement	\$ 8.7	\$ 14.6
Recognition of deferred revenue related to up. from payments	5.0	5.0
Total aflibercept	13.7	19.6
Antibody		
Regeneron expense reimbursement	135.8	84.1
Recognition of deferred revenue related to up front and other		
payments		1.4
Recognition of revenue related to <i>VelociGene®</i> agreement	0.8	1.4
Foral antibody	139.9	90.8
Total sanofi-aventis collaboration revenue	\$ 153.6	\$ 110.4

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the first half of 2010 compared to the same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities.

In the first half of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of \$63.4 million under the discovery agreement and \$72.4 million of development costs under the license agreement, compared to \$51.0 million and \$33.1 million, respectively, in the first half of 2009. The higher reimbursement amounts in the first half of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' \$85.0 million up-front payment, decreased during the first half of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration.

In August 2008, we entered into a separate *VelociGene®* agreement with sanofi-aventis. For the six months ended June 30, 2010 and 2009, we recognized \$0.8 million and \$1.4 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable \$75.0 million up-front payment received in October 2006 and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue	Six mont	hs e nd ed
(In millions)	June	30,
	2010	2009
Cost sharing of Regeneron VPCP Trap Evo development expenses Recognition of deferred revenue related to up-front and milestone	5 21.8	179
payments	4.9	4.9
Total Bayer Fleathic are colleboration revenue	\$ 26.7	\$ 22.8

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the first half of 2010, compared to the same period in 2009, due to higher clinical development costs in connection with our Phase 3 trial in CRVO and Phase 2 trial in DME and higher costs related to VEGF Trap-Eye clinical drug supplies.

Technology Licensing Revenue

In connection with our *VelocImmune®* license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments are deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the first half of both 2010 and 2009, we recognized \$20.0 million of technology licensing revenue related to these agreements.

Net Product Sales

In February 2008, we received marketing approval from the FDA for ARCALYST® for the treatment of CAPS. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, for the six months ended June 30, 2010, we recognized as revenue \$15.0 million of ARCALYST® net product sales, which included \$10.2 million of ARCALYST® net product sales made during the period and \$4.8 million of previously deferred net product sales. For the six months ended June 30, 2009, we recognized as revenue \$8.4 million of ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the first half of 2010 and 2009 included \$2.3 million and \$3.0 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to \$272.0 million in the first half of 2010 from \$198.4 million in the same period of 2009. Our average headcount increased to 1,151 in the first half of 2010 from 952 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the first half of 2010 and 2009 include a total of \$17.5 million and \$15.1 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the six months ended June 30, 2010		
	Expenses before		
	inclusion of Non-cash	Non-cash	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported
Research and development	\$ 232.0	\$ 100	\$ 242.0
Selling, general, and administrative	21.4	7.5	28.9
Cast of goods sold	11		11
Total operating expenses	\$ 254.5	\$ 17.5	\$ 272.0

	For the six months ended June 30, 2009		
	Expenses before		
	inclusion of Non-cash	Non-cash	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported
Research and development	1651	5 9.4	\$ 174.5
Selling, general, and administrative	17.4	5.7	23.1
Cast of goods sold	0.8		0.8
Total operating expenses	\$ 183.3	\$ 15.1	\$ 198.4

Research and Development Expenses

Research and development expenses increased to \$242.0 million in the first half of 2010 from \$174.5 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the six months ended June 30, 2010 and 2009:

Research and Development Expenses	For the six months	ended June 30,	
(In millions)	2010	2009	Increase
Peycoll and benefits (1)	\$ 59.6	3 46.5	\$ 13.1
Clinical trial expenses	60.8	49.5	11.3
Clinical manefacturing costs (2)	17.5	27.9	196
Research and other development costs	26.6	18.4	8.2
Occupancy and other operacing costs Cost-sharing of Bayer HealthCare VEGF Trap-	24.7	17.4	7.3
Eye development expenses (3)	22.8	14.8	8.0
Total research and development	\$ 242.0	1745	\$ 67.5

- [1] Includes \$8.5 million and \$8.0 million of Non-cash Compensation Expense for the six months ended June 30, 2010 and 2009, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$1.5 million and \$1.4 million of Non-cash Compensation Expense for the six months ended June 30, 2010 and 2009, respectively.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for (i) VEGF Trap-Eye, principally in connection with our COPERNICUS trial in CRVO, (ii) ARCALYST®, related to our Phase 3 clinical development program in gout, and (iii) monoclonal antibody candidates, which are in earlier stage clinical development. Clinical manufacturing costs increased primarily due to higher costs related to manufacturing clinical supplies of monoclonal antibodies. Research and other development costs increased primarily due to higher costs associated with our antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Costsharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

Project Costs	For the six months	ended June 30,	Increase
(In millions)	2010	20 09	(Decrease)
ARCALYST?	3 117	33.6	5 (1.9)
VEGF Trap-Eye	64.8	47.8	17.0
Affibercept	5.9	117	(4.8)
REGN88	14.7	17.5	(2.8)
Other antibody candidates in climical development	50.3	10.0	40.3
Other research programs & unallocated costs	73.6	53.9	19.7
Foral research and development expenses	\$ 242.0	174.5	\$ 67.5

For the reasons described above under "Research and Development Expenses" for the three months ended June 30, 2010 and 2009, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$28.9 million in the first half of 2010 from \$23.1 million in the same period of 2009. In the first half of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, and higher recruitment costs.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled \$1.1 million and \$0.8 million for the six months ended June 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to \$1.0 million in the first half of 2010 from \$3.1 million in the comparable quarter of 2009, primarily due to lower balances of, and lower yields on, cash and marketable securities and a \$0.1 million other-than-temporary impairment charge. Interest expense of \$4.4 million in the first half of 2010 was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® product revenue, and investment income.

Six months ended June 30, 2010 and 2009

At June 30, 2010, we had \$380.2 million in cash, cash equivalents, restricted cash, and marketable securities compared with \$390.0 million at December 31, 2009. In February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs for the new laboratory and office facilities that we lease in Tarrytown, New York. In addition, in February and June 2010, we received \$20.0 million annual technology licensing payments from AstraZeneca and Astellas, respectively.

Cash Used in Operations:

Net cash used in operations was \$22.6 million in the first six months of 2010 and \$16.0 million in the first six months of 2009. Our net losses of \$56.0 million in the first half of 2010 and \$30.3 million in the first half of 2009 included \$17.5 million and \$15.1 million, respectively, of Non-cash Compensation Expense, and \$8.7 million and \$5.7 million, respectively, of depreciation and amortization.

At June 30, 2010, accounts receivable increased by \$29.6 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at June 30, 2010 increased by \$16.6 million, compared to end-of-year 2009, primarily due to (i) the receipt of the \$20.0 million payments from AstraZeneca and Astellas, as described above, which were deferred and are being recognized ratably over the ensuing year and (ii) sanofi-aventis' funding of \$13.8 million of agreed-upon costs incurred by us during the first half of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original \$85.0 million up-front payment received from sanofi-aventis. These increases were partially offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. At June 30, 2010, accounts payable, accrued expenses, and other liabilities increased by \$18.1 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll and related costs and clinical trial expenses.

At June 30, 2009, accounts receivable increased by \$24.8 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at June 30, 2009 increased by \$5.9 million, compared to end-of-year 2008, primarily due to the receipt of \$20.0 million annual payments from AstraZeneca and Astellas in February and June 2009, respectively, which were deferred and recognized ratably over the ensuing year. This increase was partially offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. At June 30, 2009, accounts payable, accrued expenses, and other liabilities increased by \$13.0 million compared to end-of-year 2008. The increase was due primarily to higher liabilities for clinical trial and payroll-related costs, partially offset by a \$9.8 million cost-sharing payment which was due to Bayer HealthCare at December 31, 2008 in connection with the companies' VEGF Trap-Eye collaboration; no cost-sharing payment was due to Bayer HealthCare at June 30, 2009.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was \$131.4 million in the first six months of 2010 and net cash provided by investing activities was \$32.8 million in the first six months of 2009. In the first half of 2010, purchases of marketable securities exceeded sales or maturities by \$84.3 million, whereas in the first half of 2009, sales or maturities of marketable securities exceeded purchases by \$85.4 million. Capital expenditures in the first half of 2010 and 2009 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased office and laboratory facilities in Tarrytown, New York.

Cash Provided by Financing Activities:

Net cash provided by financing activities was \$58.9 million in the first six months of 2010 and \$6.9 million in the first six months of 2009. In the first half of 2010 and 2009, we received \$47.5 million and \$5.2 million, respectively, from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with FASB authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were \$12.1 million in the first six months of 2010 and \$1.7 million in the first six months of 2009.

Fair Value of Marketable Securities:

At June 30, 2010 and December 31, 2009, we held marketable securities whose aggregate fair value totaled \$264.8 million and \$181.3 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	June 30	, 2010	December 3	1, 2009
Investment type	Fair Value	Percent	F air Valu e	Percent
U.S. Fressury securities	\$ 25.0	10%	\$ 80.4	44%
U.S. government agency securities	161.7	61%	29.6	16%
U.S. government, guaranteed corporate bonds	64.0	24%	48.7	270
U.S. government guaranteed collateralized mortgage				
obligations	3.0	1%	3.7	2%
Corporate bonds	31	114	10.3	6%
Mortgage-backed securities	2.0	1%	3.2	2%
Equity security	3.8	196	5.4	3%
Other	2.2	1%		
Total marketable securities	\$ 264.8	100%	181.3	100%

In addition, at June 30, 2010 and December 31, 2009, we had \$115.4 million and \$208.7 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2009 and 2010 to date, as marketable securities in our portfolio matured or paid down, we purchased higher quality securities such as U.S. Treasury securities, U.S. government agency obligations, and U.S. government-guaranteed debt. This shift in our investment portfolio, which we initiated in 2008, has reduced the risk profile, as well as the overall yield, of our portfolio.

Funding of Antibody Discovery Activities under Collaboration with sanofi-aventis

As described above under "Antibody Collaboration and License Agreements," in November 2009, we and sanofi-aventis amended our collaboration agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to \$160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In 2010, as we scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only \$130-\$140 million of antibody discovery costs, with the balance between that amount and \$160 million added to the funding otherwise available to us in 2011-2012. The discovery agreement under the antibody collaboration will expire at the end of 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

Extension of License Agreement with Astellas

As described above under "Antibody Collaboration and License Agreements," in July 2010, the non-exclusive license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas will make a \$165.0 million up-front payment to us, and will make a \$130.0 million payment to us in June 2018 unless the license agreement has been terminated prior to that date.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled \$45.3 million and \$52.7 million for the first six months of 2010 and 2009, respectively. We expect to incur capital expenditures of approximately \$50 to \$70 million during the remainder of 2010 and approximately \$40 to \$60 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our leased Tarrytown facilities. As described above, in February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, as described above, sanofi-aventis has funded \$13.8 million of agreed-upon capital expenditures incurred by us during the first half of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at June 30, 2010. We expect to be reimbursed for a portion of additional capital expenditures in 2010 and 2011 for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the clinical development of product candidates, including ARCAYST®, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our amended and expanded antibody collaboration with sanofi-aventis.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements and our non-exclusive license agreement with Astellas, which was amended in July 2010 as described above, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, if we choose to commercialize products that are not licensed to a third party, we could incur substantial premarketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than a \$3.4 million letter of credit issued to our landlord in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of June 30, 2010, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We are required to adopt this amended guidance for the fiscal year beginning January 1, 2011, although earlier adoption is permitted. Management does not anticipate that the adoption of this guidance will have a material impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates principally in connection with our investment of excess cash in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a \$1.2 million and \$0.8 million decrease in the fair value of our investment portfolio at June 30, 2010 and 2009, respectively.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of \$2.5 million, \$0.1 million in 2008, 2009, and the first six months of 2010, respectively.

The current economic environment, the deterioration in the credit quality of issuers of securities that we hold, and the continuing volatility of securities markets increase the risk of potential declines in the current market value of marketable securities in our investment portfolio. Such declines could result in charges against income in future periods for other-than-temporary impairments and the amounts could be material.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through June 30, 2010, we had a cumulative loss of \$997.1 million. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements and our non-exclusive license agreement with Astellas, will enable us to meet operating needs through at least 2013; however, one or more of our *VelocImmune* licenses or collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. Our expenses may increase for many reasons, including for expenses in connection with the commercial launch of our products, for expenses related to new clinical trials testing ARCALYST® or VEGF Trap-Eye, or for the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of June 30, 2010, cash, cash equivalents, restricted cash, and marketable securities totaled \$380.2 million and represented 48% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled \$264.8 million at June 30, 2010, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary impairment charges related to certain marketable securities of \$2.5 million, \$0.1 million, and \$0.1 million in 2008, 2009, and the first six months of 2010, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the recent volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing affibercept, VEGF Trap-Eye, and ARCALYST $^{\circ}$ in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd-line metastatic colorectal cancer, 1st-line androgen independent prostate cancer, and 2nd-line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (bevacizumab), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of aflibercept in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of CRVO. Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis (Genentech). A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

ARCALYST® is in Phase 3 clinical trials for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Although we reported positive Phase 3 data from one trial in patients with gout initiating uric acid-lowering drug therapy, there is a risk that the results of the other ongoing trials of ARCALYST® in patients initiating uric acid-lowering drug therapy will differ from the previously reported Phase 3 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating affibercept as a 1st-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The IDMC for the VELOUR trial, which is studying aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with chemotherapy, is expected to conduct an interim analysis of the data from this trial in the second half of 2010. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s) and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), marketed by Biovitrum, Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor Ortho Biotech, Inc., ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. Treatment with Kineret (Biovitrum), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® in gout or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. Recently, another pharmaceutical company that is developing an antibody to NGF announced that it has suspended clinical programs for its agent in patients with osteoarthritis and other chronic use indications at the request of the FDA following a small number of reports of patients experiencing a worsening of osteoarthritis or osteonecrosis leading to joint replacement. Although REGN475 has some differences from this third party antibody, the safety risks reported in clinical trials with this other agent could be risks associated with all antibodies to NGF, including our product candidate. This risk or other complications or side effects could result in the discontinuation or limitation of the further development of REGN475 in osteoarthritis and other pain indications, including as a result of being placed on clinical hold by the FDA.

ARCALYST® and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of ARCALYST® were detected in patients with CAPS after treatment with ARCALYST®. Nineteen of 55 subjects (35%) who received ARCALYST® for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including affibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our $VelocImmune^{\#}$ technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye or uses thereof. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST*, aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST® and the Europeans Medicines Agency approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST® or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST® that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell $ARCALYST^{\circledast}$ in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states and were included in health care reform legislation recently enacted by the federal government. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2009, which report is included in our Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In addition, if it is determined that deficiencies in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

- changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates:
- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could
 materially increase our costs of doing business; and
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the U.S. of the Patient Protection and Affordable Care Act, or PPCA, potential regulations easing the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofi-aventis has committed to pay up to \$1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and pre-clinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, REGN475, REGN727, and REGN668 we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of VEGF Trap-Eye collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of $ARCALYST^{\oplus}$ and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST® for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST® and our product candidates at our manufacturing facilities in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for manufacturing and formulation of ARCALYST® and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST® for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of affibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® in this indication.

Our only approved product is ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009, we received European marketing authorization for rilonacept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST® in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly and Company, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis (Genentech), for the treatment of age-related macular degeneration (wet AMD), DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. In addition, in June 2010, Lucentis (Genentech) was approved by the FDA for the treatment of macular edema because of a blockage in a retinal vein. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin. The National Eye Institute and others are conducting long-term, controlled clinical trials comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. The marketing approval of Lucentis (Genentech) and the potential off-label use of Avastin (Genentech) make it more difficult for us to enroll patients in our clinical trials and successfully develop VEGF Trap-Eye. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a further competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet

The availability of highly effective FDA approved TNF-antagonists such as Enbrel (Amgen and Wyeth), Remicade (Centocor), Humira® (adalimumab), marketed by Abbott, and SimponiTM (golimumab), marketed by Centocor, and the IL-1 receptor antagonist Kineret (Biovitrum), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® in other indications, and this is one of the reasons we discontinued the development of ARCALYST® in adult rheumatoid arthritis. In addition, even if ARCALYST® is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST®, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis 'IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST*. For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST*. The successful development and/or commercialization of these competing molecules could impair our ability to successfully commercialize ARCALYST*.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. Novartis' IL-1 antibody is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST® in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs may make it difficult for us to successfully commercialize ARCALYST® in these diseases.

The successful commercialization of ARCALYST $^{\circ}$ and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® in the United States for the treatment of a group of rare genetic disorders called CAPS. We have received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST®. Physicians may not prescribe ARCALYST®, and CAPS patients may not be able to afford ARCALYST®, if third party payers do not agree to reimburse the cost of ARCALYST® therapy and this would adversely affect our ability to commercialize ARCALYST® profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the Patient Protection and Affordable Care Act or PPCA and a related reconciliation bill were signed into law. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- · progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- · fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- · arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of April 14, 2010, our six largest shareholders plus Leonard Schleifer, M.D. Ph.D., our Chief Executive Officer, beneficially owned 51.1% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2010. As of April 14, 2010, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.6% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of April 14, 2010, holders of Class A Stock held 21.5% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding, including any voting power associated with any shares of Common Stock beneficially owned by such Class A Stock holders. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of April 14, 2010:

- our current executive officers and directors beneficially owned 13.7% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2010, and 28.1% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of April 14, 2010; and
- our six largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 51.1% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of April 14, 2010. In addition, these seven shareholders held 56.3% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of April 14, 2010.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;

- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders
 consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, as amended, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit	
<u>Number</u>	Description
10.1	- Sixth Amendment to Lease, by and between BMR-Landmark at Eastview LLC and the Registrant, entered into as of June 4, 2010.
31.1	- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2	- Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
32	- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101	- Interactive Data File
101.INS	- XBRL Instance Document
101.SCH	- XBRL Taxonomy Extension Schema
101.CAL	- XBRL Taxonomy Extension Calculation Linkbase
101.LAB	- XBRL Taxonomy Extension Label Linkbase
101.PRE	- XBRL Taxonomy Extension Presentation Linkbase
101.DEF	- XBRL Taxonomy Extension Definition Document

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: July 28, 2010

By: /s/ Murray A. Goldberg

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary
(Principal Financial Officer and
Duly Authorized Officer)

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SIXTH AMENDMENT TO LEASE

THIS SIXTH AMENDMENT TO LEASE (this "Sixth Amendment") is entered into as of this 4th day of June, 2010 ("Execution Date"), by and between BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company ("Landlord"), and REGENERON PHARMACEUTICALS, INC., a New York corporation ("Tenant").

RECITALS

- A. WHEREAS, Landlord and Tenant entered into that certain Lease dated as of December 21, 2006 (the "Original Lease"), as amended by that certain First Amendment to Lease dated as of October 24, 2007 (the "First Amendment"), that certain Second Amendment to Lease dated as of September 30, 2008 (the "Second Amendment"), that certain Third Amendment to Lease dated as of April 29, 2009 (the "Third Amendment"), that certain Fourth Amendment to Lease dated as of December 3, 2009 (the "Fourth Amendment"), and that certain Fifth Amendment to Lease dated as of February 11, 2010 (the "Fifth Amendment" and, collectively with the Original Lease and the First Amendment, Second Amendment, Third Amendment, Fourth Amendment and as the same may have been further amended, supplemented or otherwise modified from time to time, the "Lease"), whereby Tenant leases certain premises (the "Premises") from Landlord at 735, 745, 755, 765 and 777 Old Saw Mill River Road in Tarrytown, New York (collectively, the "Buildings", and each a "Building");
- B. WHEREAS, Tenant desires to lease from Landlord and Landlord desires to lease to Tenant approximately six thousand eight hundred thirty-eight (6,838) rentable square feet of additional space in the 765 Building, consisting of approximately two thousand six hundred ninety-one (2,691) rentable square feet (" $\underline{Phase 1}$ ", and generally a " \underline{Phase} ") and approximately four thousand one hundred forty-seven (4,147) rentable square feet (" $\underline{Phase 2}$ ", and generally a " \underline{Phase} "), all as shown on $\underline{Exhibit\ A}$ attached hereto (Phase 1 and Phase 2 are collectively referred to herein as the " $\underline{765\ Expansion\ Premises}$ "); and
- C. WHEREAS, Landlord and Tenant desire to modify and amend the Lease only in the respects and on the conditions hereinafter stated.

AGREEMENT

NOW, THEREFORE, Landlord and Tenant, in consideration of the mutual promises contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, agree as follows:

- 1. <u>Definitions</u>. For purposes of this Sixth Amendment, capitalized terms shall have the meanings ascribed to them in the Lease unless otherwise defined herein. The Lease, as amended by this Sixth Amendment, is referred to herein as the "<u>Amended Lease</u>."
- 2. <u>765 Expansion Premises</u>. Landlord hereby leases to Tenant, and Tenant hereby leases from Landlord the 765 Expansion Premises, effective as of Landlord's delivery to Tenant of the applicable Phase thereof. Landlord shall use commercially reasonable efforts to deliver Phase 1 to Tenant on the Execution Date, or as soon as reasonably practicable thereafter, and Phase 2 on or before November 30, 2010. Landlord shall provide Tenant with sixty (60) days prior notice of delivery of Phase 2. The Term for the 765 Expansion Premises shall expire on the Term Expiration Date for the New Premises, subject to (a) Tenant's option to extend the Term of the Lease as provided in <u>Article 44</u> of the Amended Lease, and (b) Tenant's termination option set forth in <u>Section 7</u> below. Upon delivery of Phase 1 to Tenant, the total rentable square feet of space of the Premises located within Building 765 shall be one hundred six thousand eight hundred ninety (106,890) rentable square feet of space and upon delivery of Phase 2 to Tenant the total rentable square feet of space of the Premises located within Building 765 shall be one hundred eleven thousand thirty-seven (111,037) rentable square feet of space.

- 3. <u>Tenant's Pro Rata Shares</u>. From and after the delivery of Phase 1, (a) the Premises shall be deemed to include Phase 1, (b) Tenant's Pro Rata Share of the 765 Building shall increase from 58.80% to 60.23%, (c) Tenant's Pro Rata Share of the Existing Project shall increase from 23.50% to 23.83%, (d) Tenant's Pro Rata Share of the New Project shall remain at 100%, and (e) Tenant's Pro Rata Share of the Entire Project shall increase from 48.30% to 48.52%. From and after the delivery of Phase 2, (v) the Premises shall be deemed to include the entire 765 Expansion Premises, (w) Tenant's Pro Rata Share of the 765 Building shall increase from 60.32% to 62.48%, (x) Tenant's Pro Rata Share of the Existing Project shall increase from 23.85% to 24.36%, (y) Tenant's Pro Rata Share of the New Project shall remain at 100%, and (z) Tenant's Pro Rata Share of the Entire Project shall increase from 48.54% to 48.88%. Effective as of the delivery of Phase 1, Section 2.2 of the Lease is hereby deleted in its entirety and replaced with the following:
 - 2.2 The Premises, the Buildings, and certain related terms are defined as follows. In these definitions, each Rentable Area is expressed in rentable square footage. Rentable Area and Tenant's Pro Rata Shares are all subject to adjustment under this Lease, including under <u>Section 9.2</u>.

Definition or Provision	Means the Following:
" <u>Premises</u> "	Retained Premises, New Premises, Modified Additional Premises, Swap Premises, 755 Premises, Swing Premises, and Phase 1 (of the 765 Expansion Premises)
"Buildings"	735 Building, 745 Building, 755 Building, 765 Building and 777 Building
Rentable Area of Premises	539,822 square feet
Rentable Area of Buildings	117,935 for 735 Building 111,708 for 745 Building 130,877 for 755 Building 177,203 for 765 Building 311,104 for 777 Building
Rentable Area of Existing Project	751,648
Rentable Area of New Project	360,520

Definition or Provision	Means the Following:
Rentable Area of Entire Project	1,112,168
Tenant's Pro Rata Share of Buildings	100% of 735 Building 100% of 745 Building 100% of 755 Building 60.23% of 765 Building 23.28% of 777 Building
Tenant's Pro Rata Share of the Existing Project (Based on Retained Premises, Modified Additional Premises, Swap Premises, Swing Premises and Phase 1 Premises only)	23.83%
Tenant's Pro Rata Share of the New Project (Based on the New Premises and the 755 Premises)	100%
Tenant's Pro Rata Share of Entire Project	48.52%

Effective as of the delivery of Phase 2, $\underline{\text{Section 2.2}}$ of the Lease is hereby deleted in its entirety and replaced with the following:

2.2 The Premises, the Buildings, and certain related terms are defined as follows. In these definitions, each Rentable Area is expressed in rentable square footage. Rentable Area and Tenant's Pro Rata Shares are all subject to adjustment under this Lease, including under <u>Section 9.2</u>.

Definition or Provision	Means the Following:
" <u>Premises</u> "	Retained Premises, New Premises, Modified Additional Premises, Swap Premises, 755 Premises, Swing Premises, and 765 Expansion Premises
"Buildings"	735 Building, 745 Building, 755 Building, 765 Building and 777 Building
Rentable Area of Premises	543,969 square feet
Rentable Area of Buildings	117,935 for 735 Building 111,708 for 745 Building 130,877 for 755 Building 177,203 for 765 Building 311,104 for 777 Building
Rentable Area of Existing Project	751,648
Rentable Area of New Project	360,520

Definition or Provision	Means the Following:
Rentable Area of Entire Project	1,112,168
Tenant's Pro Rata Share of Buildings	100% of 735 Building 100% of 745 Building 100% of 755 Building 62.48% of 765 Building 23.28% of 777 Building
Tenant's Pro Rata Share of the Existing Project (Based on Retained Premises, Modified Additional Premises, Swap Premises, Swing Premises and 765 Expansion Premises only)	24.36%
Tenant's Pro Rata Share of the New Project (Based on the New Premises)	100%
Tenant's Pro Rata Share of Entire Project	48.88%

4. Rent.

a. <u>Basic Annual Rent</u>. Commencing as of the dates set forth below and continuing through the Term, and subject to the provisions of <u>Section 7</u> hereof, Tenant shall pay Landlord Basic Annual Rent for the 765 Expansion Premises in accordance with the following schedule (in addition to Rent otherwise due under the Lease) and in accordance with the terms for payment of Basic Annual Rent set forth in the Lease. Basic Annual Rent for the 765 Expansion Premises shall increase annually every July 1st by two and one-half percent (2.5%) of the then-current applicable Basic Annual Rent, commencing as of July 1, 2011.

Portion of	Applicable Basic Annual	Rentable	Initial Basic	Total Annual Basic	Total Monthly
Premises	Rent Commencement	s.f. of 765	Annual Rent	Annual Rent	
	Date	Expansion	Per Rentable		
		Premises	s.f.		
			Annually		
Phase 1	Upon delivery of	2,691	\$27.00	\$72,657	\$6,054.75
	Phase 1			(to be prorated)	
Phase 1 and	Upon delivery of	6,838	\$27.00	\$184,626	\$15,385.50
Phase 2	Phase 2			(to be prorated)	

b. Operating Expenses.

i. In addition to Basic Annual Rent, commencing as of the delivery date of the applicable Phase, Tenant shall pay to Landlord as Additional Rent, at times specified in the Amended Lease, Tenant's Pro Rata Share of Operating Expenses with respect to the 765 Expansion Premises, or Phase thereof, delivered to Tenant.

- ii. For the avoidance of doubt (i) HVAC for the 765 Expansion Premises, or either Phase thereof, shall be calculated in the same manner as provided in the Amended Lease with respect to the Retained Premises, and (ii) the 765 Expansion Premises, or either Phase thereof, shall be treated as Retained Premises for the purposes of allocation of the CAM Pool Charges in accordance with $\underline{\text{Exhibit O}}$ of the Amended Lease (in each case, as of the applicable commencement date for each such portion of the Premises).
- 5. <u>Tenant Improvements</u>. Landlord shall make available to Tenant a tenant improvement allowance equal to One Hundred Seventy Thousand Nine Hundred Fifty Dollars ((\$170,950), based on Twenty-Five Dollars (\$25) per rentable square foot of the 765 Expansion Premises) (the "<u>765 Expansion Allowance</u>"). The 765 Expansion Allowance shall be disbursed in the same manner as the Base TI Allowance under the applicable provisions of <u>Article 5</u> of the Lease, including, without limitation, the Disbursement Conditions, in order to finance improvements to the 765 Expansion Premises consistent with the provisions of the Lease and the Permitted Use (such improvements, the "<u>765 Expansion Improvements</u>"). Tenant shall be responsible for performing and completing the 765 Expansion Improvements. Tenant shall pay Landlord a construction oversight fee of two and one-half percent (2.5%) of the total cost of the Tenant Improvements, including, without limitation, the 765 Expansion Allowance to the extent disbursed to Tenant, which construction oversight fee may be paid out of the 765 Expansion Allowance.
- 6. <u>Parking</u>. The parties acknowledge that, in accordance with the Lease, Tenant shall be entitled to its pro rata share of unreserved parking spaces with respect to the 765 Expansion Premises.
- 7. <u>Termination Option</u>. Tenant shall be entitled to terminate the Lease with respect to the entire 765 Expansion Premises effective as of January 1, 2017; provided that (a) Tenant provides Landlord with no less than nine (9) months' prior written notice and (b) concurrently with such notice, Tenant pays to Landlord an amount equal to One Hundred Twenty-Nine Thousand, Nine Hundred Forty-Two Dollars ((\$129,942) based on Nineteen Dollars (\$19) per rentable square foot of the 765 Expansion Premises). If Tenant timely exercises its option to terminate the Lease with respect to the 765 Expansion Premises, then Tenant shall surrender the applicable Premises to Landlord on the applicable surrender date in the condition required by the Amended Lease for surrendering Premises upon the expiration. Time is of the essence with respect to the exercise of the termination option granted in this Section.
- 8. <u>Lease Extension Options</u>. From and after the Execution Date, the first paragraph of <u>Article 44</u> of the Lease is hereby deleted and replaced with the following:
 - 44. Option to Extend Term. Tenant shall have three (3) options (each, an "Option") to extend the Term of this Lease (and, in each case, the Term Expiration Date) by five (5) years, in each case on the same terms and conditions as this Lease, except as provided below. If Tenant desires to exercise any Option, Tenant must do so by giving Landlord written notice of such exercise at least one (1) year before the Term would otherwise expire. Tenant may exercise its Option to extend the Term only as to any one or more of the following: (a) the entire Retained Premises, (b) the entire New Whole Building Premises, (c) the entire New Multiple Tenant Building Premises, (d) the Modified Additional Premises, (e) the Swap Premises, (f) the Swing Premises, (g) each full floor of the 755 Premises, and (h) the 765 Expansion Premises. If Tenant fails to exercise an Option with respect to less than all of the Premises and the time to do so has lapsed (or if a Retained Premises Early Termination or a termination pursuant to a Swap Premises Termination Option has occurred), then Tenant shall no longer have an Option with respect to those portions of the Premises for which it failed to exercise an Option. Tenant's Options for the remaining Premises shall remain in full force and effect.

- 9. <u>Condition of Premises</u>. Except as otherwise provided herein, Tenant acknowledges that neither Landlord nor any agent of Landlord has made any representation or warranty with respect to the condition of the 765 Expansion Premises with respect to the suitability of the same for the conduct of Tenant's business. Tenant acknowledges that (a) it is generally familiar with the condition of the 765 Expansion Premises, notwithstanding anything contained in the Amended Lease to the contrary, agrees to take the 765 Expansion Premises in its condition "as is" as of the applicable delivery date. Tenant's taking of possession of the 765 Expansion Premises shall, except as otherwise agreed to in writing by Landlord and Tenant, conclusively establish that the same were at such time in good, sanitary and satisfactory condition and repair. Notwithstanding the foregoing, Landlord represents and warrants that the Building Systems in the 765 Expansion Premises (and each Phase thereof) are, and will be, as of the applicable commencement date for each Phase thereof, in good working condition and that the 765 Expansion Premises (and each Phase thereof) are adequately serviced by Utilities and other base building services.
- 10. <u>Insurance</u>. From and after the Execution Date, the provisions of <u>Section 22</u> of the Lease shall apply to all Buildings in which the Premises are located at any time during the Term.
- 11. <u>Hazardous Materials</u>. From and after the Execution Date, the second to last sentence of <u>Section 40.1</u> of the Lease shall be deleted and replaced in its entirety with the following:

Landlord acknowledges that Tenant shall not be responsible for environmental conditions or contamination now or hereafter existing on, under or in the Entire Project, in the New Whole Building, in the New Multiple Tenant Building, in the Retained Premises, in the Modified Additional Premises, in the Swap Premises, in the 755 Premises, in the Swing Premises, or in the 765 Expansion Premises caused by Landlord or tenants other than Tenant or by third parties in the Entire Project prior to the Execution Date or after such date, or for environmental conditions or contamination coming from off-site so long as Tenant, Tenant's Affiliates, its permitted sublessees or its agents did not cause or contribute to such environmental conditions or contamination.

- 12. <u>Broker</u>. Each of Landlord and Tenant represents and warrants to the other that it has not dealt with any broker or agent in the negotiation for or the obtaining of this Sixth Amendment, other than Studley ("<u>Broker</u>") on behalf of Tenant, and each agrees to indemnify, defend and hold the other harmless from any and all cost or liability for compensation claimed by any such broker or agent, other than Broker, employed or engaged by it or claiming to have been employed or engaged by it. Broker is entitled to a leasing commission in connection with this Sixth Amendment, and Landlord shall pay such commission to Broker pursuant to a separate agreement between Landlord and Broker, which commission shall be calculated on the rentable square footage of the 765 Expansion Premises only.
- 13. No Default; Authority; Non-Contravention. Each of Landlord and Tenant represents, warrants and covenants that, to the best of its respective knowledge, neither Landlord nor Tenant is in default of any of its respective obligations under the Lease and no event has occurred that, with the passage of time or the giving of notice (or both), would constitute a default by either Landlord or Tenant thereunder. Each of Landlord and Tenant further represents, warrants and covenants that it has the full power and authority to execute, deliver and comply with the terms of this Sixth Amendment, and doing so will not conflict with or result in the violation of or default under any provision of any agreement or other instrument to which it is a party.
- 14. Effect of Amendment. Except as modified by this Sixth Amendment, the Lease and all the covenants, agreements, terms, provisions and conditions thereof shall remain in full force and effect and are hereby ratified and affirmed. The covenants, agreements, terms, provisions and conditions contained in this Sixth Amendment shall bind and inure to the benefit of the parties hereto and their respective successors and, except as otherwise provided in the Lease, their respective assigns. In the event of any conflict between the terms contained in this Sixth Amendment and the Lease, the terms herein contained shall supersede and control the obligations and liabilities of the parties. From and after the date hereof, the term "Lease" as used in the Lease shall mean the Lease, as modified by this Sixth Amendment.
- 15. <u>Miscellaneous</u>. This Sixth Amendment becomes effective only upon execution and delivery hereof by Landlord and Tenant. The captions of the paragraphs and subparagraphs in this Sixth Amendment are included solely for convenience and shall not be considered or given any effect in construing the provisions hereof. All exhibits hereto are incorporated herein by reference.
- 16. <u>Counterparts</u>. This Sixth Amendment may be executed in one or more counterparts that, when taken together, shall constitute one original.

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IN WITNESS WHEREOF, Landlord and Tenant have hereunto set their hands as of the date and year first above written, and acknowledge that they possess the requisite authority to enter into this transaction and to execute this Sixth Amendment to Lease.

LANDLORD:

BMR-LANDMARK AT EASTVIEW LLC, a Delaware limited liability company

By: /s/ Matthew McDevitt

Name: Matthew G. McDevitt

Title: EVP, Real Estate

TENANT:

REGENERON PHARMACEUTICALS, INC.,

a New York corporation

By: /s/ Murray Goldberg
Name: Murray A. Goldberg

Title: Senior Vice President, Finance & Administration and Chief Financial Officer

EXHIBIT A

765 Expansion Premises

[IMAGE]

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

- I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 28, 2010 /s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Murray A. Goldberg, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: July 28, 2010 /s/ Murray A. Goldberg

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended June 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ LEONARD S. SCHLEIFER
Leonard S. Schleifer, M.D., Ph.D.
Chief Executive Officer
July 28, 2010

/s/ Murray A. Goldberg
Murray A. Goldberg
Chief Financial Officer
July 28, 2010

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 10/28/2010

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Form 10-Q

(X)	(Mark One) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SE EXCHANGE ACT OF 1934	ECURITIES
	For the quarterly period ended September 30, 2010	
	OR	
()	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE S EXCHANGE ACT OF 1934	ECURITIES
	For the transition period from to	
	Commission File Numb	er <u>0-19034</u>
	REGENERON PHARMACEI (Exact name of registrant as spec	
	New York (State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
	777 Old Saw Mill River Road <u>Tarrytown, New York</u> (Address of principal executive offices)	10591-6707 (Zip Code)
	(Registrant's telephone number,	
1934	dicate by check mark whether the registrant: (1) has filed all reports required to 34 during the preceding 12 months (or for such shorter period that the regist ch filing requirements for the past 90 days.	
such	· · ·	No
requi	dicate by check mark whether the registrant has submitted electronically and puired to be submitted and posted pursuant to Rule 405 of Regulation S-T (§2 orter period that the registrant was required to submit and post such files). Yes X	
	dicate by check mark whether the registrant is a large accelerated filer, an accelerate definitions of "large accelerated filer", "accelerated filer" and "smaller registrant".	lerated filer, a non-accelerated filer, or a smaller reporting company.
Large	rge accelerated filer X	Accelerated filer
_	on-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
Indic	dicate by check mark whether the registrant is a shell company (as defined in R Yes	tule 12b-2 of the Exchange Act). No X
Num	imber of shares outstanding of each of the registrant's classes of common stoc	k as of October 15, 2010:

Number of Shares

2.181.831 APOTEX V. REGENERON IPR2022-01524 REGENERON EXHIBIT 2008 PAGE 5373

Class of Common Stock Class A Stock, \$0.001 par value

REGENERON PHARMACEUTICALS, INC. Table of Contents September 30, 2010

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PART I. FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AT SEPTEMBER 30, 2010 AND DECEMBER 31, 2009 (Unaudited) (In thousands, except share data)

ASSETS	September 30, 2010	December 31, 2009
Current assets	0.0000	
Cash and cash equivalents Marketable securities	\$ 325,286 153,767	\$ 207,075 134,255
Accounts receivable from the sanofi-aventis Group	79,239	62,703
Accounts receivable - other Prepaid expenses and other current assets	3.048 14.379	2,865 18,610
Total current assets	\$75.719	425.508
Restricted cash	3.400	1.600
Marketable securities Property, plant, and equipment, at cost, net of accumulated	37,956	47,080
depreciation and amortization	318,498	259.676
Other assets Total assets	6,860 \$ 942.433	7,338 5 741,202
Tutal assute		
EIABILITIES and STOCKHOLDERS EQUITY Current liabilities		
Accounts payable and accrued expenses	\$ 74,976	\$ 49,031
Deferred revenue from sanofi-aventis, current portion Deferred revenue of their current portion	19,335 3 8.888	17,523 27,021
Facility lease obligations, current portion	634	
Total current habilities	133,833	93,575
Deferred revenue from sanofi-aventis	99,726	90.933
Deferred revenue - other Facility lease obligations	197,139 158,382	46,951 109,022
Other long term liabilities	5,289	3,959
Total liabilities	594 369	344 440
Commitments and contingencies		
Stockholders equity Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and		
outstanding - none Class A Stock convertible \$ 001 par value, 40,000,000 shares authorized.		
shares issued and outstanding = 2.181.831 in 2010 and 2.244.698 in 2009 Common Stock, \$.001 par value; 160,000,000 shares authorized;	2	2
shares issued and outstanding - 80,042,523 in 2010 and 78,860,862 in 2009	80	79
Additional paid-in capital Accumulated deficit	1,379,123 (1,030,966)	(941,095)
Accumulated other comprehensive (loss) income	(175)	1,044
Total stockholders' equity Total liabilities and stockholders' equity	348,064 \$ 942,433	396,762 \$ 741,202
толи надинезана заосущавиз стрих	******	***************************************

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share data)

	Three months ended	September 30,	Nine months ended	l September 30,
	2010	2009	2010	2009
Revenues				
Sanofi-aventis collaboration revenue	\$ 75,583 \$	68,536	\$ 229,195	\$ 178,928
Other collaboration revenue	13.761	32,153	40.483	54,947
Technology licensing	10,037	10,000	30,112	30,000
Net product sales	4 936	4,973	19 985	13,364
Contract research and other	1,662	1,793	5,624	5,229
	105,979	117.455	325,399	282 468
		~~		
Expenses				
Research and development	122,043	105,434	364,040	279,972
Selling, general, and administrative	15,658	12.840	44,560	35.892
Cost of goods sold	372	472	1,494	1,299
	138.073	118,746	410.094	317,163
Loss from operations	(32,094)	(1.291)	(84,695)	(34.695)
Other income (expense)				
Investment income	453	857	1,484	3,935
Interest expense	(2,234)	(581)	(6.660)	(581)
	(1,781)	276	(5,176)	3,354
Net loss	\$ (33,875) \$	(1015)	5 (89,871)	\$ (31,341)
				<u></u>
Net loss per share, basic and diluted	\$ (0.41) \$	(0.01)	\$ (1.10)	S (0.39)
Weighted average shares outstanding, basic and diluted	81638	79.866	81.433	79.663
***				***************************************

The accompanying notes are an integral part of the financial statements.

CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)

For the nine months ended September 30, 2010 and 2009

(In thousands)

					Additional		Accumulated Other	Total	
	Class 2	A Stock	Comm	on Stock	Paid-in	Accumulated	Comprehensive	Stockholders'	Comprehensive
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Equity	Loss
Balance, December 31, 2009 Issuance of Common Stock in connection with	2245	1	78,861	ş 79	\$ 1,336,732	\$ (941,095)	\$ 1,044	\$ 196,762	
exercise of stock options, net of shares tendered Issuance of Common Stock in connection with Company 401(k) Savings Plan contribution Issuance of restricted Common Stock under			993 III	1	13,193 2,867			13,194 3,867	
Long-Term Incentive Plan Conversion of Class A Stock to Common Stock	(63)		15 63						
Stock-based compensation expense Net-loss					26,331	(89.871)		26,331 (89. 8 71)	§ (80,871)
Change in net unrealized gain (loss) on marketable securities							(1,219)	(1,219)	(1,219)
Balance, September 39, 2019	2.197	<u></u>	80.043	\$ 80	<u>\$ 1,379,123</u>	\$11.030.9661	<u>\$ (175)</u>	\$ 348,064	\$ (91,090)
Balance, December 31, 2008 Issuance of Common Stock in connection with	2,249	\$ 2	77,642	\$ 78	\$ 1,294.813	\$ (873,265)	\$ (114)	3 121514	
exercise of stock options, net of shares tendered Issumice of Common Stock in connection with Company 401(k) Savings Plan contribution			518 81		4,626 1,391			4,626 1,391	
Conversion of Class A Stock to Common Stock Stock-based compensation expense	(2)		2		22,662			22,602	
Net loss Change in net unrealized gain (loss) on marketable securities						(31,341)	3.651	(31,341)	\$ (31,341)
Balance, September 30, 2009	2.247	<u></u>	<u>78,243</u>	<u>5 78</u>	<u>\$ 1,323,432</u>	\$ (904,606)	1.537	\$ 422,443	\$ (27,690)

The accompanying notes are an integral part of the financial statements.

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF CASH FLOWS (Unaudited) (In thousands)

	Nine months ended	September 30, 2009
Cash flows from operating activities		
Net loss	\$ (89,871) \$	31,341)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities		
Depreciation and amortization	13,601	9,312
Non-cash compensation expense	26,331	22,602
Net realized loss (gain) on marketable securities	242	(56)
Changes in assets and habilities Increase in accounts receivable	(17.710)	(22.554)
Decrease (increase) in prepaid expenses and other assets	(16,719) 3, 44 6	(32,554) (370)
Increase (decrease) in deferred revenue	172,660	(11,379)
Increase in accounts payable, accined expenses,		(==,===)
and other liabilities	28.353	17.960
Total adjustments	227,914	5,515
Net cash provided by (used in) operating activities	138,043	(25.826)
Cash flows from investing activities		
Purchases of marketable securities	(241,665)	(190,666)
Sales or maturities of marketable securities	230.513	284,934
Capital expenditures (Increase) decrease in restricted cash	(67,427) (1.800)	(75,002)
Net cash (used in) provided by investing activities	(80,379)	19,316
The table (asset in) provided by investing activities	(00,013)	13,010
Cash flows from financing activities		
Proceeds in connection with facility lease obligations	47,544	5,182
Payments in connection with facility lease obligations	(757)	(773)
Net proceeds from the issuance of Common Stock	13,760	4,626
Net eash provided by financing activities	60,547	9 ()35
Net increase in each and cash equivalents	118211	2 525
Cash and cash equivalents at beginning of period	207.075	247.796
Cash and cash equivalents at end of period	\$ 325,286	250.321
The accompanying notes are an integral part of the financial statements.		

Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2009 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

Effective in the first quarter of 2010, the estimated useful lives of certain capitalized laboratory and other equipment, which is a component of property, plant, and equipment, were extended. The effect of this change in estimate was to lower depreciation expense by \$1.0 million and \$3.0 million and to lower the Company's net loss per share by \$0.02 and \$0.04 for the three and nine months ended September 30, 2010, respectively.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, \$4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010.

ARCALYST® net product sales totaled \$4.9 million and \$5.0 million for the three months ended September 30, 2010 and 2009, respectively, and \$20.0 million and \$13.4 million for the nine months ended September 30, 2010 and 2009, respectively. ARCALYST® net product sales during the first nine months of 2010 included \$15.2 million of net product sales made during this period and \$4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at September 30, 2010. At September 30, 2009, deferred ARCALYST® net product sales revenue was \$5.0 million. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by \$0.06 for the nine months ended September 30, 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled \$0.4 million and \$0.5 million for the three months ended September 30, 2010 and 2009, respectively, and \$1.5 million and \$1.3 million for the nine months ended September 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to the Company's customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® for the treatment of CAPS; therefore, the costs of these supplies were not included in costs of goods sold. At both September 30, 2010 and December 31, 2009, the Company had \$0.4 million of inventoried work-in-process costs related to ARCALYST®, which is included in prepaid expenses and other current assets.

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Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three and nine months ended September 30, 2010 and 2009, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

	Three Months End	led September 30,
	2010	2009
Net loss (Numerator)	\$ (31875)	\$ (1015)
Weighted-average shares in thousands (Denominator)	81 638	79 866
Basic and diluted not loss per share	\$ (0.41)	\$ (0.01)
	Nine Months End	ad Cantombou 20
		eu September 30,
	2010	2009
Net loss (Numerator)		
Net loss (Numerator) Weighted-average shares, in thousands (Denominator)	2010	

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the September 30, 2010 and 2009 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months en	ded September 30,
	2010	2009
Stock Options		
Weighted average number, in thousands	21,265	19,860
Weighted average exercise price	S 18.76	\$ 1765
Restricted Stock		
Weighted average number, in thousands	511	500

	Nine months ende	ed September 30,
	2010	2009
Stock Options		
Weighted average number, in thousands	21,317	20,059
Weighted average exercise price	\$ 18.67	\$ 17.59
Restricted Stock: Weighted average number, in thousands	507	500

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at September 30, 2010 and December 31, 2009 were \$12.0 million and \$9.8 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at September 30, 2009 and December 31, 2008 were \$10.5 million and \$7.0 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2009 and 2008 were \$2.6 million and \$1.5 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2010 and 2009, the Company contributed 111,419 and 81,086 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Pursuant to the application of authoritative guidance issued by the Financial Accounting Standards Board ("FASB") to the Company's lease of office and laboratory facilities in Tarrytown, New York, the Company recognized a facility lease obligation of \$4.0 million for the nine months ended September 30, 2009, in connection with capitalizing, on the Company's books, the landlord's costs of constructing new facilities that the Company has leased.

Included in facility lease obligations and property, plant, and equipment at September 30, 2010 was \$2.6 million of capitalized and deferred interest for the nine months ended September 30, 2010, as the related facilities being leased by the Company are currently under construction and lease payments on these facilities do not commence until January 2011.

Included in other assets at September 30, 2010 and December 31, 2009 was \$0.1 million and \$0.7 million, respectively, due to the Company in connection with employee exercises of stock options.

Included in marketable securities at September 30, 2010 and December 31, 2009 were \$1.3 million and \$0.6 million, respectively, of accrued interest income. Included in marketable securities at September 30, 2009 and December 31, 2008 were \$1.0 million and \$1.7 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at September 30, 2010 and December 31, 2009 consisted of debt securities, as detailed below, and an equity security, the aggregate fair value of which was \$4.0 million and \$5.5 million at September 30, 2010 and December 31, 2009, respectively, and the aggregate cost basis of which was \$4.0 million at both September 30, 2010 and December 31, 2009. The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at September 30, 2010 and December 31, 2009. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Amortized	Fair		Unrealized	
At September 30, 2010	Cost Basis	Value	Gains	(Losses)	Net
Maturities within one year					
U.S. government obligations	\$ 106,140	\$106,238	\$ 101	\$ (3)	\$ 98
U.S. government guaranteed corporate bonds	44,054	44,237	183		183
U.S. government guaranteed	2.401	2.611	120		120
collateralized mortgage obligations Mortgage-backed securities	2,481 689	2,611 6 8 1	130	(8)	130
Analyzige-onescu seemates	153,364	153,767	414	(11)	403
Maturities between one and five years	155,501	155,767	111	(11)	103
U.S. government obligations	9,046	9,072	26		26
U.S. government guaranteed corporate	· · · · · · · · · · · · · · · · · · ·				
bonds	21,502	21,829	327		327
Municipal bonds	2,206	2,202	4	(8)	(4)
Mortgage-backed securities	842	675	257	(167)	(167)
	33,596	33,778	357	(175)	182
Maturities between five and seven years Mortgage-backed securities	182	142		(40)	(40)
Mortgage-backed securities	102			(40)	(40)
	\$ 187,142	\$187,687	\$ 771	\$ (226)	\$ 545
At December 31, 2009					<u></u>
Maturities within one year					
U.S. government obligations	\$ 100,491	\$100,573	\$ 82		\$ 82
U.S. government guaranteed corporate					
bonds Comparts hands	17.176	17,340	164 200		164
Corporate bonds U.S. government guaranteed	10,142	10,342	200		200
collateralized mortgage obligations	3,612	3,662	50		50
Mortgage-backed securities	2,471	2,338		\$ (133)	(133)
	133,892	134,255	496	(133)	363
Maturities between one and two years					0000000000000
U.S. government obligations	9,413	9,367		(46)	(46)
U.S. government guaranteed corporate bonds	31,064	21 244	280		280
Mortgage-backed securities	31,064 1,168	31,344 900	∠00	(268)	280 (268)
	41,645	41,611	280	(314)	(34)
	\$ 175,537	\$175.866	<u>\$ 776</u>	<u>S (417)</u>	<u>8 329</u>
			<u></u>		

At December 31, 2009, marketable securities included an additional unrealized gain of \$1.4 million related to the equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at September 30, 2010 and December 31, 2009. The debt securities listed at September 30, 2010, excluding mortgage-backed securities, mature at various dates through January 2012. The mortgage-backed securities listed at September 30, 2010 mature at various dates through November 2016.



Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Less than	12 Months	12 Months	or Greater	To	tal
		Unrealized		Unrealized		Unrealized
At September 30, 2010	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss
U.S. government obligations	\$ 12,624	\$ (3)			S 12,624	\$ (3)
Municipal bonds	1,193	(8)			1,193	(8)
Mortgage-backed securities			\$ 1,489	S (215)	1,489	(215)
Equity security	4,036	(9)			4,036	(9)
	9 17,853	S (20)	\$ 1,489	§ (215)	\$ 19.342	<u>\$ (235)</u>
At December 31, 2009						
U.S. government obligations	\$ 9,367	\$ (46)			\$ 9,367	\$ (46)
Mortgage-backed securities			\$ 3,238	\$ (401)	3,238	(401)
	\$ 9,367	\$ (46)	\$ 3,238	\$ (401)	\$ 12,605	\$ (447)

Realized gains and losses are included as a component of investment income. For the three and nine months ended September 30, 2010 and 2009, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at September 30, 2010 and December 31, 2009, were as follows:

		Fair Value Measurements at Reporting Date I			
		Quoted Prices	Significant		
		in Active	Other	Significant	
		Markets for	Observable	Unobservable	
		Identical Assets	Inputs	Inputs	
	Fair Value	(Level 1)	(Level 2)	(Level 3)	
At September 30, 2010					
Available-for-sale marketable securities					
U.S. government obligations	\$ 115,310		\$ 115,310		
U.S. government guaranteed corporate					
bonds	66,066		66,066		
U.S. government guaranteed					
collateralized mortgage obligations	2,611		2.611		
Municipal bonds	2,202		2,202		
Mortgage-backed securities	1,498		1 498		
Equity security	4,036	\$ 4,036			
	\$ 191.723	\$ 4,036	S 187,687		
At December 31, 2009					
Available-for-sale marketable securities	•••••				
U.S. government obligations	\$ 109,940		\$ 109,940		
U.S. government guaranteed corporate	***************************************				
bonds	48,684		48,684		
Corporate bonds	10,342		10,342		
U.S. government guaranteed					
collateralized mortgage obligations	3,662		3,662		
Mortgage-backed securities	3,238		3,238		
Equity security	5,469	\$ 5,469			
	A D.	OTEXAL DECEME	ON IDD2022 04	F04	

\$ 181,335 \$ 5,469 \$ 175,866

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Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the nine months ended September 30, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover the carrying value of the security. As a result, the Company recognized a \$0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. During the three months ended September 30, 2010, and the three and nine months ended September 30, 2009, the Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities.

At December 31, 2008, the Company held one Level 3 marketable security whose fair value was \$0.1 million. This Level 3 security was valued using information provided by the Company's investment advisors, including quoted bid prices which took into consideration the securities' lack of liquidity. During the three and nine months ended September 30, 2009, the Company recorded charges for other-than-temporary impairment of this Level 3 marketable security totaling \$0.1 million. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three and nine months ended September 30, 2010 and 2009. The Company held no Level 3 marketable securities at September 30, 2010 and December 31, 2009. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three and nine months ended September 30, 2010 and 2009.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of September 30, 2010 and December 31, 2009 consist of the following:

	September 30,	December 31,
	2010	2009
Accounts payable	\$ 22,576	\$ 18.638
Accrued payroll and related costs	23,583	9,444
Accrued clinical trial expense	14213	11.673
Accrued property, plant, and equipment expenditures	8,495	1,883
Accrued expenses, other	6,109	6,207
Payable to Bayer HealthCare		1,186
	\$ 74,976	\$ 49.031

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

7. Comprehensive Income (Loss)

Comprehensive income (loss) of the Company includes net loss adjusted for the change in net unrealized gain (loss) on marketable securities, net of any tax effect. For the three and nine months ended September 30, 2010 and 2009, the components of comprehensive income (loss) are:

	Three months ended September 30,	
	2010	2009
Net loss	\$ (33,875)	\$ (1.015)
Change in net unrealized gain (loss) on marketable securities	131	2,523
Total comprehensive (loss) income	5 (33,744)	\$ 1,508

	Nine months ended September 30.	
	2010	2009
Natioss	S (89.871)	\$ (31,341)
Change in net unrealized gain (loss) on marketable securities	(1,219)	3,651
Total comprehensive loss	\$ (91,090)	\$ (27,690)

8. Extension of Technology Licensing Agreement with Astellas

In March 2007, the Company entered into a six-year non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize the Company's *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million annual, non-refundable payment to the Company in each of 2010, 2009, 2008, and 2007. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a \$165.0 million up-front payment to the Company in August 2010, which was deferred upon receipt and will be recognized as revenue ratably over the seven-year period beginning in mid-2011. In addition, Astellas will make a \$130.0 million second payment to the Company in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as a material breach of the agreement by the Company, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to the Company under the July 2010 amendment to the agreement. The Company is entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using the Company's *VelocImmune*® technology. In connection with the Astellas license agreement, the Company recognized \$15.0 million of technology revenue for both the nine months ended September 30, 2010 and 2009. In addition, deferred revenue at September 30, 2010 and December 31, 2009 was \$178.7 million and \$8.7 million, respectively.

9. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of its business. The Company does not expect any such current legal proceedings to have a material adverse effect on the Company's business or financial condition.

10. Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. The Company will adopt this amended guidance for the fiscal year beginning January 1, 2011. Management does not anticipate that the adoption of this guidance will have a material impact on the Company's financial statements.

11. Subsequent Event - Public Offering of Common Stock

In October 2010, the Company completed an underwritten public offering of 6,325,000 shares of Common Stock and received net proceeds of approximately \$174.7 million.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially. These statements concern, among other things, the possible success and therapeutic applications of our product candidates and research programs, anticipated sales of our marketed product, the timing and nature of the clinical and research programs now underway or planned, and the future sources and uses of capital and our financial needs. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have eight product candidates in clinical development, including three product candidates that are in late-stage (Phase 3) clinical development. Our late stage programs are ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment; VEGF Trap-Eye (aflibercept ophthalmic solution), which is being developed using intraocular delivery for the treatment of eye diseases in collaboration with Bayer HealthCare LLC; and aflibercept (VEGF Trap), which is being developed in oncology in collaboration with the sanofi-aventis Group. Our earlier stage clinical programs are REGN727, an antibody to PCSK9, which is being developed for low density lipoprotein (LDL) cholesterol reduction; REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and ankylosing spondylitis; REGN421, an antibody to Delta-like ligand-4 (Dll4), which is being developed in oncology; REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis; and REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain. In addition, we expect to file an IND for REGN910, an antibody to Angiopoietin-2 (ANG2), a novel angiogenesis target in the oncology setting, by the end of 2010. We also plan to initiate clinical trials with two additional antibodies by the end of the year, REGN846 and REGN728. Our earlier stage clinical programs are fully human antibodies that are being developed in collaboration with sanofi-aventis.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies and combine that foundation with our clinical development and manufacturing capabilities. Our long-term objective is to build a successful, integrated biopharmaceutical company that provides patients and medical professionals with new and better options for preventing and treating human diseases. However, developing and commercializing new medicines entails significant risk and expense.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*TM technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene®* technology to understand the role of these proteins in normal physiology as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune®*) and cell line expression technologies (*VelociMab®*) may then be utilized to design and produce new product candidates directed against the disease target. Our five antibody product candidates currently in clinical trials, as well as REGN910, REGN846, and REGN728, were developed using *VelocImmune®*. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® - Cryopyrin-Associated Periodic Syndromes (CAPS)

Net product sales of ARCALYST® Injection for Subcutaneous Use in the third quarter of 2010 were \$4.9 million, compared to \$5.0 million during the same period of 2009. We recognized \$20.0 million of net product sales during the first nine months of 2010, which included \$15.2 million of ARCALYST® net product sales made during that period and \$4.8 million of previously deferred net product sales, as described below under "Results of Operations." In the first nine months of 2009, we recognized \$13.4 million of ARCALYST® net product sales. ARCALYST® is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. CAPS is a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. ARCALYST®- Inflammatory Diseases

ARCALYST® is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which, as in CAPS, IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthritis that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly with allopurinol, is prescribed to eliminate the urate crystals and prevent reformation. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We are conducting a Phase 3 clinical development program with ARCALYST® in gout patients initiating uric acid-lowering therapy. The program currently consists of PRE-SURGE 1 (\underline{PRE} vention \underline{S} tudy against \underline{UR} ate-lowering drug-induced \underline{G} out \underline{E} xacerbations), PRE-SURGE 2, and RE-SURGE (\underline{RE} view of \underline{S} afety \underline{U} tilizing \underline{R} ilonacept in \underline{G} out \underline{E} xacerbations), each of which are described below.

In June 2010, we announced that PRE-SURGE 1 showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period. Patients initiating urate-lowering therapy who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 milligrams (mg) had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, p<0.0001). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, p<0.0001).

All secondary endpoints of the study were highly positive (p<0.001 vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88% (3.7% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo, p<0.0001). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST® 160 mg, 18.8% with ARCALYST® 80 mg, and 46.8% with placebo, p<0.001).

A total of 241 patients were randomized in PRE-SURGE 1, a North America-based double-blind, placebo-controlled study. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Adverse events that occurred at a frequency of at least 5% in any study group were: injection site reaction (19.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 1.3% with placebo), upper respiratory tract infection (9.9% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 7.6% with placebo), lower respiratory tract infection (0% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 2.5% with placebo), musculoskeletal pain/ discomfort (6.2% with ARCALYST® 160 mg, 7.5% with ARCALYST® 80 mg, and 8.9% with placebo), and headache, (3.7% with ARCALYST® 160 mg, 6.3% with ARCALYST® 80 mg, and 1.3% with placebo).

There are two ongoing studies in the Phase 3 program with ARCALYST® in the prevention of gout flares in patients initiating uric acid-lowering therapy. The global PRE-SURGE 2 study, which has a similar trial design as PRE-SURGE 1, is evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. The global RE-SURGE study is evaluating the safety of ARCALYST® versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. PRE-SURGE 2 and RE-SURGE are fully enrolled, and we expect to have initial data from both studies by early 2011. We own worldwide rights to ARCALYST®.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis Pharma AG (that replaced a previous collaboration and license agreement), we receive tiered royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1ß antibody. The multi-tiered royalty rates in the agreement start at 4% and reach 15% when annual sales exceed \$1.5 billion. Canakinumab is approved to treat CAPS and is in development for gout, type 2 diabetes, and other inflammatory diseases.

2. VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We and Bayer HealthCare are testing VEGF Trap-Eye in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD) and central retinal vein occlusion (CRVO). We and Bayer HealthCare are also conducting a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME). Wet AMD and diabetic retinopathy (which includes DME) are two of the leading causes of adult blindness in the developed world. In both conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), are comparing VEGF Trap-Eye and Lucentis® (ranibizumab injection), owned by Genentech, Inc., an anti-angiogenic agent approved for use in wet AMD. VIEW 1 is being conducted in North America and VIEW 2 is being conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials are both evaluating VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (after three monthly doses) compared with Lucentis (Genentech) dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents will be evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks. VIEW 1 and VIEW 2 are fully enrolled, and initial data from both studies are expected in the fourth quarter of 2010.

VEGF Trap-Eye is also in Phase 3 development for the treatment of CRVO, another cause of visual impairment. The COPERNICUS (Controlled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study is being led by Regeneron and the GALILEO (General Assessment Limiting InfiLtration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study is being led by Bayer HealthCare. Patients in both studies will receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment. At the end of the initial six months, patients will be dosed on a PRN basis for another six months. All patients will be eligible for rescue laser treatment. Both studies are fully enrolled, and initial data from both studies are anticipated in the first half of 2011.

The Phase 2 DME study, known as DA VINCI (DME And VEGF Trap-Eye: Investigation of Clinical Impact), is a double-masked, randomized, controlled trial that is evaluating four different dosing regimens of VEGF Trap-Eye versus laser treatment. In February 2010, we and Bayer HealthCare announced that treatment with VEGF Trap-Eye demonstrated a statistically significant improvement in visual acuity compared to focal laser therapy, the primary endpoint of the study. Visual acuity was measured by the mean number of letters gained over the initial 24 weeks of the study. Patients in each of the four dosing groups receiving VEGF Trap-Eye achieved statistically significantly greater mean improvements in visual acuity (8.5 to 11.4 letters of vision gained) compared to patients receiving focal laser therapy (2.5 letters gained) at week 24 (p< 0.01 for each VEGF Trap-Eye group versus focal laser). VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported. The adverse events reported were those typically associated with intravitreal injections or the underlying disease. Following the initial 24 weeks of treatment, patients continue to be treated for another 24 weeks on the same dosing regimens. Initial one-year results from this trial will be available in the fourth quarter of 2010.

Collaboration with Bayer HealthCare

In October 2006, we entered into a collaboration agreement with Bayer HealthCare for the global development and commercialization outside the United States of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare will collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan that encompasses wet AMD, DME, and CRVO. Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. If VEGF Trap-Eye is granted marketing authorization in a major market country outside the United States, we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. Within the United States, we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We can earn up to \$70 million in future development and regulatory milestone payments related to the development of VEGF Trap-Eye and marketing approvals in major market countries outside the United States. We can also earn up to \$135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the United States achieve certain specified levels starting at \$200 million.

3. Aflibercept (VEGF Trap) - Oncology

Aflibercept is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A), VEGF-B, and the related Placental Growth Factor (called PlGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PlGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

Aflibercept is being developed globally in cancer indications in collaboration with sanofi-aventis. We and sanofi-aventis are conducting three randomized, double-blind Phase 3 trials, all of which are fully enrolled, that are evaluating combinations of standard chemotherapy regimens with either aflibercept or placebo for the treatment of cancer. One trial (VELOUR) is evaluating aflibercept as a 2nd-line treatment for metastatic colorectal cancer in combination with FOLFIRI (folinic acid [leucovorin], 5-fluorouracil, and irinotecan). A second trial (VITAL) is evaluating aflibercept as a 2nd-line treatment for locally advanced or metastatic non-small cell lung cancer in combination with docetaxel. A third trial (VENICE) is evaluating aflibercept as a 1st-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel/prednisone. In addition, a Phase 2 study (AFFIRM) of aflibercept in 1st-line metastatic colorectal cancer in combination with FOLFOX (folinic acid [leucovorin], 5-fluorouracil, and oxaliplatin) is also fully enrolled.

Each of the Phase 3 studies is monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the studies and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a pre-specified number of events have occurred in each trial. In September 2010, we and sanofi aventis announced that, following a planned interim analysis, the VELOUR study's IDMC recommended that the VELOUR study continue to completion as planned, with no modifications due to efficacy or safety concerns. Both sanofi-aventis and our management and staff remain blinded to the interim study results. Based on projected event rates, final results are anticipated in the first half of 2011 from the VITAL study and in the second half of 2011 from the VELOUR study. Based on projected event rates, an interim analysis of the VENICE study is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012. Initial data from the AFFIRM study are anticipated in the second half of 2011.

Aflibercept Collaboration with the sanofi-aventis Group

We and sanofi-aventis U.S. (successor to Aventis Pharmaceuticals, Inc.) globally collaborate on the development and commercialization of aflibercept. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of aflibercept outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of aflibercept, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million related to the receipt of marketing approvals for up to eight aflibercept oncology and other indications in the United States or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the aflibercept collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis for 50% of aflibercept development expenses in accordance with a formula based on the amount of development expenses and our share of the collaboration profits and Japan royalties, or at a faster rate at our option.

4. REGN727 (Anti-PCSK9 Antibody) for LDL cholesterol reduction

Elevated low density lipoprotein (LDL) cholesterol levels is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 (proprotein convertase substilisin/kexin type 9) is a protein that binds to LDLR and prevents LDLR from binding to and removing LDL from circulation. People who have a mutation that reduces the activity of PCSK9 have lower levels of LDL, as well as a reduced risk of adverse cardiovascular events. We used our *VelocImmune*® technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to robustly lower LDL cholesterol through a novel mechanism of action. REGN727 is targeted at inhibiting PCSK9, which results in prevention of the degradation of LDLRs in the liver, thereby facilitating LDL clearance from the systemic circulation leading to lower LDL levels in the blood.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL (bad) cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from this Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. No serious adverse events and no dose limiting toxicities have been reported. Dose escalation is ongoing in both studies.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested at that time, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean additional reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities were reported. Dose escalation in this study is ongoing. We expect to begin a Phase 2 program in the first half of 2011. REGN727 is being developed in collaboration with sanofi-aventis.

5. REGN88 (Anti-IL-6R Antibody) for inflammatory diseases

Interleukin-6 (IL-6) is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to the IL-6 receptor (IL-6R), Actemra® (tocilizumab), marketed by Genentech, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our *VelocImmune*® technology that has completed Phase 1 studies, the results of which were presented at the annual meeting of the European League Against Rheumatism (EULAR) in June 2010. REGN88 was well tolerated by patients with rheumatoid arthritis, and no dose-limiting toxicities were reported. Treatment with REGN88 resulted in dose-related reductions in biomarkers of inflammation. REGN88 is currently in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients. REGN88 is being developed in collaboration with sanofi-aventis.

6. REGN421 (Anti-Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Delta-like ligand 4 (Dll4), inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our *VelocImmune*® technology. REGN421, which is being developed in collaboration with sanofi-aventis, is in Phase 1 clinical development.

7. REGN668 (Anti-IL-4R Antibody) for allergic and immune conditions

Interleukin-4 receptor (IL-4R) is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis.

REGN668 is a fully human monoclonal antibody generated using our *VelocImmune*® technology that is designed to bind to IL-4R. REGN668, which is being developed in collaboration with sanofi-aventis, has completed a Phase 1 trial in healthy volunteers, and will be initiating a Phase 2 trial in atopic dermatitis in the fourth quarter of 2010.

8. REGN475 (Anti-NGF Antibody) for pain

Nerve growth factor (NGF) is a member of the neurotrophin family of secreted proteins. NGF antagonists have been shown to prevent increased sensitivity to pain and abnormal pain response in animal models of neuropathic and chronic inflammatory pain. Mutations in the genes that code for the NGF receptors were identified in people suffering from a loss of deep pain perception. For these and other reasons, we believe blocking NGF could be a promising therapeutic approach to a variety of pain indications.

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune*® technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF. REGN475 is being developed in collaboration with sanofi-aventis.

In May 2010, we announced an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks. The primary endpoint of this study is safety, and REGN475 was generally well tolerated. Serious treatment emergent adverse events were rare and balanced between placebo and drug arms with three events (5.5%) in the placebo group and four events (2.5%) in the combined REGN475 groups. The most frequent adverse events reported among patients receiving REGN475 included sensory abnormalities, arthralgias, hyper/hypo-reflexia, peripheral edema, and injection site reactions. The types and frequencies of adverse events reported were similar to those previously reported from other investigational studies involving an anti-NGF antibody.

In the first interim efficacy analysis, REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 8 weeks following a single intravenous infusion (p<0.01). In July 2010, we reported that REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 16 weeks following a second intravenous infusion at week 8 (p<0.01). Pain was measured by the Numeric Rating Scale (NRS), as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) pain and function subscales.

Analysis of efficacy data from a Phase 2 trial in the acute setting of nerve root compression induced pain (acute sciatica) suggests that REGN475 therapy will not be effective in this setting.

At the request of the U.S. Food and Drug Administration (FDA), another pharmaceutical company has suspended its anti-NGF antibody clinical program in osteoarthritis and certain other chronic pain indications. We have responded to FDA requests for information about patients in our REGN475 clinical trials. REGN475 is currently not on clinical hold, and our Phase 2 trials in patients with vertebral fracture pain and chronic pancreatitis pain are ongoing. Our Phase 2 trial in osteoarthritis of the knee has been completed.

9. REGN910 (Anti-ANG2 Antibody) for oncology

We expect to file an IND for REGN910, an antibody to Angiopoietin-2 (ANG2), a novel angiogenesis target in the oncology setting, by the end of 2010. REGN910 is being developed in collaboration with sanofi-aventis.

10. Additional antibody candidates

We plan to initiate clinical trials with two additional antibodies by the end of the year, REGN846 and REGN728, both being developed in collaboration with sanofi-aventis.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions, and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types, to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as aflibercept and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. $VelociSuite^{TM}$ is our second technology platform and it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuiteTM

VelociSuiteTM consists of VelocImmune[®], VelociGene[®], VelociMouse[®], and VelociMab[®]. The VelocImmune[®] mouse platform is utilized to produce fully human monoclonal antibodies. VelocImmune[®] was generated by exploiting our VelociGene[®] technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. VelocImmune[®] mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. VelocImmune[®] and our entire VelociSuiteTM offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the VelocImmune[®] technology to produce our next generation of drug candidates for preclinical and clinical development.

Our *VelociGene*® platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of pre-clinical development and pharmacology programs, *VelociGene*® offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, *VelociGene*® allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse*® technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, the VelociMice are suitable for direct phenotyping or other studies. We have also developed our *VelociMab*® platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *VelocImmune*® human monoclonal antibodies.

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. We received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis under the discovery agreement. In addition, sanofi-aventis is funding research at Regeneron to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. Sanofi-aventis funded approximately \$175 million of research from the collaboration's inception through December 31, 2009.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to \$160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In addition, sanofi-aventis will fund up to \$30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities. In 2010, as we scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only \$130-\$140 million of antibody discovery costs, with the balance between that amount and \$160 million added to the funding otherwise available to us in 2011-2012. As under the original 2007 agreement, sanofi-aventis also has an option to extend the discovery program for up to an additional three years for further antibody development and preclinical activities. We will lead the design and conduct of research activities, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017.

For each drug candidate identified under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs will be shared between the companies, with sanofi-aventis generally funding drug candidate development costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate will be shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the United States. The parties will share profits outside the United States on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the United States at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the United States exceed \$1.0 billion on a rolling 12-month basis.

In August 2008, we entered into an agreement with sanofi-aventis to use our $VelociGene^{\circledast}$ platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Sanofi-aventis will pay us a minimum of \$21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

AstraZeneca UK Limited. In February 2007, we entered into a non-exclusive license agreement with AstraZeneca UK Limited that allows AstraZeneca to utilize our *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made \$20.0 million annual, non-refundable payments to us in the first quarter of 2007, 2008, 2009, and 2010. AstraZeneca is required to make up to two additional annual payments of \$20.0 million, subject to its ability to terminate the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by AstraZeneca using our *VelocImmune*® technology.

Astellas Pharma Inc. In March 2007, we entered into a non-exclusive license agreement with Astellas Pharma Inc. that allows Astellas to utilize our *VelocImmune*® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made \$20.0 million annual, non-refundable payments to us in the second quarter of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a \$165.0 million up-front payment to us in August 2010. In addition, Astellas will make a \$130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our *VelocImmune*® technology.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received \$19.3 million from the grant's inception through September 30, 2010 and are entitled to receive an additional \$6.0 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through September 30, 2010, we had a cumulative loss of \$1.0 billion. In the absence of significant revenues from the commercialization of ARCALYST® or our other product candidates or other sources, the amount, timing, nature, and source of which cannot be predicted, our losses will continue as we conduct our research and development activities. We expect to incur substantial losses over the next several years as we continue the clinical development of VEGF Trap-Eye and ARCALYST®; advance new product candidates into clinical development from our existing research programs utilizing our technology for discovering fully human monoclonal antibodies; continue our research and development programs; and commercialize additional product candidates that receive regulatory approval, if any. Also, our activities may expand over time and require additional resources, and we expect our operating losses to be substantial over at least the next several years. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the progress of our research and development efforts, the timing of certain expenses, and the amount and timing of payments that we receive from collaborators.

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events to date in 2010 and plans over the next 12 months are as follows:

		2010-11 Plans
Clinical Program ARCALYST® (rilonacept)	Reported positive results from PRE-SURGE 1 and completed patient enrollment of PRE-SURGE 2 and RE-SURGE. PRE-SURGE 1 and 2 are Phase 3 studies that are evaluating ARCALYST® in the prevention of gout flares associated with the initiation of uric acid-lowering drug therapy Reported results showing no significant improvement in pain relief from a separate Phase 3 study evaluating ARCALYST® in the treatment of acute gout flares	 (next 12 months) Report data from PRE-SURGE 2 and RE-SURGE in early 2011
VEGF Trap – Eye	 Completed patient enrollment in two Phase 3 CRVO trials (COPERNICUS and GALILEO) Reported positive 24-week primary endpoint results from the Phase 2 DME trial (DA VINCI) 	 Report data from VIEW 1 and VIEW 2 trials in the fourth quarter of 2010 Report data from GALILEO and COPERNICUS trials in the first half of 2011 Report one-year results from the DA VINCI trial in the fourth quarter of 2010
Aflibercept (VEGF Trap – Oncology)	 Completed patient enrollment in the Phase 3 studies in non-small cell lung cancer (VITAL), prostate cancer (VENICE), and colorectal cancer (VELOUR) Completed patient enrollment in a Phase 2 1st-line study in metastatic colorectal cancer (AFFIRM) in combination with chemotherapy An IDMC conducted an interim analysis of the VELOUR study in colorectal cancer and recommended that the study continue to completion as planned with no modifications due to efficacy or safety concerns 	 Report data from the VITAL study in non-small cell lung cancer in the first half of 2011 An IDMC is expected to conduct an interim analysis of the VENICE study in prostate cancer in mid-2011 Report data from the VELOUR study in metastatic colorectal cancer in the second half of 2011
	22	

Clinical Program REGN727 (PCSK9 Antibody)	 2010 Events to Date Reported proof-of-concept data from a Phase 1 study for LDL cholesterol reduction 	 2010-11 Plans (next 12 months) Report additional data from the Phase 1 program and initiate a Phase 2 program for LDL cholesterol reduction
REGN88 (IL-6R Antibody)	 Initiated a Phase 2/3 dose-ranging study in rheumatoid arthritis and a Phase 2 dose-ranging study in ankylosing spondylitis Reported data from the Phase 1 program in rheumatoid arthritis 	• Report data from the Phase 2 portion of a Phase 2/3 study in rheumatoid arthritis
REGN421 (Dll4 Antibody)		• Initiate a Phase 2 program in advanced malignancies
REGN668 (IL-4RAntibody)	• Completed a Phase 1 study in healthy volunteers	• Initiate a Phase 2 program in the treatment of atopic dermatitis in the fourth quarter of 2010
REGN475 (NGF Antibody)	• Reported interim data from the Phase 2 studies in osteoarthritis of the knee and acute sciatica	• Report additional data from the Phase 2 study in osteoarthritis of the knee
REGN910 (ANG2 Antibody)	Completed preclinical development	• Initiate a Phase 1 study in oncology by the end of 2010

Results of Operations

Three Months Ended September 30, 2010 and 2009

Net Loss

Regeneron reported a net loss of \$33.9 million, or \$0.41 per share (basic and diluted), for the third quarter of 2010, compared to a net loss of \$1.0 million, or \$0.01 per share (basic and diluted) for the third quarter of 2009. The increase in our net loss was principally due to higher research and development expenses in 2010, as detailed below, as well as a decrease in collaboration revenue due to the receipt of a \$20.0 million substantive milestone payment from Bayer HealthCare in 2009.

Revenues

Revenues for the three months ended September 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	\$ 75.6	\$ 68.5
Bayer HealthCare	13.8	32.2
Total collaboration revenue	89.4	100.7
Technology licensing revenue	10.0	10.0
Net product sales	4.9	5.0
Contract research and other revenue	17	1.8
Total revenue	\$106.0	\$117.5

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

	Th	ree mo	onths	ended
Sanofi-aventis Collaboration Revenue		Septer	nber	30,
(In millions)	20	010		2009
Affibereept				
Regeneron expense reimbursement	\$	3.9	\$	7.0
Recognition of deferred revenue related to up-front payments		2,5		2.5
Total aflibercept		6.4		9.5
Antibody				
Regeneron expense reimbursement		66.8		55.7
Recognition of deferred revenue related to up-front and other payments		2.0		26
Recognition of revenue related to VelociGene® agreement		0.4		0.7
Total ambody		69.2	<u> </u>	59.0
Total sanofi-aventis collaboration revenue	\$	75.6	\$	68.5

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the third quarter of 2010 compared to same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities. As of September 30, 2010, \$35.0 million of the original \$105.0 million of up-front payments related to our aflibercept collaboration with sanofi-aventis was deferred and will be recognized as revenue in future periods.

In the third quarter of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of \$36.9 million under the discovery agreement and \$29.9 million of development costs under the license agreement, compared to \$25.7 million and \$30.0 million, respectively, in the third quarter of 2009. The higher reimbursement of our antibody expenses in the third quarter of 2010 compared to the same period in 2009 was due to an increase in our research activities conducted under the discovery agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' \$85.0 million up-front payment, decreased during the third quarter of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to \$30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities, of which \$21.6 million was received or receivable from sanofi-aventis as of September 30, 2010. Payments for such funding from sanofi-aventis are deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the original \$85.0 million up-front payment. As of September 30, 2010, \$80.0 million of the original up-front payment and subsequent payments to fund expansion of our Rensselaer facilities was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate *VelociGene*® agreement with sanofi-aventis. For the three months ended September 30, 2010 and 2009, we recognized \$0.4 million and \$0.7 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses, substantive performance milestone payments, and recognition of revenue related to a non-refundable \$75.0 million up-front payment received in October 2006 and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

Bayer HealthCare Collaboration Revenue September	30,
September	
(In millions) 2010	2009
Cost-sharing of Regeneron VEGF Trap-Eye development expenses S 11.3 S	9.7
Substantive performance milestone payment	20.0
Recognition of deferred revenue related to up-from and milestone payments	2.5
Total Bayer HealthCare collaboration revenue <u>\$ 13.8 \$</u>	32.2

In periods when we recognize VEGF Trap-Eye development expenses that we incur under our collaboration with Bayer HealthCare, we also recognize, as collaboration revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. Costsharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the third quarter of 2010, compared to the same period in 2009, due to higher internal development activities and higher costs related to manufacturing VEGF Trap-Eye clinical supplies. In 2010 and 2009, development expenses incurred by Regeneron and Bayer HealthCare under the VEGF Trap-Eye global development plan were shared equally. As of September 30, 2010, \$49.4 million of the \$75.0 million up-front licensing and \$20.0 million milestone payments was deferred and will be recognized as revenue in future periods. In July 2009, we received a \$20.0 million substantive milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO. The payment was recognized in other collaboration revenue for the three months ended September 30, 2009.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments have been deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement. In the third quarter of both 2010 and 2009, we recognized \$10.0 million of technology licensing revenue related to these agreements. In addition, in connection with the amendment and extension of our license agreement with Astellas, as described above under "Antibody Collaboration and License Agreements," the \$165.0 million up-front payment was deferred upon receipt in August 2010 and will be recognized as revenue ratably over a seven-year period beginning in mid-2011.

Net Product Sales

For the three months ended September 30, 2010, ARCALYST® net product sales were \$4.9 million, compared to \$5.0 million during the same period in 2009. There was no deferred ARCALYST® net product sales revenue at September 30, 2010. At September 30, 2009, deferred ARCALYST® net product sales revenue was \$5.0 million.

Contract research and other revenue for the three months ended September 30, 2010 and 2009 included \$1.2 million and \$1.4 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to \$138.1 million in the third quarter of 2010 from \$118.7 million in the third quarter of 2009. Our average headcount increased to 1,317 in the third quarter of 2010 from 998 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the third quarter of 2010 and 2009 include a total of \$8.8 million and \$7.5 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

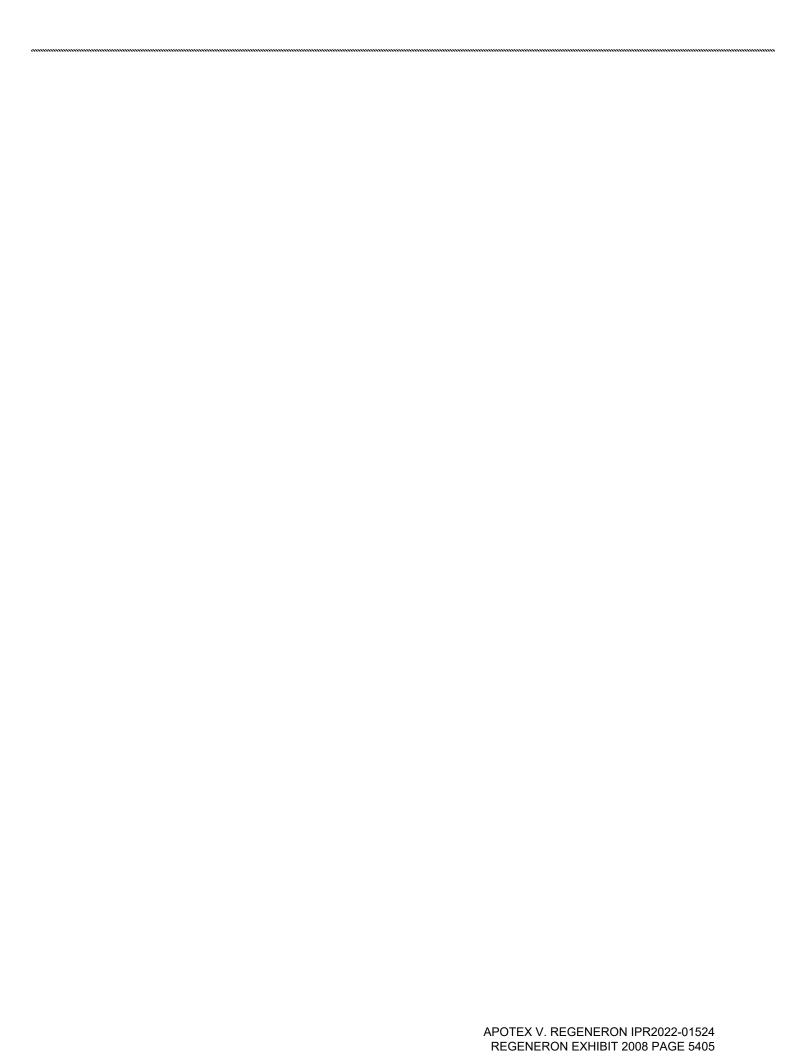
	For the three months ended September 30, 2010		
	Expenses before		
	inclusion of Non-cash	Non-cash	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported
Research and development	5 116.7	\$ 53	S 122.0
Selling, general, and administrative	12.2	3.5	15.7
Cost of goods sold	0.4		0.4
Total operating expenses	\$ 129.3	\$ 8.8	\$ 138.1

	For the three months ended September 30, 2009			
	Expenses before			
	inclusion of Non-cash	Non-cash		
Expenses	Compensation	Compensation	Expenses as	
(In millions)	Expense	Expense	Reported	
Research and development	\$ 1(X) 8	\$ 4.6	\$ 105.4	
Selling, general, and administrative	9.9	2.9	12.8	
Cost of goods sold	0.5		0.5	
Total operating expenses	\$ 111.2	\$ 7.5	\$ 118.7	

Research and Development Expenses

Research and development expenses increased to \$122.0 million in the third quarter of 2010 from \$105.4 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the three months ended September 30, 2010 and 2009:

	For the three months ended		
Research and Development Expenses	September 30, Increase		Increase
(In millions)	2010	2009	(Decrease)
Payroll and benefits (1)	\$ 347	\$ 24.5	S 10.2
Clinical trial expenses	23.1	29.4	(6.3)
Clinical manufacturing costs (2)	251	18.0	71
Research and other development costs	13.8	11.1	2.7
Occupancy and other operating costs	13.5	10.5	10
Cost-sharing of Bayer HealthCare VEGF			
Trap-Eye development expenses (3)	11.8	11.9	(0.1)
Total research and development expenses	<u>\$ 122.0</u>	<u>§ 105.4</u>	\$ 16.6



- (1) Includes \$4.6 million and \$3.9 million of Non-cash Compensation Expense for the three months ended September 30, 2010 and 2009, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.7 million of Non-cash Compensation Expense for both the three months ended September 30, 2010 and 2009.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our ARCALYST® clinical development program in gout and certain monoclonal antibodies which are in earlier stage clinical development. Clinical manufacturing costs increased primarily due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility. In addition, we incurred higher costs related to manufacturing clinical supplies of ARCALYST® and VEGF Trap-Eye, partly offset by lower costs related to manufacturing clinical supplies of monoclonal antibodies and aflibercept. Research and other development costs increased primarily due to higher costs associated with our VEGF Trap-Eye, ARCALYST®, and antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses decreased slightly primarily due to lower costs associated with the VIEW 2 trial in wet AMD which were offset by higher costs in connection with the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	For the three n	onths ended	
Project Costs	Septemb	er 30,	Increase
(In millions)	2010	2009	(Decrease)
ARCALYST®	\$ 16.5	\$ 15.5	\$ 10
VEGF Trap-Eye	33.2	29.9	3.3
Aflibercept	2.8	6.1	(3.3)
REGN88	6.0	10.0	(4.0)
Other antibody candidates in clinical development	18.4	9,5	8.9
Other research programs & unallocated costs	45.1	34.4	10.7
Total research and development expenses	<u>5 122 0</u>	\$ 105.4	\$ 16.6

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, aflibercept, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Item 1A, "Risk Factors" under "Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates," "Regulatory and Litigation Risks," and "Risks Related to Commercialization of Products." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$15.7 million in the third quarter of 2010 from \$12.8 million in the same period of 2009. In the third quarter of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, and higher recruitment costs.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled \$0.4 million and \$0.5 million for the quarters ended September 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® for the treatment of CAPS in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to \$0.5 million in the third quarter of 2010 from \$0.9 million in the comparable quarter of 2009, primarily due to lower average balances of, and lower yields on, cash and marketable securities. Interest expense of \$2.2 million and \$0.6 million in the third quarter of 2010 and 2009, respectively, was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Nine Months Ended September 30, 2010 and 2009

Net Loss

Regeneron reported a net loss of \$89.9 million, or \$1.10 per share (basic and diluted), for the first nine months of 2010, compared to a net loss of \$31.3 million, or \$0.39 per share (basic and diluted) for the first nine months of 2009. The increase in our net loss was principally due to higher research and development expenses in 2010, as detailed below, partly offset by higher collaboration revenue in 2010 primarily in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the nine months ended September 30, 2010 and 2009 consist of the following:

(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	\$229.2	\$ 178.9
Bayer HealthCare	40.5	54.9
Total collaboration revenue	269.7	233.8
Technology licensing revenue	30.]	30.0
Net product sales	20.0	13.4
Contract research and other revenue	56	5.3
Total revenue	\$325.4	\$ 282.5

Sanofi-aventis Collaboration Revenue

The collaboration revenue we earn from sanofi-aventis, as detailed below, consists primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the aflibercept collaboration and \$85.0 million related to the antibody collaboration.

	Nine mo	nths ended
Sanofi-aventis Collaboration Revenue	Septer	nber 30,
(In millions)	2010	2009
Aflibercept		
Regeneron expense reimbursement	\$ 12.6	\$ 21.6
Recognition of deferred revenue related to up-front payments	74	74
Total aflibercept	20.0	29.0
Antibody:		
Regeneron expense reimbursement	202.7	139.8
Recognition of deferred revenue related to up-front and other payments	5.3	7.9
Recognition of revenue related to VelociGene® agreement	1.2	2.2
Total antibody	209.2	149.9
Total sanofi-aventis collaboration revenue	\$ 229.2	\$ 178.9

Sanofi-aventis' reimbursement of our aflibercept expenses decreased in the first nine months of 2010 compared to the same period in 2009, primarily due to lower costs related to manufacturing aflibercept clinical supplies as well as a decrease in internal research activities.

In the first nine months of 2010, sanofi-aventis' reimbursement of our antibody expenses consisted of \$100.3 million under the discovery agreement and \$102.4 million of development costs under the license agreement, compared to \$76.7 million and \$63.1 million, respectively, in the first nine months of 2009. The higher reimbursement amounts in the first nine months of 2010 compared to the same period in 2009 were due to an increase in our research activities conducted under the discovery agreement and increases in our development activities for antibody candidates under the license agreement.

Recognition of deferred revenue, related primarily to sanofi-aventis' \$85.0 million up-front payment, decreased during the first nine months of 2010 compared to the same period in 2009 due to the November 2009 amendments to expand and extend the companies' antibody collaboration.

In August 2008, we entered into a separate *VelociGene*® agreement with sanofi-aventis. For the nine months ended September 30, 2010 and 2009, we recognized \$1.2 million and \$2.2 million, respectively, in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earn from Bayer HealthCare, as detailed below, consists of cost sharing of Regeneron VEGF Trap-Eye development expenses, substantive performance milestone payments, and recognition of revenue related to a non-refundable \$75.0 million up-front payment received in October 2006 and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

	Nine	mont	hs er	ıded
Bayer HealthCare Collaboration Revenue	Se	pteml	er 3	0,
(In millions)	201	10	20	009
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	5 3	31	\$	27.5
Substantive performance milestone payment				20.0
Recognition of deferred revenue related to up-front and milestone payments		7.4		7.4
Total Bayer HealthCare collaboration revenue	\$ 4	0.5	\$	54.9

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare increased in the first nine months of 2010, compared to the same period in 2009, due to higher internal development activities, higher costs related to manufacturing VEGF Trap-Eye clinical supplies, and higher clinical development costs in connection with our Phase 3 trial in CRVO. In July 2009, we received a \$20.0 million substantive milestone payment from Bayer HealthCare in connection with the dosing of the first patient in a Phase 3 trial of VEGF Trap-Eye in CRVO. The payment was recognized in other collaboration revenue for the nine months ended September 30, 2009.

Technology Licensing Revenue

In connection with our *VelocImmune*® license agreements with AstraZeneca and Astellas, each of the \$20.0 million annual, non-refundable payments have been deferred upon receipt and recognized as revenue ratably over approximately the ensuing year of each agreement In the first nine months of both 2010 and 2009, we recognized \$30.0 million of technology licensing revenue related to these agreements. In addition, in connection with the amendment and extension of our license agreement with Astellas, the \$165.0 million up-front payment was deferred upon receipt in August 2010 and will be recognized as revenue ratably over a seven-year period beginning in mid-2011.

Net Product Sales

In February 2008, we received marketing approval from the FDA for ARCALYST® for the treatment of CAPS. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, for the nine months ended September 30, 2010, we recognized as revenue \$20.0 million of ARCALYST® net product sales, which included \$15.2 million of ARCALYST® net product sales. For the nine months ended September 30, 2009, we recognized as revenue \$13.4 million of ARCALYST® net product sales.

Contract research and other revenue for the first nine months of 2010 and 2009 included \$3.5 million and \$4.4 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to \$410.1 million in the first nine months of 2010 from \$317.2 million in the same period of 2009. Our average headcount increased to 1,206 in the first nine months of 2010 from 967 in the same period of 2009 principally as a result of our expanding research and development activities, which are primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the first nine months of 2010 and 2009 include a total of \$26.3 million and \$22.6 million, respectively, of Non-cash Compensation Expense, as detailed below:

	For the nine months ended September 30, 2010		
	Expenses before		_
	inclusion of Non-cash	Non-cash	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported
Research and development	\$ 348.7	\$ 15.3	\$ 364.0
Selling, general, and administrative	33.6	11.0	44.6
Cost of goods sold	1.5		1.5
Total operating expenses	\$ 383.8	\$ 26.3	\$ 410.1

	For the nine months ended September 30, 2009			
	Expenses before			
	inclusion of Non-cash	Non-cash		
Expenses	Compensation	Compensation	Expenses as	
(In millions)	Expense	Expense	Reported	
Research and development	\$ 266.0	\$ 14.0	\$ 280.0	
Selling, general, and administrative	27.3	8.6	35.9	
Cost of goods sold	13		13	
Total operating expenses	\$ 294.6	\$ 22.6	\$ 317.2	

Research and Development Expenses

Research and development expenses increased to \$364.0 million in the first nine months of 2010 from \$280.0 million in the same period of 2009. The following table summarizes the major categories of our research and development expenses for the nine months ended September 30, 2010 and 2009:

	For the nine m	onths ended	
Research and Development Expenses	Septemb	oer 30,	
(In millions)	2010	2009	Increase
Payroll and benefits (1)	\$ 94.3	\$ 71.0	\$ 23.3
Clinical trial expenses	83.8	78.9	4.9
Climical manufacturing costs (2)	72.6	46.0	26.6
Research and other development costs	40.4	29.5	10.9
Occupancy and other operating costs	38.3	27.0	10.4
Cost-sharing of Bayer HealthCare VEGF			
Trap-Eye development expenses (3)	34.6	26.7	7.9
Total research and development expenses	\$ 3640	\$ 280.0	\$ 84.0

⁽¹⁾ Includes \$13.1 million and \$11.8 million of Non-cash Compensation Expense for the nine months ended September 30, 2010 and 2009, respectively.

- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$2.2 million of Non-cash Compensation Expense for both the nine months ended September 30, 2010 and 2009.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses increased due primarily to higher costs related to our clinical development programs for VEGF Trap-Eye, principally in connection with our COPERNICUS trial in CRVO, and certain monoclonal antibody candidates, which are in earlier stage clinical development, partly offset by lower costs related to our Phase 3 clinical development program for ARCALYST® in gout. Clinical manufacturing costs increased primarily due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility. In addition, we incurred higher costs related to manufacturing clinical supplies of VEGF Trap-Eye, ARCALYST®, and certain monoclonal antibodies partly offset by lower costs related to manufacturing clinical supplies of aflibercept. Research and other development costs increased primarily due to higher costs associated with our VEGF Trap-Eye, ARCALYST®, and antibody programs. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with the VIEW 2 trial in wet AMD and the GALILEO trial in CRVO, both of which are being conducted by Bayer HealthCare.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	For the nine n	onths ended	
Project Costs	Septeml	per 30,	Increase
(In millions)	2010	2009	(Decrease)
ARCALYST®	\$ 48.2	\$ 49.1	\$ (0.9)
VEGF Trap-Eye	98.0	77.7	20.3
Aflibercept	9.8	17.7	(7.9)
REGN88	20.7	27.5	(6.8)
Other antibody candidates in clinical development	68.7	194	49.3
Other research programs & unallocated costs	118.6	88.6	30.0
Total research and development expenses	\$ 364.0	S 280.0	\$ 84.0

For the reasons described above under "Research and Development Expenses" for the three months ended September 30, 2010 and 2009, and due to the variability in the costs necessary to develop a product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates in clinical development will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$44.6 million in the first nine months of 2010 from \$35.9 million in the same period of 2009. In the first nine months of 2010, we incurred higher compensation expense due primarily to increases in headcount, higher Non-cash Compensation Expense, higher recruitment costs, and higher patent-related costs associated with our monoclonal antibody programs.

Cost of Goods Sold

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties and other period costs, totaled \$1.5 million and \$1.3 million for the nine months ended September 30, 2010 and 2009, respectively. To date, ARCALYST® shipments to our customers have consisted of supplies of inventory manufactured and expensed prior to FDA approval of ARCALYST® for the treatment of CAPS in February 2008; therefore, the costs of these supplies were not included in costs of goods sold.

Other Income and Expense

Investment income decreased to \$1.5 million in the first nine months of 2010 from \$3.9 million in the comparable period of 2009, primarily due to lower average balances of, and lower yields on, cash and marketable securities and a \$0.1 million other-than-temporary impairment charge. Interest expense of \$6.7 million and \$0.6 million in the first nine months of 2010 and 2009, respectively, was attributable to the imputed interest portion of payments to our landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York. These payments commenced in the third quarter of 2009.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® product revenue, and investment income.

Nine months ended September 30, 2010 and 2009

At September 30, 2010, we had \$520.4 million in cash, cash equivalents, restricted cash, and marketable securities compared with \$390.0 million at December 31, 2009. In February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs for the new laboratory and office facilities that we lease in Tarrytown, New York. In February and June 2010, we received \$20.0 million annual technology licensing payments from both AstraZeneca and Astellas. In August 2010, we received a \$165.0 million up-front payment in connection with the amendment and extension of our *VelocImmune* license agreement with Astellas, as described above under "Antibody Collaboration and License Agreements."

Cash Provided by (Used in) Operating Activities:

Net cash provided by operating activities was \$138.0 million in the first nine months of 2010 and net cash used in operating activities was \$25.8 million in the first nine months of 2009. Our net losses of \$89.9 million in the first nine months of 2010 and \$31.3 million in the first nine months of 2009 included \$26.3 million and \$22.6 million, respectively, of Non-cash Compensation Expense, and \$13.6 million and \$9.3 million, respectively, of depreciation and amortization.

At September 30, 2010, accounts receivable increased by \$16.7 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at September 30, 2010 increased by \$172.7 million, compared to end-of-year 2009, primarily due to (i) the receipt of the \$165.0 million up-front payment from Astellas, as described above, which was deferred and will be recognized ratably over the seven-year period commencing in mid-2011, (ii) the receipt of the \$20.0 million payments from AstraZeneca and Astellas, as described above, which were deferred and are being recognized ratably over the ensuing year, and (iii) sanofiaventis' funding of \$21.1 million of agreed-upon costs incurred by us during the first nine months of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was deferred and is being recognized as collaboration revenue prospectively over the related performance period in conjunction with the original \$85.0 million up-front payment received from sanofi-aventis. These increases were partially offset by amortization of previously received deferred payments under our sanofi-aventis and Bayer HealthCare collaborations. At September 30, 2010, accounts payable, accrued expenses, and other liabilities increased by \$28.4 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for payroll and related costs and clinical trial expenses.

At September 30, 2009, accounts receivable increased by \$32.6 million, compared to end-of-year 2008, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. Also, our deferred revenue balances at September 30, 2009 decreased by \$11.4 million, compared to end-of-year 2008, primarily due to the amortization of previously received deferred payments under our collaborations with sanofi-aventis and Bayer HealthCare. This decrease was partly offset by the receipt of \$20.0 million payments from AstraZeneca and Astellas in February and June 2009, respectively, which were deferred and recognized ratably over the ensuing year. At September 30, 2009, accounts payable, accrued expenses, and other liabilities increased by \$18.0 million compared to end-of-year 2008. The increase was due primarily to higher liabilities for clinical trial and payroll-related costs, partially offset by a \$7.0 million decrease in the cost-sharing payment due to Bayer HealthCare at September 30, 2009 compared to December 31, 2008 in connection with the companies' VEGF Trap-Eye collaboration.

Cash (Used in) Provided by Investing Activities:

Net cash used in investing activities was \$80.4 million in the first nine months of 2010 and net cash provided by investing activities was \$19.3 million in the first nine months of 2009. In the first nine months of 2010, purchases of marketable securities exceeded sales or maturities by \$11.2 million, whereas in the first nine months of 2009, sales or maturities of marketable securities exceeded purchases by \$94.3 million. Capital expenditures in the first nine months of 2010 and 2009 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our leased office and laboratory facilities in Tarrytown, New York.

Cash Provided by Financing Activities:

Net cash provided by financing activities was \$60.5 million in the first nine months of 2010 and \$9.0 million in the first nine months of 2009. In the first nine months of 2010 and 2009, we received \$47.5 million and \$5.2 million, respectively, from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with FASB authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were \$13.8 million in the first nine months of 2010 and \$4.6 million in the first nine months of 2009.

Fair Value of Marketable Securities:

At September 30, 2010 and December 31, 2009, we held marketable securities whose aggregate fair value totaled \$191.7 million and \$181.3 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	September	September 30, 2010		31, 2009
Investment type	Fair Value	Percent	Fair Value	Percent
U.S. government agency securities	\$ 115.3	60%	\$ 296	16%
U.S. Treasury securities			80.4	44%
U.S. government-guaranteed corporate bonds	66. I	34%	48.7	2796
U.S. government guaranteed collateralized mortgage				
obligations	2.6	2%	3.7	2%
Corporate bonds			10.3	6%
Mortgage-backed securities	1.5	1%	3.2	2%
Equity security	4.0	$2^{\alpha}\alpha$	5.4	390
Other	2.2	1%		
Total marketable securities	\$ 1917	100%	5 1813	100%

In addition, at September 30, 2010 and December 31, 2009, we had \$328.7 million and \$208.7 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

During 2009 and 2010 to date, as marketable securities in our portfolio matured or paid down, we purchased higher quality securities such as U.S. government agency obligations, U.S. government-guaranteed debt, and U.S. Treasury securities. This shift in our investment portfolio, which we initiated in 2008, has reduced the risk profile, as well as the overall yield, of our portfolio.

Funding of Antibody Discovery Activities under Collaboration with sanofi-aventis

As described above under "Antibody Collaboration and License Agreements," in November 2009, we and sanofi-aventis amended our collaboration agreements to expand and extend our antibody collaboration. Sanofi-aventis will now fund up to \$160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria are not satisfied. In 2010, as we scale up our capacity to conduct antibody discovery activities, we will incur and seek reimbursement of only \$130-\$140 million of antibody discovery costs, with the balance between that amount and \$160 million added to the funding otherwise available to us in 2011-2012. The discovery agreement under the antibody collaboration will expire at the end of 2017; however, sanofi-aventis has an option to extend the agreement for up to an additional three years for further antibody development and preclinical activities.

Extension of License Agreement with Astellas

As described above under "Antibody Collaboration and License Agreements," in July 2010, the non-exclusive license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a \$165.0 million up-front payment to us in August 2010, and will make a \$130.0 million payment to us in June 2018 unless the license agreement has been terminated prior to that date.

Public Offering of Common Stock

In October 2010, the Company completed an underwritten public offering of approximately 6.3 million shares of Common Stock and received net proceeds of approximately \$174.7 million. We intend to use the net proceeds from this offering for general corporate purposes.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled \$67.4 million and \$75.0 million for the first nine months of 2010 and 2009, respectively. We expect to incur capital expenditures of approximately \$30 to \$50 million during the remainder of 2010 and approximately \$40 to \$70 million in 2011, primarily in connection with expanding our Rensselaer, New York manufacturing facilities and tenant improvements at our leased Tarrytown facilities. As described above, in February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, as described above, sanofi-aventis has funded \$21.1 million of agreed-upon capital expenditures incurred by us during the first nine months of 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at September 30, 2010. We expect to be reimbursed for a portion of additional capital expenditures in 2010 and 2011 for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements:

We expect to continue to incur substantial funding requirements primarily for research and development activities (including preclinical and clinical testing). Before taking into account reimbursements from our collaborators, and exclusive of anticipated funding for capital expenditures as described above, we currently anticipate that approximately 65-75% of our expenditures for 2010 will be directed toward the clinical development of product candidates, including ARCALYST®, aflibercept, VEGF Trap-Eye, and clinical stage monoclonal antibodies; approximately 15-25% of our expenditures for 2010 will be applied to our basic research and preclinical activities; and the remainder of our expenditures for 2010 will be used for the continued development of our novel technology platforms and general corporate purposes. While we expect that funding requirements for our research and development activities will continue to increase in 2010, we also expect that a greater proportion of our research and development expenditures will be reimbursed by our collaborators, especially in connection with our antibody collaboration with sanofi-aventis.

The amount we need to fund operations will depend on various factors, including the status of competitive products, the success of our research and development programs, the potential future need to fund costs to commercialize our product candidates, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights, the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Currently, we are required to remit royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or otherwise share the profits generated on such sales in connection with our collaboration and licensing agreements.

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements and the net proceeds from our October 2010 public offering of Common Stock, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, if we choose to commercialize products that are not licensed to a third party, we could incur substantial pre-marketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we would expect to prioritize available capital to fund selected preclinical and clinical development programs or license selected products.

Other than a \$3.4 million letter of credit issued to our landlord in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of September 30, 2010, we had no established banking arrangements through which we could obtain short-term financing or a line of credit. In the event we need additional financing for the operation of our business, we will consider collaborative arrangements and additional public or private financing, including additional equity financing. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

Future Impact of Recently Issued Accounting Standards

In March 2010, the FASB amended its authoritative guidance on the milestone method of revenue recognition. The milestone method of revenue recognition has now been codified as an acceptable revenue recognition model when a milestone is deemed to be substantive. This guidance may be applied retrospectively to all arrangements or prospectively for milestones achieved after the adoption of the guidance. We will adopt this amended guidance for the fiscal year beginning January 1, 2011. Management does not anticipate that the adoption of this guidance will have a material impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk:

Our earnings and cash flows are subject to fluctuations due to changes in interest rates principally in connection with our investment of excess cash in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a \$0.4 million and \$0.9 million decrease in the fair value of our investment portfolio at September 30, 2010 and 2009, respectively.

Credit Quality Risk:

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We have recognized other-than-temporary impairment charges related to certain marketable securities of \$2.5 million, \$0.1 million, and \$0.1 million in 2008, 2009, and the first nine months of 2010, respectively.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current legal proceedings to have a material adverse effect on our business or financial condition.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ substantially from those discussed in these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through September 30, 2010, we had a cumulative loss of \$1.0 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates. We believe our existing capital resources, including funding we are entitled to receive under our collaboration agreements and the net proceeds from our October 2010 public offering of Common Stock, will enable us to meet operating needs through at least 2013; however, one or more of our *VelocImmune*® licenses or collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase and that would lead to our capital being consumed significantly before such time. Our expenses may increase for many reasons, including for expenses in connection with the commercial launch of our products, for expenses related to new clinical trials testing ARCALYST® or VEGF Trap-Eye, or for the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise such additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. If we are unable to raise sufficient funds to complete the development of our product candidates, we may face delay, reduction or elimination of our research and development programs or preclinical or clinical trials, in which case our business, financial condition or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income.

As of September 30, 2010, cash, cash equivalents, restricted cash, and marketable securities totaled \$520.4 million and represented 55% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities and, to a lesser extent, investment grade debt securities issued by corporations, bank deposits, and asset-backed securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled \$191.7 million at September 30, 2010, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security to its current fair value and recognize a loss which may be fully charged against income. For example, we recognized other-than-temporary impairment charges related to certain marketable securities of \$2.5 million, \$0.1 million, and \$0.1 million in 2008, 2009, and the first nine months of 2010, respectively. The current economic environment, the deterioration in the credit quality of some of the issuers of securities that we hold, and the continued volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to ARCALYST® (rilonacept) and the Development of Our Product Candidates

Successful development of any of our product candidates is highly uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. Even if clinical trials demonstrate the safety and effectiveness of any of our product candidates for a specific disease and the necessary regulatory approvals are obtained, the commercial success of any of our product candidates will depend upon their acceptance by patients, the medical community, and third-party payers and on our partners' ability to successfully manufacture and commercialize our product candidates. Our product candidates are delivered either by intravenous infusion or by intravitreal or subcutaneous injections, which are generally less well received by patients than tablet or capsule delivery. If our products are not successfully commercialized, we will not be able to recover the significant investment we have made in developing such products and our business would be severely harmed.

We are testing aflibercept, VEGF Trap-Eye, and ARCALYST® in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness.

Aflibercept is in Phase 3 clinical trials in combination with standard chemotherapy regimens for the treatment of 2nd-line metastatic colorectal cancer, 1st-line androgen independent prostate cancer, and 2nd-line metastatic non-small cell lung cancer. Aflibercept may not demonstrate the required safety or efficacy to support an application for approval in any of these indications. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that aflibercept will be safe or effective in any of these cancer settings. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (bevacizumab), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of aflibercept in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD and the treatment of CRVO. Although we reported positive Phase 2 trial results with VEGF Trap-Eye in wet AMD, based on a limited number of patients, the results from the larger Phase 3 trials may not demonstrate that VEGF Trap-Eye is safe and effective or compares favorably to Lucentis (Genentech). A number of other potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. VEGF Trap-Eye has not been previously studied in CRVO.

ARCALYST® is in Phase 3 clinical trials for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Although we reported positive Phase 3 data from one trial in patients with gout initiating uric acid-lowering drug therapy, there is a risk that the results of the other ongoing trials of ARCALYST® in patients initiating uric acid-lowering drug therapy will differ from the previously reported Phase 3 trial. A number of potential new drugs and biologics which showed promising results in initial clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, we will have to delay or may be unable to obtain regulatory approval for our product candidates.

We must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan or protocol. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

Many of our clinical trials are conducted under the oversight of Independent Data Monitoring Committees (or IDMCs). These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating aflibercept as a 1st-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s) and our business may be materially harmed.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. Even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials. The failure of clinical trials to demonstrate safety and effectiveness for the desired indication(s) could harm the development of our product candidate(s), and our business, financial condition, and results of operations may be materially harmed.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

Aflibercept (VEGF Trap) is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of vascular endothelial growth factor, or VEGF, that may limit our ability to successfully develop aflibercept and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. These and other complications or side effects could harm the development of aflibercept for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

We have tested ARCALYST® in only a small number of patients. As more patients begin to use our product and as we test it in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Kineret® (anakinra), marketed by Biovitrum, Enbrel® (etanercept), marketed by Amgen Inc. and Wyeth Pharmaceuticals, Inc., and Remicade® (infliximab) marketed by Centocor Ortho Biotech, Inc., ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. Treatment with Kineret (Biovitrum), a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® in gout or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. Recently, another pharmaceutical company that is developing an antibody to NGF announced that it has suspended clinical programs for its agent in patients with osteoarthritis and other chronic use indications at the request of the FDA following a small number of reports of patients experiencing a worsening of osteoarthritis or osteonecrosis leading to joint replacement. Although REGN475 has some differences from this third party antibody, the safety risks reported in clinical trials with this other agent could be risks associated with all antibodies to NGF, including our product candidate. This risk or other complications or side effects could result in the discontinuation or limitation of the further development of REGN475 in osteoarthritis and other pain indications, including as a result of being placed on clinical hold by the FDA.

ARCALYST® and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of ARCALYST® were detected in patients with CAPS after treatment with ARCALYST®. Nineteen of 55 subjects (35%) who received ARCALYST® for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test aflibercept and VEGF Trap-Eye with more sensitive assays in different patient populations and larger clinical trials, we will find that subjects given aflibercept and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including aflibercept, VEGF Trap-Eye, and our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the United States may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third party patents or other proprietary rights.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. Although we do not believe that aflibercept or VEGF Trap-Eye infringes any valid claim in these patents or patent applications, Genentech could initiate a lawsuit for patent infringement and assert that its patents are valid and cover aflibercept or VEGF Trap-Eye or uses thereof. Genentech may be motivated to initiate such a lawsuit at some point in an effort to impair our ability to develop and sell aflibercept or VEGF Trap-Eye, which represent potential competitive threats to Genentech's VEGF-binding products and product candidates. An adverse determination by a court in any such potential patent litigation would likely materially harm our business by requiring us to seek a license, which may not be available, or resulting in our inability to manufacture, develop, and sell aflibercept or VEGF Trap-Eye or in a damage award.

We are aware of patents and pending applications owned by Roche that claim antibodies to the interleukin-6 receptor and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to the interleukin-6 receptor, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST®, aflibercept, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the United States.

Further, we are aware of a number of other third party patent applications that, if granted, with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Regulatory and Litigation Risks

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS, the value of our company and our results of operations will be harmed. In the United States, we must obtain and maintain approval from the United States Food and Drug Administration (FDA) for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for the FDA approval of ARCALYST® and the Europeans Medicines Agency approval of rilonacept for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the United States or any other country. We may never receive regulatory approval for any of our product candidates.

The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with Good Clinical Practice regulations (GCPs), the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs and substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, following approval, in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the United States, we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the United States, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of ARCALYST® or any of our product candidates in those countries.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of our marketed product and clinical candidates, we could incur substantial remedial costs, delays in the development of our clinical candidates, and a reduction in sales.

We and our third party providers are required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application to the FDA and acceptance of the change by the FDA prior to release of product. Because we produce multiple product candidates at our facility in Rensselaer, New York, there are increased risks associated with cGMP compliance. Our inability, or the inability of our third party service providers, to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall product, halt or interrupt clinical trials, and/or interrupt commercial supply of our marketed product. Any delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our marketed product and product candidates as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our ability to develop and commercialize our products. Any finding of non-compliance could increase our costs, cause us to delay the development of our product candidates, and cause us to lose revenue from our marketed product.

If the testing or use of our products harms people, we could be subject to costly and damaging product liability claims.

The testing, manufacturing, marketing, and sale of drugs for use in people expose us to product liability risk. Any informed consent or waivers obtained from people who sign up for our clinical trials may not protect us from liability or the cost of litigation. We may be subject to claims by CAPS patients who use ARCALYST® that they have been injured by a side effect associated with the drug. Our product liability insurance may not cover all potential liabilities or may not completely cover any liability arising from any such litigation. Moreover, in the future we may not have access to liability insurance or be able to maintain our insurance on acceptable terms.

If we market and sell ARCALYST® in a way that violates federal or state fraud and abuse laws, we may be subject to civil or criminal penalties.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally or state financed health care programs.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in promotion for uses that the FDA has not approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses, and submitting inflated best price information to the Medicaid Rebate program.

The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would also harm our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

In recent years, several states and localities, including California, the District of Columbia, Massachusetts, Maine, Minnesota, Nevada, New Mexico, Vermont, and West Virginia, have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Similar requirements are being considered in other states and were included in health care reform legislation recently enacted by the federal government. Many of these requirements are new and uncertain, and the penalties for failure to comply with these requirements are unclear. Nonetheless, if we are found not to be in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

Our operations may involve hazardous materials and are subject to environmental, health, and safety laws and regulations. We may incur substantial liability arising from our activities involving the use of hazardous materials.

As a biopharmaceutical company with significant manufacturing operations, we are subject to extensive environmental, health, and safety laws and regulations, including those governing the use of hazardous materials. Our research and development and manufacturing activities involve the controlled use of chemicals, viruses, radioactive compounds, and other hazardous materials. The cost of compliance with environmental, health, and safety regulations is substantial. If an accident involving these materials or an environmental discharge were to occur, we could be held liable for any resulting damages, or face regulatory actions, which could exceed our resources or insurance coverage.

In future years, if we are unable to conclude that our internal control over financial reporting is effective, the market value of our Common Stock could be adversely affected.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on the Company's internal control over financial reporting in their annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal control over financial reporting. In addition, the independent registered public accounting firm auditing our financial statements must attest to and report on the effectiveness of our internal control over financial reporting. Our independent registered public accounting firm provided us with an unqualified report as to the effectiveness of our internal control over financial reporting as of December 31, 2009, which report is included in our Annual Report on Form 10-K. However, we cannot assure you that management or our independent registered public accounting firm will be able to provide such an unqualified report as of future year-ends. In this event, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the market value of our Common Stock. In addition, if it is determined that deficiencies in the design or operation of internal controls exist and that they are reasonably likely to adversely affect our ability to record, process, summarize, and report financial information, we would likely incur additional costs to remediate these deficiencies and the costs of such remediation could be material.

Changes in laws and regulations affecting the healthcare industry could adversely affect our business.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable federal and state laws and agency regulations could have a material adverse effect on our business. These include:

• changes in the FDA and foreign regulatory processes for new therapeutics that may delay or prevent the approval of any of our current or future product candidates;

- new laws, regulations, or judicial decisions related to healthcare availability or the payment for healthcare products and services, including prescription drugs, that would make it more difficult for us to market and sell products once they are approved by the FDA or foreign regulatory agencies;
- changes in FDA and foreign regulations that may require additional safety monitoring prior to or after the introduction of new products to market, which could materially increase our costs of doing business; and
- changes in FDA and foreign current Good Manufacturing Practice, or cGMPs, that make it more difficult for us to manufacture our marketed product and clinical candidates in accordance with cGMPs.

The enactment in the U.S. of the Patient Protection and Affordable Care Act, or PPACA, potential regulations easing the entry of competing follow-on biologics in the marketplace, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

Risks Related to Our Reliance on Third Parties

If our antibody collaboration with sanofi-aventis is terminated, our business operations and our ability to discover, develop, manufacture, and commercialize our pipeline of product candidates in the time expected, or at all, would be materially harmed.

We rely heavily on funding from sanofi-aventis to support our target discovery and antibody research and development programs. Sanofiaventis has committed to pay up to \$1.28 billion between 2010 and 2017 to fund our efforts to identify and validate drug discovery targets and preclinically develop fully human monoclonal antibodies against such targets. In addition, sanofi-aventis funds almost all of the development expenses incurred by both companies in connection with the clinical development of antibodies that sanofi-aventis elects to co-develop with us. We rely on sanofi-aventis to fund these activities. In addition, with respect to those antibodies that sanofi-aventis elects to co-develop with us, such as REGN88, REGN421, REGN475, REGN727, and REGN668, we rely on sanofi-aventis to lead much of the clinical development efforts and assist with obtaining regulatory approval, particularly outside the United States. We also rely on sanofi-aventis to lead the commercialization efforts to support all of the antibody products that are co-developed by sanofi-aventis and us. If sanofi-aventis does not elect to co-develop the antibodies that we discover or opts-out of their development, we would be required to fund and oversee on our own the clinical trials, any regulatory responsibilities, and the ensuing commercialization efforts to support our antibody products. If sanofi-aventis terminates the antibody collaboration or fails to comply with its payment obligations thereunder, our business, financial condition, and results of operations would be materially harmed. We would be required to either expend substantially more resources than we have anticipated to support our research and development efforts, which could require us to seek additional funding that might not be available on favorable terms or at all, or materially cut back on such activities. While we cannot assure you that any of the antibodies from this collaboration will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations with respect to antibodies that it elects to co-develop, our ability to develop, manufacture, and commercialize these antibody product candidates will be significantly adversely affected.

If our collaboration with sanofi-aventis for aflibercept (VEGF Trap) is terminated, or sanofi-aventis materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop, manufacture, and commercialize aflibercept in the time expected, or at all, would be materially harmed.

We rely heavily on sanofi-aventis to lead much of the development of aflibercept. Sanofi-aventis funds all of the development expenses incurred by both companies in connection with the aflibercept program. If the aflibercept program continues, we will rely on sanofi-aventis to assist with funding the aflibercept program, provide commercial manufacturing capacity, enroll and monitor clinical trials, obtain regulatory approval, particularly outside the United States, and lead the commercialization of aflibercept. While we cannot assure you that aflibercept will ever be successfully developed and commercialized, if sanofi-aventis does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize aflibercept in cancer indications will be significantly adversely affected. Sanofi-aventis has the right to terminate its collaboration agreement with us at any time upon twelve months advance notice. If sanofi-aventis were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or manufacture of aflibercept and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities. Termination of the sanofi-aventis collaboration agreement for aflibercept would create substantial new and additional risks to the successful development and commercialization of aflibercept.

If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed.

We rely heavily on Bayer HealthCare to assist with the development of VEGF Trap-Eye. Under our agreement with them, Bayer HealthCare is required to fund approximately half of the development expenses incurred by both companies in connection with the global VEGF Trap-Eye development program. If the VEGF Trap-Eye program continues, we will rely on Bayer HealthCare to assist with funding the VEGF Trap-Eye development program, lead the development of VEGF Trap-Eye outside the United States, obtain regulatory approval outside the United States, and provide all sales, marketing, and commercial support for the product outside the United States. In particular, Bayer HealthCare has responsibility for selling VEGF Trap-Eye outside the United States using its sales force. While we cannot assure you that VEGF Trap-Eye will ever be successfully developed and commercialized, if Bayer HealthCare does not perform its obligations in a timely manner, or at all, our ability to develop, manufacture, and commercialize VEGF Trap-Eye outside the United States will be significantly adversely affected. Bayer HealthCare has the right to terminate its collaboration agreement with us at any time upon six or twelve months advance notice, depending on the circumstances giving rise to termination. If Bayer HealthCare were to terminate its collaboration agreement with us, we would not have the resources or skills to replace those of our partner, which could require us to seek additional funding that might not be available on favorable terms or at all, and could cause significant delays in the development and/or commercialization of VEGF Trap-Eye outside the United States and result in substantial additional costs to us. We have limited commercial capabilities and would have to develop or outsource these capabilities outside the United States. Termination of the Bayer HealthCare collaboration agreement would create substantial new and additional risks to the successful development and commercialization of VEGF Trap-Eye.

Our collaborators and service providers may fail to perform adequately in their efforts to support the development, manufacture, and commercialization of ARCALYST® and our drug candidates.

We depend upon third-party collaborators, including sanofi-aventis, Bayer HealthCare, and service providers such as clinical research organizations, outside testing laboratories, clinical investigator sites, and third-party manufacturers and product packagers and labelers, to assist us in the manufacture and preclinical and clinical development of our product candidates. If any of our existing collaborators or service providers breaches or terminates its agreement with us or does not perform its development or manufacturing services under an agreement in a timely manner or in compliance with applicable Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), or Good Clinical Practice (GCP) Standards, we could experience additional costs, delays, and difficulties in the manufacture or development or in obtaining approval by regulatory authorities for our product candidates.

We rely on third party service providers to support the distribution of ARCALYST® and many other related activities in connection with the commercialization of ARCALYST® for the treatment of CAPS. We cannot be certain that these third parties will perform adequately. If these service providers do not perform their services adequately, our efforts to market and sell ARCALYST® for the treatment of CAPS will not be successful.

Risks Related to the Manufacture of Our Product Candidates

We have limited manufacturing capacity, which could inhibit our ability to successfully develop or commercialize our drugs.

Our manufacturing facility is likely to be inadequate to produce sufficient quantities of product for commercial sale. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce the large quantities of drug material needed for commercialization of our products. We rely entirely on third-party manufacturers for filling and finishing services. We will have to depend on these manufacturers to deliver material on a timely basis and to comply with regulatory requirements. If we are unable to supply sufficient material on acceptable terms, or if we should encounter delays or difficulties in our relationships with our corporate collaborators or contract manufacturers, our business, financial condition, and results of operations may be materially harmed.

We must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we may expand our manufacturing capacity to support commercial production of active pharmaceutical ingredients, or API, for our product candidates. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. We may be unable to develop manufacturing facilities that are sufficient to produce drug material for clinical trials or commercial use. This may delay our clinical development plans and interfere with our efforts to commercialize our products. In addition, we may be unable to secure adequate filling and finishing services to support our products. As a result, our business, financial condition, and results of operations may be materially harmed.

We may be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

If any of our clinical programs are discontinued, we may face costs related to the unused capacity at our manufacturing facilities.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, we will have to absorb one hundred percent of related overhead costs and inefficiencies.

Third-party supply failures, business interruptions, or natural disasters affecting our manufacturing facilities in Rensselaer, New York could adversely affect our ability to supply our products.

We manufacture all of our bulk drug materials for ARCALYST® and our product candidates at our manufacturing facilities in Rensselaer, New York. We would be unable to supply our product requirements if we were to cease production due to regulatory requirements or action, business interruptions, labor shortages or disputes, contaminations, fire, natural disasters, or other problems at the facilities.

Certain raw materials necessary for manufacturing and formulation of ARCALYST® and our product candidates are provided by single-source unaffiliated third-party suppliers. In addition, we rely on certain third parties to perform filling, finishing, distribution, and other services related to the manufacture of our products. We would be unable to obtain these raw materials or services for an indeterminate period of time if any of these third-parties were to cease or interrupt production or otherwise fail to supply these materials, products, or services to us for any reason, including due to regulatory requirements or action, adverse financial developments at or affecting the supplier, failure by the supplier to comply with GMPs, business interruptions, or labor shortages or disputes. This, in turn, could materially and adversely affect our ability to manufacture or supply ARCALYST® or our product candidates for use in clinical trials, which could materially and adversely affect our business and future prospects.

Also, certain of the raw materials required in the manufacturing and the formulation of our clinical candidates may be derived from biological sources, including mammalian tissues, bovine serum, and human serum albumin. There are certain European regulatory restrictions on using these biological source materials. If we are required to substitute for these sources to comply with European regulatory requirements, our clinical development activities may be delayed or interrupted.

Risks Related to Commercialization of Products

If we are unable to establish sales, marketing, and distribution capabilities, or enter into agreements with third parties to do so, we will be unable to successfully market and sell future products.

We are marketing and selling ARCALYST® for the treatment of CAPS ourselves in the United States, primarily through third party service providers. We have no sales or distribution personnel in the United States and have only a small staff with commercial capabilities. We currently have no sales, marketing, commercial, or distribution capabilities outside the United States. If we are unable to obtain those capabilities, either by developing our own organizations or entering into agreements with service providers, even if our current or future product candidates receive marketing approval, we will not be able to successfully sell those products. In that event, we will not be able to generate significant revenue, even if our product candidates are approved. We cannot guarantee that we will be able to hire the qualified sales and marketing personnel we need or that we will be able to enter into marketing or distribution agreements with third-party providers on acceptable terms, if at all. Under the terms of our collaboration agreement with sanofi-aventis, we will rely on sanofi-aventis for sales, marketing, and distribution of aflibercept in cancer indications, should it be approved in the future by regulatory authorities for marketing. We will have to rely on a third party or devote significant resources to develop our own sales, marketing, and distribution capabilities for our other product candidates, including VEGF Trap-Eye in the United States and ARCALYST® for patients with gout initiating uric acid-lowering drug therapy, and we may be unsuccessful in developing our own sales, marketing, and distribution organization.

There may be too few patients with CAPS to profitably commercialize ARCALYST® in this indication.

Our only approved product is ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases. These rare diseases affect a very small group of people. The incidence of CAPS has been reported to be approximately 1 in 1,000,000 people in the United States. Although the incidence rate of CAPS in Europe has not been reported, it is known to be a rare set of diseases. In October 2009, we received European marketing authorization for rilonacept for CAPS. In 2009, Novartis received regulatory approval in the U.S. and Europe for its IL-1 antibody product for the treatment of CAPS. Given the very rare nature of the disease and the competition from Novartis' IL-1 antibody product, we may be unable to profitably commercialize ARCALYST® in this indication.

Even if our product candidates are approved for marketing, their commercial success is highly uncertain because our competitors have received approval for products with a similar mechanism of action, and competitors may get to the marketplace with better or lower cost drugs.

There is substantial competition in the biotechnology and pharmaceutical industries from pharmaceutical, biotechnology, and chemical companies. Many of our competitors have substantially greater research, preclinical and clinical product development and manufacturing capabilities, and financial, marketing, and human resources than we do. Our smaller competitors may also enhance their competitive position if they acquire or discover patentable inventions, form collaborative arrangements, or merge with large pharmaceutical companies. Even if we achieve product commercialization, our competitors have achieved, and may continue to achieve, product commercialization before our products are approved for marketing and sale.

Genentech has an approved VEGF antagonist, Avastin, on the market for treating certain cancers and many different pharmaceutical and biotechnology companies are working to develop competing VEGF antagonists, including Novartis, Amgen, Imclone LLC/Eli Lilly and Company, Pfizer, AstraZeneca, and GlaxoSmithKline. Many of these molecules are farther along in development than aflibercept and may offer competitive advantages over our molecule. Each of Pfizer and Onyx Pharmaceuticals, (together with its partner Bayer HealthCare) has received approval from the FDA to market and sell an oral medication that targets tumor cell growth and new vasculature formation that fuels the growth of tumors. The marketing approvals for Genentech's VEGF antagonist, Avastin, and their extensive, ongoing clinical development plan for Avastin in other cancer indications, make it more difficult for us to enroll patients in clinical trials to support aflibercept and to obtain regulatory approval of aflibercept in these cancer settings. This may delay or impair our ability to successfully develop and commercialize aflibercept. In addition, even if aflibercept is ever approved for sale for the treatment of certain cancers, it will be difficult for our drug to compete against Avastin (Genentech) and the FDA approved kinase inhibitors, because doctors and patients will have significant experience using these medicines. In addition, an oral medication may be considerably less expensive for patients than a biologic medication, providing a competitive advantage to companies that market such products.

The market for eye disease products is also very competitive. Novartis and Genentech are collaborating on the commercialization and further development of a VEGF antibody fragment, Lucentis (Genentech), for the treatment of age-related macular degeneration (wet AMD), DME, and other eye indications. Lucentis (Genentech) was approved by the FDA in June 2006 for the treatment of wet AMD. In addition, in June 2010, Lucentis (Genentech) was approved by the FDA for the treatment of macular edema because of a blockage in a retinal vein. Many other companies are working on the development of product candidates for the potential treatment of wet AMD and DME that act by blocking VEGF and VEGF receptors, and through the use of small interfering ribonucleic acids (siRNAs) that modulate gene expression. In addition, ophthalmologists are using off-label, with success for the treatment of wet AMD, a third-party repackaged version of Genentech's approved VEGF antagonist, Avastin.

The National Eye Institute and others are conducting long-term, controlled clinical trials comparing Lucentis (Genentech) to Avastin (Genentech) in the treatment of wet AMD. Data from these trials are expected in 2011. Even if VEGF Trap-Eye is ever approved for sale for the treatment of eye diseases, it may be difficult for our drug to compete against Lucentis (Genentech), because doctors and patients will have significant experience using this medicine. Moreover, the relatively low cost of therapy with Avastin (Genentech) in patients with wet AMD presents a significant competitive challenge in this indication. While we believe that aflibercept would not be well tolerated if administered directly to the eye, if aflibercept is ever approved for the treatment of certain cancers, there is a risk that third parties will attempt to repackage aflibercept for use and sale for the treatment of wet AMD and other diseases of the eye, which would present a potential low-cost competitive threat to the VEGF Trap-Eye if it is ever approved for sale.

The availability of highly effective FDA approved TNF-antagonists such as Enbrel (Amgen and Wyeth), Remicade (Centocor), Humira® (adalimumab), marketed by Abbott, and SimponiTM (golimumab), marketed by Centocor, and the IL-1 receptor antagonist Kineret (Biovitrum), and other marketed therapies makes it more difficult to successfully develop and commercialize ARCALYST® in other indications, and this is one of the reasons we discontinued the development of ARCALYST® in adult rheumatoid arthritis. In addition, even if ARCALYST® is ever approved for sale in indications where TNF-antagonists are approved, it will be difficult for our drug to compete against these FDA approved TNF-antagonists because doctors and patients will have significant experience using these effective medicines. Moreover, in such indications these approved therapeutics may offer competitive advantages over ARCALYST®, such as requiring fewer injections.

There are both small molecules and antibodies in development by other companies that are designed to block the synthesis of interleukin-1 or inhibit the signaling of interleukin-1. For example, Eli Lilly, Xoma Ltd., and Novartis are each developing antibodies to interleukin-1 and Amgen is developing an antibody to the interleukin-1 receptor. Novartis received marketing approval for its IL-1 antibody for the treatment of CAPS from the FDA in June 2009 and from the European Medicines Agency in October 2009. Novartis is also developing this IL-1 antibody in gout and other inflammatory diseases. Novartis' IL-1 antibody and these other drug candidates could offer competitive advantages over ARCALYST®. For example, Novartis' IL-1 antibody is dosed once every eight weeks compared to the once-weekly dosing regimen for ARCALYST®. The successful development and/or commercialization of these competing molecules could impair our ability to successfully commercialize ARCALYST®.

We are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. In October 2009, Novartis announced positive Phase 2 results showing that canakinumab is more effective than an injectable corticosteroid at reducing pain and preventing recurrent attacks or "flares" in patients with hard-to-treat gout. Novartis' IL-1 antibody is dosed less frequently for the treatment of CAPS and may be perceived as offering competitive advantages over ARCALYST® in gout by some physicians, which would make it difficult for us to successfully commercialize ARCALYST® in that disease.

Currently, inexpensive, oral therapies such as analgesics and other non-steroidal anti-inflammatory drugs are used as the standard of care to treat the symptoms of gout diseases. These established, inexpensive, orally delivered drugs will make it difficult for us to successfully commercialize ARCALYST® in these diseases.

The successful commercialization of ARCALYST® and our product candidates will depend on obtaining coverage and reimbursement for use of these products from third-party payers and these payers may not agree to cover or reimburse for use of our products.

Our product candidates, if commercialized, may be significantly more expensive than traditional drug treatments. For example, we are developing ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. Patients suffering from this gout indication are currently treated with inexpensive therapies, including non-steroidal anti-inflammatory drugs. These existing treatment options are likely to be considerably less expensive and may be preferable to a biologic medication for some patients. Our future revenues and profitability will be adversely affected if United States and foreign governmental, private third-party insurers and payers, and other third-party payers, including Medicare and Medicaid, do not agree to defray or reimburse the cost of our products to the patients. If these entities refuse to provide coverage and reimbursement with respect to our products or provide an insufficient level of coverage and reimbursement, our products may be too costly for many patients to afford them, and physicians may not prescribe them. Many third-party payers cover only selected drugs, making drugs that are not preferred by such payers more expensive for patients, and require prior authorization or failure on another type of treatment before covering a particular drug. Payers may especially impose these obstacles to coverage on higher-priced drugs, as our product candidates are likely to be.

We market and sell ARCALYST® in the United States for the treatment of a group of rare genetic disorders called CAPS. We have received European Union marketing authorization for rilonacept for the treatment of CAPS. There may be too few patients with CAPS to profitably commercialize ARCALYST®. Physicians may not prescribe ARCALYST®, and CAPS patients may not be able to afford ARCALYST®, if third party payers do not agree to reimburse the cost of ARCALYST® therapy and this would adversely affect our ability to commercialize ARCALYST® profitably.

In addition to potential restrictions on coverage, the amount of reimbursement for our products may also reduce our profitability. Government and other third-party payers are challenging the prices charged for healthcare products and increasingly limiting, and attempting to limit, both coverage and level of reimbursement for prescription drugs. In March 2010, the Patient Protection and Affordable Care Act, or PPACA, and a related reconciliation bill were enacted in the U.S. This legislation imposes cost containment measures that are likely to adversely affect the amount of reimbursement for our future products. The full effects of this legislation are unknown at this time and will not be known until regulations and guidance are issued by the Centers for Medicare and Medicaid Services and other federal and state agencies. Some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future that will impose additional constraints on prices and reimbursements for our products.

Since ARCALYST® and our product candidates in clinical development will likely be too expensive for most patients to afford without health insurance coverage, if our products are unable to obtain adequate coverage and reimbursement by third-party payers our ability to successfully commercialize our product candidates may be adversely impacted. Any limitation on the use of our products or any decrease in the price of our products will have a material adverse effect on our ability to achieve profitability.

In certain foreign countries, pricing, coverage, and level of reimbursement of prescription drugs are subject to governmental control, and we may be unable to negotiate coverage, pricing, and reimbursement on terms that are favorable to us. In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Our results of operations may suffer if we are unable to market our products in foreign countries or if coverage and reimbursement for our products in foreign countries is limited or delayed.

Risk Related to Employees

We are dependent on our key personnel and if we cannot recruit and retain leaders in our research, development, manufacturing, and commercial organizations, our business will be harmed.

We are highly dependent on certain of our executive officers. If we are not able to retain any of these persons or our Chairman, our business may suffer. In particular, we depend on the services of P. Roy Vagelos, M.D., the Chairman of our board of directors, Leonard Schleifer, M.D., Ph.D., our President and Chief Executive Officer, George D. Yancopoulos, M.D., Ph.D., our Executive Vice President, Chief Scientific Officer and President, Regeneron Research Laboratories, and Neil Stahl, Ph.D., our Senior Vice President, Research and Development Sciences. There is intense competition in the biotechnology industry for qualified scientists and managerial personnel in the development, manufacture, and commercialization of drugs. We may not be able to continue to attract and retain the qualified personnel necessary for developing our business.

Risks Related to Our Common Stock

Our stock price is extremely volatile.

There has been significant volatility in our stock price and generally in the market prices of biotechnology companies' securities. Various factors and events may have a significant impact on the market price of our Common Stock. These factors include, by way of example:

- progress, delays, or adverse results in clinical trials;
- announcement of technological innovations or product candidates by us or competitors;
- fluctuations in our operating results;
- third party claims that our products or technologies infringe their patents;
- public concern as to the safety or effectiveness of ARCALYST® or any of our product candidates;
- developments in our relationship with collaborative partners;
- developments in the biotechnology industry or in government regulation of healthcare;
- large sales of our common stock by our executive officers, directors, or significant shareholders;
- arrivals and departures of key personnel; and
- general market conditions.

The trading price of our Common Stock has been, and could continue to be, subject to wide fluctuations in response to these and other factors, including the sale or attempted sale of a large amount of our Common Stock in the market. Broad market fluctuations may also adversely affect the market price of our Common Stock.

Future sales of our Common Stock by our significant shareholders or us may depress our stock price and impair our ability to raise funds in new share offerings.

A small number of our shareholders beneficially own a substantial amount of our Common Stock. As of September 30, 2010, our six largest shareholders plus Leonard Schleifer, M.D., Ph.D., our Chief Executive Officer, beneficially owned 62.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2010. As of September 30, 2010, sanofi-aventis beneficially owned 14,799,552 shares of Common Stock, representing approximately 18.5% of the shares of Common Stock then outstanding. Under our investor agreement, as amended, with sanofi-aventis, sanofi-aventis may not sell these shares until December 20, 2017 except under limited circumstances and subject to earlier termination of these restrictions upon the occurrence of certain events. Notwithstanding these restrictions, if sanofi-aventis, or our other significant shareholders or we, sell substantial amounts of our Common Stock in the public market, or the perception that such sales may occur exists, the market price of our Common Stock could fall. Sales of Common Stock by our significant shareholders, including sanofi-aventis, also might make it more difficult for us to raise funds by selling equity or equity-related securities in the future at a time and price that we deem appropriate.

Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval.

Holders of Class A Stock, who are generally the shareholders who purchased their stock from us before our initial public offering, are entitled to ten votes per share, while holders of Common Stock are entitled to one vote per share. As of September 30, 2010, holders of Class A Stock held 21.4% of the combined voting power of all shares of Common Stock and Class A Stock then outstanding. These shareholders, if acting together, would be in a position to significantly influence the election of our directors and to effect or prevent certain corporate transactions that require majority or supermajority approval of the combined classes, including mergers and other business combinations. This may result in our taking corporate actions that other shareholders may not consider to be in their best interest and may affect the price of our Common Stock. As of September 30, 2010:

- our current executive officers and directors beneficially owned 13.6% of our outstanding shares of Common Stock, assuming conversion of their Class A Stock into Common Stock and the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2010, and 28.0% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by such persons which are exercisable within 60 days of September 30, 2010; and
- our six largest shareholders plus Leonard S. Schleifer, M.D., Ph.D. our Chief Executive Officer, beneficially owned 62.5% of our outstanding shares of Common Stock, assuming, in the case of our Chief Executive Officer, the conversion of his Class A Stock into Common Stock and the exercise of all options held by him which are exercisable within 60 days of September 30, 2010. In addition, these seven shareholders held 65.5% of the combined voting power of our outstanding shares of Common Stock and Class A Stock, assuming the exercise of all options held by our Chief Executive Officer which are exercisable within 60 days of September 30, 2010.

Pursuant to an investor agreement, as amended, sanofi-aventis has agreed to vote its shares, at sanofi-aventis' election, either as recommended by our board of directors or proportionally with the votes cast by our other shareholders, except with respect to certain change of control transactions, liquidation or dissolution, stock issuances equal to or exceeding 10% of the then outstanding shares or voting rights of Common Stock and Class A Stock, and new equity compensation plans or amendments if not materially consistent with our historical equity compensation practices.

The anti-takeover effects of provisions of our charter, by-laws, and of New York corporate law and the contractual "standstill" provisions in our investor agreement with sanofi-aventis, could deter, delay, or prevent an acquisition or other "change in control" of us and could adversely affect the price of our Common Stock.

Our amended and restated certificate of incorporation, our by-laws, and the New York Business Corporation Law contain various provisions that could have the effect of delaying or preventing a change in control of our company or our management that shareholders may consider favorable or beneficial. Some of these provisions could discourage proxy contests and make it more difficult for shareholders to elect directors and take other corporate actions. These provisions could also limit the price that investors might be willing to pay in the future for shares of our Common Stock. These provisions include:

- authorization to issue "blank check" preferred stock, which is preferred stock that can be created and issued by the board of directors without prior shareholder approval, with rights senior to those of our common shareholders;
- a staggered board of directors, so that it would take three successive annual meetings to replace all of our directors;
- a requirement that removal of directors may only be effected for cause and only upon the affirmative vote of at least eighty percent (80%) of the outstanding shares entitled to vote for directors, as well as a requirement that any vacancy on the board of directors may be filled only by the remaining directors;
- any action required or permitted to be taken at any meeting of shareholders may be taken without a meeting, only if, prior to such action, all of our shareholders consent, the effect of which is to require that shareholder action may only be taken at a duly convened meeting;
- any shareholder seeking to bring business before an annual meeting of shareholders must provide timely notice of this intention in writing and meet various other requirements; and
- under the New York Business Corporation Law, in addition to certain restrictions which may apply to "business combinations" involving the Company and an "interested shareholder", a plan of merger or consolidation of the Company must be approved by two-thirds of the votes of all outstanding shares entitled to vote thereon. See the risk factor immediately above captioned "Our existing shareholders may be able to exert significant influence over matters requiring shareholder approval."

Until the later of the fifth anniversaries of the expiration or earlier termination of our antibody collaboration agreements with sanofi-aventis or our aflibercept collaboration with sanofi-aventis, sanofi-aventis will be bound by certain "standstill" provisions, as amended, which contractually prohibit sanofi-aventis from acquiring more than certain specified percentages of our Class A Stock and Common Stock (taken together) or otherwise seeking to obtain control of the Company.

In addition, we have a Change in Control Severance Plan and our Chief Executive Officer has an employment agreement that provides severance benefits in the event our officers are terminated as a result of a change in control of the Company. Many of our stock options issued under our Amended and Restated 2000 Long-Term Incentive Plan may become fully vested in connection with a "change in control" of our company, as defined in the plan. These contractual provisions may also have the effect of deterring, delaying, or preventing an acquisition or other change in control.

ITEM 6. EXHIBITS

(a) Exhibits

Exhibit

Number Description
10.1* Amendment to the Non Exclusive License and Material Transfer Agreement, dated as of March 30, 2007 by and between
Astellas Pharma Inc. and the Registrant, dated as of July 28, 2010
- Certification of CEO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.
31.2 Certification of CFO pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934
- Certification of CEO and CFO pursuant to 18 U.S.C. Section 1350.
101 - Interactive Data File
101.INS - XBRL Instance Document
101 SCH - XBRL Taxonomy Extension Schema
101.CAL - XBRL Taxonomy Extension Calculation Linkbase
101 LAB - XBRL Taxonomy Extension Label Linkbase 101.PRE - XBRL Taxonomy Extension Presentation Linkbase
101 DEF - XBRL Taxonomy Extension Definition Document

^{*} Portions of this document have been omitted and filed separately with the Commission pursuant to a request for confidential treatment pursuant to Rule 24b-2.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

Date: October 28, 2010 By: /s/ MURRAY A. GOLDBERG

Murray A. Goldberg Senior Vice President, Finance & Administration, Chief Financial Officer, Treasurer, and Assistant Secretary (Principal Financial Officer and

Duly Authorized Officer)

Exhibit 10.1
Portions of this Exhibit Have Been
Omitted and Separately Filed with the Securities
And Exchange Commission with a Request
For Confidential Treatment

Amendment to the Non-Exclusive License and Material Transfer Agreement dated as of March 30, 2007

This Amendment ("<u>Amendment</u>"), dated as of July 28, 2010 (the "<u>Amendment Effective Date</u>"), is by and between Astellas Pharma Inc. ("<u>Company</u>"), a Japanese company with a principal place of business located at 2-3-11 Nihonbashi-Honcho, Chuo-ku, Tokyo 103-8411, Japan and Regeneron Pharmaceuticals, Inc. ("<u>Regeneron</u>"), a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

WHEREAS, Company and Regeneron (collectively, the "Parties") entered into a Non-Exclusive License and Material Transfer Agreement, dated as of March 30, 2007 (the "Original Agreement"); and

WHEREAS, the Parties now desire to amend the Original Agreement to extend the term of the Original Agreement and make such other amendments to the terms of the Original Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the premises and mutual agreements set forth in the Original Agreement and this Amendment and for other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. <u>Definitions</u>. Capitalized terms used herein and not otherwise defined in this Amendment shall have the meanings ascribed to them in the Original Agreement.

Section 1.25 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"1.25 "Progeny" shall mean any mice that are produced or developed by or on behalf of Astellas in accordance with the terms of this Agreement by breeding or otherwise reproducing Mice delivered to it pursuant to Article III."

Section 1.27 of the Original Agreement is hereby deleted in its entirety and replaced with the following:

"1.27 "Regeneron Patent Rights" shall mean all Patent Rights owned or Controlled by Regeneron and/or its Affiliates during the term of this Agreement, which claim the Mice, Mice Materials or Mice Inventions or the use of the Mice, Mice Materials or Mice Inventions to make Antibodies in general, including, without limitation, the Patent Rights that are listed in Exhibit B. For the avoidance of doubt, Regeneron Patent Rights shall not include (i) any Patent Rights claiming methods relating to Antibody or Antibody Material generation that are not directly related to the Mice or Mice Materials and (ii) any Patent Rights claiming the use of Mice or Mice Materials to make Antibodies against any specific target. For the avoidance of doubt, Regeneron Patent Rights shall include any Patent Rights which Regeneron acquired from a Third Party to the extent included in this Agreement pursuant to Section 2.5, during the term of the Agreement."

2.	<u>Amendment to Section 3.4</u> . The fifth sentence of Section 3.4 of the Original Agreement is hereby deleted in its entirety and replaced with the following:
	··************************************

3.

"Company shall pay Regeneron one hundred sixty-five million United States dollars (US\$165,000,000) on or before August 31, 2010 ("<u>Up-Front Payment</u>"). In addition, Company shall pay Regeneron one hundred thirty million United States dollars (US\$130,000,000) on or before June 7, 2018, the eleventh anniversary of the Transfer Date (the "<u>Second Payment</u>"), unless this Agreement shall have been terminated prior to June 7, 2018 in accordance with Section 9.2. All payments to be made pursuant to this Section 4.1 shall be made by bank wire transfer in immediately available funds to an account designated by Regeneron."

Amendment to Section 4.1. Section 4.1 of the Original Agreement is hereby deleted and void in its entirety and replaced with the following:

For the avoidance of doubt, Company shall no longer be liable for the Adjusted Annual Fee which Company should pay on each of the fourth and fifth anniversaries of the Transfer Date under the Original Agreement.

- 4. <u>Amendment to EXHIBIT B</u>: Exhibit B of the Original Agreement is hereby deleted in its entirety and replaced with Exhibit B annexed to this Amendment.
- 5. Amendments to Section 5.2: The phrase of "as of the Effective Date" used in Section 5.2(g) and (k) in Section 5.2 of the Original Agreement is hereby deleted in its entirety and replaced with the phrase of "as of the Amendment Effective Date". The last sentence of Section 5.2 is hereby deleted in its entirety and replaced with the sentence "For purposes hereof, 'to its knowledge' shall mean actual knowledge as of the Amendment Effective Date with no duty of inquiry or investigation."

- 6. Amendment to Section 9.1. Section 9.1 of the Original Agreement is hereby deleted in its entirety and replaced with the following:
 - "Term. The term of this Agreement shall commence on the Effective Date and shall expire on June 7, 2023, the sixteenth anniversary of the Transfer Date, unless earlier terminated under the terms of this Agreement. For the avoidance of doubt, Company shall have the right to terminate this Agreement without cause upon written notice to Regeneron in accordance with Section 9.2(a). For the further avoidance of doubt, Company's obligation to pay royalties to Regeneron under Section 4.2 survives the expiration or termination of this Agreement in accordance with the terms of Article IV and Section 9.5."
- 7. Amendment to Section 9.2(a): Section 9.2(a) of the Original Agreement is hereby deleted in its entirety and replaced with the following:
 - "Convenience. Company may elect to terminate this Agreement at any time by providing ninety (90) days' prior written notice to Regeneron. If such notice is sent with an effective date of termination prior to June 7, 2018, then Company shall not be required to make the Second Payment to Regeneron."
- 8. Amendment to Section 9.4: Section 9.4 of the Original Agreement is hereby amended as follows:
 - (i) The third sentence of Section 9.4(a) is hereby deleted and void in its entirety.
 - (ii) The following shall be added to the end of Section 9.4 as a new Section 9.4(e):
 - "(e) Upon termination of this Agreement by Company in accordance with Section 9.2(b) or 9.2(d), (i) Company shall not be required to make any further payments to Regeneron under Section 4.1, except that neither Party shall be relieved of any obligations arising prior to such termination, including any payment obligations which arose and are due with respect to any period prior to such termination and (ii) Regeneron shall return to Astellas part of the Up-Front Payment or Second Payment paid to Regeneron under Section 4.1 based on a pro-rata basis as calculated using the formula set forth below." All payments to be made pursuant to this Section 9.4(e) shall be made by bank wire transfer in immediately available funds to an account designated by Astellas.
 - *In the event such termination occurs before the 11th anniversary of the Transfer Date:
 - =Up-Front Payment (US\$165M) x (the number of years from the next anniversary of the Transfer Date following such termination until the 11th anniversary of the Transfer Date/7)

- *In the event such termination occurs on and after the 11th anniversary date of the Transfer Date:
- =Second Payment (US\$130M) x (the number of years from the next anniversary of the Transfer Date following such termination until the 16th anniversary of the Transfer Date/5)"
- 9. <u>Press Release</u>. The Parties shall both issue a press release on the Amendment Effective Date with respect to the execution of this Amendment in the form annexed hereto as Exhibit A.
- 10. <u>Term.</u> This Amendment shall become effective on the Amendment Effective Date and be in force until the later to occur of the expiration or earlier termination of the Original Agreement.
- 11. Continuing Effect. Except as specifically modified in this Amendment, all of the terms of the Original Agreement shall remain in full force and
- 12. <u>Entire Agreement</u>. The Original Agreement, as modified by, and together with, this Amendment, is the entire agreement between the Parties with respect to the subject matter of the Original Agreement, provided that, in the event of a conflict between the terms of the Original Agreement and the terms of this Amendment, the terms of this Amendment control.
- 13. <u>Counterparts</u>; <u>Facsimile Signatures</u>. This Amendment may be executed in counterparts, each of which shall be deemed an original but which together shall constitute one and the same instrument. Signatures provided by facsimile or other electronic transmission shall be deemed to be original signatures.
- 14. Governing Law; Submission to Jurisdiction. This Amendment shall be construed and the respective rights of the Parties determined according to the substantive laws of the State of New York notwithstanding any provisions governing conflict of laws under such New York law to the contrary and without giving effect to the United States Convention on Contracts for the International Sale of Goods. Section 10.4 of the Original Agreement shall be deemed incorporated into and made a part of this Amendment.

IN WITNESS WHEREOF, the Parties have executed and delivered this Amendment in accordance with Section 10.8 of the Original Agreement as of the Amendment Effective Date.

ASTELLAS PHARMA INC.

By: /s/ Shinichi Tsukamoto

Name: Shinichi Tsukamoto Title: Senior Corporate Executive, Drug Discovery Research

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray Goldberg

Name: Murray A. Goldberg

Title: Senior Vice President, Finance & Administration and Chief Financial Officer

EXHIBIT A

[LOGOS]

FOR IMMEDIATE RELEASE

Press Release

Astellas to Pay \$295 Million to Extend License of Regeneron's VelocImmune® Antibody Technology through 2023

Tarrytown, NY and Tokyo, Japan – (**July XX, 2010**) – Regeneron Pharmaceuticals, Inc. ("Regeneron"; Nasdaq: **REGN**) and Astellas Pharma Inc. ("Astellas"; Headquarters: Tokyo, Japan; President & CEO: Masafumi Nogimori) announced today that Astellas has extended through 2023 the non-exclusive license agreement that allows Astellas to utilize Regeneron's *VelocImmune*® technology in its internal research programs to discover fully human monoclonal antibody product candidates.

Astellas will pay \$165 million upfront and another \$130 million in June 2018 unless it terminates the agreement prior to that date. Upon commercialization of any antibody products discovered utilizing *VelocImmune*, Astellas will pay a mid-single-digit royalty on product sales.

In March 2007, Astellas and Regeneron entered into a six-year *VelocImmune* license agreement pursuant to which Astellas made license payments of \$20 million per year in 2007 through 2010. This amendment supersedes the original agreement and as such, Astellas will no longer make annual license payments in 2011 and 2012. Approximately 20 monoclonal antibody projects using *VelocImmune* technology are ongoing at Astellas and Agensys, Inc., a U.S. affiliate of Astellas.

"VelocImmune is the centerpiece of Regeneron's suite of technologies for the discovery and development of fully human monoclonal antibodies," said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories and Regeneron's Chief Scientific Officer. "We are pleased that Astellas, a company with a clear strategic commitment to developing therapeutic antibodies, has elected to continue to utilize the VelocImmune platform for its internal development programs."

"We are excited about this extension of the license agreement with Regeneron," said Shinichi Tsukamoto, Ph.D., Astellas' Senior Vice President, Drug Discovery Research. "As described in our recently announced mid-term management plan toward FY2014, Astellas is putting the highest strategic priority on the development of antibody drugs, and *VelocImmune* will continue to be the indispensable technology for our antibody drug development program."

VelocImmune

Regeneron's *VelocImmune* technology offers the potential to increase dramatically the speed and efficiency of discovering fully-human, therapeutic monoclonal antibodies. The *VelocImmune* platform generates fully human monoclonal antibodies (hMAbs) to address clinically relevant targets of therapeutic interest. The *VelocImmune* mouse, unlike other hMAb mice, mounts a robust immune response that is virtually indistinguishable from that of a wild type mouse, resulting in a reliable and efficient platform for discovering fully human monoclonal antibodies.

About Astellas

Astellas Pharma Inc., located in Tokyo, Japan, is a pharmaceutical company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. Astellas has approximately 15,000 employees worldwide. The organization is committed to becoming a global category leader by rapidly establishing a business model in urology, immunology & infectious diseases, neuroscience, DM complications & metabolic diseases and oncology. Astellas has discovered a treatment for over-active bladder (OAB), Vesicare® (solifenacin succinate) and an immunosuppressant, Prograf® (tacrolimus), which have enabled Astellas to become an established leader in both Urology and Transplant. For more information on Astellas Pharma Inc., please visit Astellas' website at http://www.astellas.com/en.

About Regeneron Pharmaceuticals

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration and central retinal vein occlusion), and certain cancers. Additional therapeutic candidates developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates, uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any license or collaboration agreement, including Regeneron's agreements with Astellas, the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. A more complete description of these and other material risks can be found in Regeneron's filings with the United States Securities and Exchange Commission (SEC), including its Form 10-K for the year ended December 31, 2009 and Form 10-Q for the quarter ended March 31, 2010. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, unless required by law.

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Contact Information:

Astellas

Corporate Communications

Tel: +81-3-3244-3201 Fax: +81-3-5201-7473

http://www.astellas.com/en

Regeneron

Michael Aberman, M.D. Investor Relations 914.345.7799 michael.aberman@regeneron.com Peter Dworkin
Corporate Communications
914.345.7640
peter.dworkin@regeneron.com

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EXHIBIT B

REGENERON PATENT RIGHTS

Patent No.: 6,586,251 USSN: 09/732,234

Inventors: Economides, Murphy, Valenzuela, Yancopoulos

Title: Methods of Modifying Eukaryotic Cells

Filing Date: 7 December 2000

Patent No.: 6,596,541 USSN: 09/784,859 PCT: 2003/6275

Inventors: Murphy, Yancopoulos

Title: Methods of Modifying Eukaryotic Cells

Filing Date: 16 February 2001 (continuation-in-part of 09/732,234)

Patent No.: 7,105,348 USSN: 10/076,840

Inventors: Murphy, Yancopoulos

Title: Methods of Modifying Eukaryotic Cells

Filing Date: 15 February 2002

780D AU Patent No. 2002244023

Granted 23 August 2007

780D IN Patent No. 234335

Granted 25 May 2009

780D JP Patent No. 4412900

Granted 27 November 2009

780D NZ Patent No. 527629

Granted 7 July 2005

780D SG Patent No. 100103

Granted 30 November 2005

780D ZA Patent No. 2003/6275

Granted 27 October 2004

Certification of CEO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Leonard S. Schleifer, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make
 the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered
 by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about
 the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such
 evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 28, 2010 /s/ Leonard S. Schleifer-

Leonard S. Schleifer, M.D., Ph.D.

President and Chief Executive Officer

Certification of CFO Pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

- I, Murray A. Goldberg, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Regeneron Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(f)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about
 the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such
 evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 28, 2010 /s/ MURRAY A. GOLDBERG

Murray A. Goldberg
Senior Vice President, Finance & Administration,
Chief Financial Officer, Treasurer, and
Assistant Secretary

Certification of CEO and CFO Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report of Regeneron Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended September 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Leonard S. Schleifer, M.D., Ph.D., as Chief Executive Officer of the Company, and Murray A. Goldberg, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to the best of his knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Leonard S. Schleifer

Leonard S. Schleifer, M.D., Ph.D. Chief Executive Officer October 28, 2010

/s/ Murray A. Goldberg

Murray A. Goldberg Chief Financial Officer October 28, 2010

Lexis* Securities Mosaic*

Company: REGENERON PHARMACEUTICALS INC

Form Type: 10-Q

Filing Date: 5/3/2011

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

Form 10-Q

(X)	(Mark One) QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the quarterly period ended March 31, 2011
	OR
()	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the transition period from to
	Commission File Number 0-19034
	REGENERON PHARMACEUTICALS, INC.
	(Exact name of registrant as specified in its charter)
	<u>New York</u> 13-3444607
	(State or other jurisdiction of (I.R.S. Employer Identification No.)
	incorporation or organization)
	777 Old Saw Mill River Road
	Tarrytown, New York <u>10591-6707</u>
	(Address of principal executive offices) (Zip Code)
	(Registrant's telephone number, including area code)
	ate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or fo shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
	Yes X No
	ate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuan le 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
	Yes X No
	ate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.
Large	accelerated filer X Accelerated filer
Non-	accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Indic	ate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No X
Num	per of shares outstanding of each of the registrant's classes of common stock as of April 13, 2011:
	<u>Class of Common Stock</u> <u>Number of Shares</u>
	Class A Stock, \$0.001 par value 2,151,854
	Common Stock, \$0.001 par value 88,739,294

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PART I. FINANCIAL INFORMATION ITEM 1. FINANCIAL STATEMENTS

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS AT MARCH 31, 2011 AND DECEMBER 31, 2010 (Unaudited)

(In thousands, except share data)

ASSETS	March 31, 2011	December 31, 2010
Carrient assers Cash and cash equivalents	\$ 135,376	\$ 112,572
Marketable securities Accounts receivable from the sanofi-aventis Group	91.965 84,391	112,572 136,796 79,603
Accounts receivable - other	3763	11,509
Prepaid expenses and other current assets Fotal current assets	10,904 325,501	15,142 357,622
Restricted cash and marketable securities	7,520	7.518
Marketable securities Property: plant, and equipment, af cust, net of accumulated depreciation and amortization	373,621 357,423	370,053 347,4 5 0
Other assets Fotal assets	10,228 \$ 1,074,293	6,789 1,089,432
LIABILITIES and STOCKHOLDERS' FOUTY Current liabilities		
Accounts payable and accrued expenses Deferred revenue from sanofi-aventis, current portion	\$ 58.602 19,561	\$ \$3.6 58 19,506
Deferred revenue - other current portion Facility lease obligations, current portion Total current liabilities	#3 29 l 798 #12 25 2	35 217 675 109,036
Deferred revenue from sanofr-avents	94 398	97.081
Deferred revenue - other Facility lease obligations Other long term liabilities	183,019 1 59,333 7,180	188,775 159,35 8 7,350
Total listoitties	\$56,202	561,617
Commitments and contingencies		
Stockholders' equity Preferred stock, \$.01 par value; 30,000,000 shares authorized; issued and		
outstanding - none Class A Stock, convenible, \$ 001 per value; 40,000,000 shares autherized, shares assed and outstanding + 2,182,056 in 2011 and 2010 Common Stock, \$ 001 per value; 160,000,000 shares authorized;	2	*
shares issued and outstanding - 88,548,041 in 2011 and 87,238,301 in 2010 Additional paid-incapping	89 £609.185	87 1575 780
Accumulated deficit Accumulated other comprehensive toss	(1,089,010)	(1,045,563)
Total stockholders' equity Total lutritues and stockholders' equity	518,091 \$ 1,074,293	527,815 \$ 1.089.432
The accompanying notes are an integral part of the financial statements.		

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REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited) (In thousands, except per share data)

	Three months e	nded March 31,
	2011	2010
Revenues		
Sanofi-aventis collaboration revenue	\$ 85,329	\$ 68,671
Other collaboration revenue	12.481	11,087
Technology licensing	7,845	10,038
Net product sales	4.427	9,832
Contract research and other	2,122	1,886
	112,204	103,534
	·· <u>·····</u> ···	··· <u>·····</u>
Expenses		
Research and development	129,392	117,471
Selling general and advertigative	23,411	14.223
Cost of goods sold	382	717
Cost of goods sort	153.185	122,411
Loss fram operations	(40.981)	(28,877)
10.52 1.1111 (April 10.11)		···
Other income (expense)		
Investment income	1,037	439
Interest expense	(3.719)	(2,084)
	(2,682)	(1,645)
	(2,082)	(1,043)
Ner luss before meome tax benefit	(45.663)	(30,522)

Income tax benefit	(216)	
Net loss	% (43,447)	\$ (30,522)
Net less per share, basic and diduted	\$ (049)	\$ (0.38)
NET ILES DO SHATE. DOSSE AND LIMITED	(0.49)	
Weighted average shares outstanding: basic and diluted	89 162	81,169
The accompanying notes are an integral part of the financial statements.		
4		

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited) For the three months ended March 31, 2011 and 2010 (In thousands)

							Accumula
					Additional		Other
	Class A		Commo		Paid-in	Accumulated	Comprehe
Balance, December 31, 3919	Shares	Amount	Shares 87.218	Amount	Capital	Deficit \$ 11 ftg8 (63)	Income (1
Issuance of Common Stock in connection with			****************			****************	000000000000000000000000000000000000000
exercise of stock options, net of shares tendered			1,218	2	15,102		
ISSUANCE OF CHINARION AFFOR IN CHINACITON WITH COMPRISE HANGE SPACES Plans CHIRACITON			ž3		3,405		
Stock-based compensation charges				**********	14,898	******************	
Neclas:						(43,447)	
Change in net unrealized gain (loss) on marketable securities, net of tax effect of \$0.2 million							
Balance, March 31, 3111	2,182		88,548	<u> 89</u>	9 1,609,185	\$ (1:089,010)	
Spiners, December 31, 2009	2,245	8 2	78,861	\$ 79	\$ 1,336,732	\$ (941,099)	•
Issuance of Common Stock in connection with							
exercise of stock options, net of shares tendered	***********	************	685	1	8,656		
Issuing of Common Stock in connection #90 Company #0100- Sovings Plan-contribution			111		1867		
Conversion of Class A Stock to Common Stock Stock-Based an appendition of larges	(33)		33		8.834		
Net loss			*************			(30,522)	
Change striket susenbard solis (mas) na markandid summiss							
Belance: March 31, 2013			79.600	\$ 86	¥ 1.45°,088	\$ (\$71,637)	•
The accompanying notes are an integral part of the	ïnancial st	atements.					
5							

	Three months	ended March 31,
	2011	2010
Cash flows from operating activities Net loss	\$ (43,447)	\$ (30,522)
Adjustments to reconcile net loss to net eash used in operating petivities	3 (+3,+47)	\$ (30,322)
Depreciation and amortization Non-cish comparisation expense	6,978 14,801	4,183 8, 83 4
Other non-cash charges and expenses	582	544
Changes in assets and habilities		
Decrease (increase) in accounts receivable Decrease (increase) in prepaid expenses and other assets	4,956 2,28 6	(6,290) (2,483)
(Decrease) increase in deferred revenue	(10,310)	3,513
Increase in accounts payable, accrued expenses and other habilines	13,574	12,643
Total adjustments	32,867	20,944
Not cash used in operating octivities	(10.580)	(9.578)
Cash flows from investing activities		
Purchases of marketable securities Sales or maturities of marketable securities	(15,638) 58.151	(177,594) 63,936
Capital expenditures	(22,166)	(22,743)
Net cosh provided by (used in) investing activities	20,347	(136,401)
Cash flows from financing activities Proceeds in connection with facility lease obligations		47,544
Payments in connection with facility lease obligations	(89)	(555)
Net proceeds from the issuance of Common Stock	13,343	9,226
Previous in connection with capital lease obligation	(217)	5/ 015
Net cash provided by financing activities	13,037	56,215
Net increase (decrease) in cash and cash equivalents	22,804	(89.764)
Cash and cash equivalents at beginning of period	112,572	207,075
Cash and cash equivalents at end of period	135,776	117311
The accompanying notes are an integral part of the financial statements.		

REGENERON PHARMACEUTICALS, INC. Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

1. Interim Financial Statements

The interim Condensed Financial Statements of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") have been prepared in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and disclosures necessary for a presentation of the Company's financial position, results of operations, and cash flows in conformity with accounting principles generally accepted in the United States of America. In the opinion of management, these financial statements reflect all adjustments, consisting only of normal recurring accruals, necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for such periods. The results of operations for any interim periods are not necessarily indicative of the results for the full year. The December 31, 2010 Condensed Balance Sheet data were derived from audited financial statements, but do not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2010.

Certain reclassifications have been made to the financial statements for the three months ended March 31, 2010 to conform with the current period's presentation.

2. ARCALYST® (rilonacept) Product Revenue

In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration ("FDA") for ARCALYST® Injection for Subcutaneous Use for the treatment of Cryopyrin-Associated Periodic Syndromes ("CAPS"). The Company had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, the Company determined that it had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, \$4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. The effect of this change in estimate related to ARCALYST® net product sales revenue was to lower the Company's net loss per share by \$0.06 for the three months ended March 31, 2010.

ARCALYST® net product sales totaled \$4.4 million and \$9.9 million for the three months ended March 31, 2011 and 2010, respectively. ARCALYST® net product sales during the first three months of 2010 included \$5.1 million of net product sales made during this period and \$4.8 million of previously deferred net product sales, as described above. There was no deferred ARCALYST® net product sales revenue at March 31, 2011 or 2010.

Cost of goods sold related to ARCALYST® sales, which consisted primarily of royalties, totaled \$0.4 million and \$0.7 million for the three months ended March 31, 2011 and 2010, respectively. ARCALYST® shipments to the Company's customers primarily consisted of supplies of inventory manufactured and expensed as research and development costs prior to 2008; therefore, the costs of these supplies were not included in costs of goods sold.

3. Per Share Data

The Company's basic and diluted net loss per share amounts have been computed by dividing net loss by the weighted average number of shares of Common Stock and Class A Stock outstanding. Net loss per share is presented on a combined basis, inclusive of Common Stock and Class A Stock outstanding, as each class of stock has equivalent economic rights. For the three months ended March 31, 2011 and 2010, the Company reported net losses; therefore, no common stock equivalents were included in the computation of diluted net loss per share for these periods, since such inclusion would have been antidilutive. The calculations of basic and diluted net loss per share are as follows:

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Three Months E	nded March 31,
	2011	2010
Net loss (Numerator)	\$ (41,447)	\$ (30,522)
Weighted-everage shores, in thousands (Denominator)	89,162	81,169
Basic and differed uet loss per shore	\$ (0.49)	\$ (0.38)

Shares issuable upon the exercise of stock options and vesting of restricted stock awards, which have been excluded from the March 31, 2011 and 2010 diluted per share amounts because their effect would have been antidilutive, include the following:

	Three months end	ded March 31,
	2011	2010
Stock Options:		
Weighted average number, in thousands	22,378	21,400
Weighted average exercise price	\$ 20.36	\$ 18,59
Restricted Stock Weighted average number, in thousands	845	501

4. Statement of Cash Flows

Supplemental disclosure of noncash investing and financing activities:

Included in accounts payable and accrued expenses at March 31, 2011 and December 31, 2010 were \$5.7 million and \$10.7 million, respectively, of accrued capital expenditures. Included in accounts payable and accrued expenses at March 31, 2010 and December 31, 2009 were \$5.4 million and \$9.8 million, respectively, of accrued capital expenditures.

Included in accounts payable and accrued expenses at December 31, 2010 and 2009 were \$2.9 million and \$2.6 million, respectively, of accrued Company 401(k) Savings Plan contribution expense. In the first quarter of 2011 and 2010, the Company contributed 91,761 and 111,419 shares, respectively, of Common Stock to the 401(k) Savings Plan in satisfaction of these obligations.

Included in facility lease obligations and property, plant, and equipment at March 31, 2010 was \$0.8 million of capitalized and deferred interest for the quarter ended March 31, 2010, as the related facilities being leased by the Company were under construction and lease payments on these facilities did not commence until January 2011.

Included in other assets at March 31, 2011 and December 31, 2010 was \$1.9 million and \$0.2 million, respectively, due to the Company in connection with employee exercises of stock options.

Included in marketable securities at March 31, 2011 and December 31, 2010 were \$2.0 million and \$1.4 million, respectively, of accrued interest income. Included in marketable securities at March 31, 2010 and December 31, 2009 were \$1.3 million and \$0.6 million, respectively, of accrued interest income.

5. Marketable Securities

Marketable securities at March 31, 2011 and December 31, 2010 consisted of debt securities, as detailed below, and equity securities, the aggregate fair value of which was \$4.6 million and \$3.6 million at March 31, 2011 and December 31, 2010, respectively, and the aggregate cost basis of which was \$4.0 million at both March 31, 2011 and December 31, 2010. The Company also held restricted marketable securities at both March 31, 2011 and December 31, 2010, which consisted of debt securities, as detailed below, that collateralize (i) a letter of credit in connection with the Company's lease of facilities in Tarrytown, New York and (ii) capital lease obligations.

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

The following tables summarize the amortized cost basis of debt securities included in marketable securities, the aggregate fair value of those securities, and gross unrealized gains and losses on those securities at March 31, 2011 and December 31, 2010. The Company classifies its debt securities, other than mortgage-backed securities, based on their contractual maturity dates. Maturities of mortgage-backed securities have been estimated based primarily on repayment characteristics and experience of the senior tranches that the Company holds.

	Amortized	Fair		Unrealized	
At March 31, 2011	Cost Basis	Value	Gains	(Losses)	Net
Directricled					
Maturities within one year E.S. government obligations	\$ 38,551	\$ 38,593	\$ 42		S 42
U.S. government guaranteed corporate		***************************************			************
bonds	39,670	39,939	269		269
U.S. government guaranteed					
colleteralized montrage obligations	1,588	1 590	*		2
Municipal bonds Morgage backed securities	10,786 146	10,799 144	13	\$ (2)	13 (2)
wantengankan salamins	90,741	91.065	326	(2)	324
Manurities between one and five years	20,741	71,000	320	(2)	324
U.S. government obligations	348,753	346,784	10	(1,979)	(1,969)
U.S. government guaranteed corporate					
bonds	15.546	15,503		(43)	(43)
Municipal bonds	6,546	6,552	6		6
Maturities between five and six years	170,845	368.819	16	(2,922)	(2,006)
Mortange-hacked securities	281	144		(137)	(137)
	461,867	460,048	342	(2,161)	(1,819)
Restricted					
Maturities within one year	<u>.</u>			***************************************	
U.S. government obligarious	2,924	2,926			
Maturities between one and three years					
U.S. government obligations	4,138	4,115	~~~~~	(23)	(23)
	7,062	7.841		(23)	(21)
	\$ 468,929	\$ 467,089	\$ 344	\$ (2,184)	\$ (1,840)
At December 31, 2010	-				
Grestrated Maturities within one year					
U.S. government utiligations	5 83,615	\$ 83,684	\$ 54	5 (5)	\$ 49
U.S. government guaranteed corporate	•	•••••		•••••	•••••
bonds	48,173	48,531	358		358
U.S. government guaranteed	2,027	4.00	100		100
collainalized mongage obligations Municipal bonds	1,597	2,131 1,603	104 6		104 6
Managage-backed securities	1,577 875	1,003 847	, , ,	(28)	(28)
	136,307	136,796	522	(33)	489

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Amortized	Fair	Unrealized		
At December 31, 2010 (continued)	Cost Basis	Value	Gains	(Losses)	Net
Manurties between one and five years					
U.S. government obligations	352,345	350,683	64	(1,726)	(1,662)
U.S. government guarantzed corporate bonds	15,522	15.477		(45)	(45)
Мопgage-backed securities	110	38		(72)	(72)
	367.977	366,198	64	(1.843)	(1,779)
Maturities between five and seven years					
Mortgage-backed securities	284	243		(41)	(41)
	504,568	503,237	586	(1,917)	(1,331)
Restricted					
Maturities within one year					
U.S. government obligations	2,922	2,921		(1)	(1)
Maturities between one and three years	4,135	4,118		(17)	(17)
U.S. government obligations	4,133	7,939		183	(17)
	<u> </u>	<u>\$510.276</u>	\$ 586	\$ (1.935)	(1,149)

At March 31, 2011 and December 31, 2010, marketable securities included an additional unrealized gain of \$0.6 million and an unrealized loss of \$0.4 million, respectively, related to one equity security in the Company's marketable securities portfolio.

The following table shows the fair value of the Company's marketable securities that have unrealized losses and that are deemed to be only temporarily impaired, aggregated by investment category and length of time that the individual securities have been in a continuous unrealized loss position, at March 31, 2011 and December 31, 2010. The debt securities listed at March 31, 2011, excluding mortgage-backed securities, mature at various dates through December 2013. The mortgage-backed securities listed at March 31, 2011 mature at various dates through February 2017

Less than 1	12 Months	12 Months	or Greater	To	tal
	Unrealized		Unrealized		Unrealized
Fair Value	Loss	Fair Value	Loss	Fair Value	Loss
\$ 331,731	\$ (1,979)			\$ 331,731	\$ (1,979)
15,504	(43)			15,503	(43)
		\$ 288	\$ (139)	288	(139)
347,234	(2,022)	288	(139)	347,522	(2.161)
4,115	(23)			4,115	(23)
4,115	1231			4 115	(23)
\$ 381,349	\$ (2,045)	<u>* 188</u>	<u>\$ (139)</u>	5 351.637	5 (2,184)
	Fair Value \$ 331,731 13,503 347,234	Fair Value Loss \$ 331,731 \$ (1,979) 15,563 (43) 347,234 (2,022) 4,115 (23)	Unrealized Loss Fair Value	Unrealized Loss Fair Value Loss	Unrealized Loss Fair Value Loss Fair Value Loss Fair Value Loss Fair Value S 331,731 S (1,979) S 331,731 S (23) S 288 S (139) S 28

REGENERON PHARMACEUTICALS, INC.
Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Less than 12 Months		s than 12 Months 12 Months or Greate		12 Months or Greater Tot	
		Unrealized		Unrealized		Unrealized
At December 31, 2010	Fair Value	Loss	Fair Value	Loss	Fair Value	Loss
Sprestreted.						
U.S. government obligations	\$ 340,444	\$ (1,731)			\$ 340,444	\$ (1,731)
U.S. government guaranteed						
corporate bands	19,005	(422)			19,005	(400)
Equity securities	3,612	(433)			3,612	(433)
Morteage-backed securities	2/2.0/1	(2.200)	1 128	<u></u>	274 100	(141)
	363,061	(2,209)	1,128	(141)	364,189	(2,350)
Darkston /						
U.S. government obligations	6.154	(18)			6.154	(18)
0.3. government obligations	6.154	(18)			6.134	(10)
	······································	·			·	·····
	% 360.71%	\$ (2.227)	S 1.128	\$ (141)	\$ 370343	S. (2.368)
		<u></u>	***************************************	***************************************	· <u>*********</u> ***	200000000000000000000000000000000000000

Realized gains and losses are included as a component of investment income. For the three months ended March 31, 2011 and 2010, realized gains and losses on sales of marketable securities were not significant. In computing realized gains and losses, the Company computes the cost of its investments on a specific identification basis. Such cost includes the direct costs to acquire the security, adjusted for the amortization of any discount or premium.

The Company's assets that are measured at fair value on a recurring basis, at March 31, 2011 and December 31, 2010, were as follows:

		Fair Value Measurements at Reporting Date Using		
		Quoted Prices	Significant	
		in Active	Other	Significant
		Markets for	Observable	Unobservable
		Identical Assets	Inputs	Inputs
	Fair Value	(Level 1)	(Level 2)	(Level 3)
Essestrated				
Available-for-sale marketable securities U.S. governmen obligations S	965 499		6 704 777	
U.S. government guaranteed corporate			a	
bonds	55,442		55,442	
U.S. government guaranteed	33,772		33,442	
collateralized mortusers obligations	1.590		1.590	
Municipal bonds	17,351		17,351	***************************************
Моньгуу-Баскей securities	288		288	
Equity securities	4,638	\$ 4,638		
	464,686	4,638	460,048	
Restricted				
Available-for-sale marketable securities				
U.S. gavernment obligations	7,941		7941	
<u></u>	471,797	<u>\$ 4,638</u>	\$ 467,089	
11				

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	Fair	Fair Value Measurements at Reporting Date Using		
	Quo	ted Prices	Significant	
	ir	1 Active	Other	Significant
	Ma	irkets for	Observable	Unobservable
		tical Assets	Inputs	Inputs
At December 31, 2010 Fair Val	ue (I	Level 1)	(Level 2)	(Level 3)
arestressi.				
Available-for-sale marketable securities				
U.S. government obligations \$ 434.5	167		434,367	
U.S. government guaranteed corporate				
bonds 64,0	008		64,008	
U.S. government guaranteed collateratived mortgage obligations 2.1	131		2,131	
Municipal bonds l,6	503		1,603	
Mortgage-backeti securites	128		1,128	
Equity securities 3,6	512 \$	3,612		
5065	349	3,612	503,237	
Restricted				
Available-for-sale marketable securities				
U.S. government obligations	139		7,039	
<u>5 513,</u>	388 S	1612	510.276	

Marketable securities included in Level 2 were valued using a market approach utilizing prices and other relevant information, such as interest rates, yield curves, prepayment speeds, loss severities, credit risks and default rates, generated by market transactions involving identical or comparable assets. The Company considers market liquidity in determining the fair value for these securities. During the three months ended March 31, 2010, deterioration in the credit quality of a marketable security from one issuer subjected the Company to the risk of not being able to recover a portion of the security's \$1.1 million carrying value. As a result, the Company recognized a \$0.1 million impairment charge related to this Level 2 marketable security, which the Company considered to be other-than-temporarily impaired. The Company did not record any charges for other-than-temporary impairment of its Level 2 marketable securities during the three months ended March 31, 2011.

The Company holds one Level 3 marketable security, which had no fair value at March 31, 2011 and December 31, 2010. This Level 3 security was valued using information provided by the Company's investment advisors and other sources, including quoted bid prices which took into consideration the security's lack of liquidity. There were no purchases, sales, or maturities of Level 3 marketable securities and no unrealized gains or losses related to Level 3 marketable securities for the three months ended March 31, 2011 and 2010. There were no transfers of marketable securities between Levels 1, 2, or 3 classifications during the three months ended March 31, 2011 and 2010.

On a quarterly basis, the Company reviews its portfolio of marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below cost are other-than-temporary. With respect to debt securities, this review process also includes an evaluation of the Company's (a) intent to sell an individual debt security or (b) need to sell the debt security before its anticipated recovery or maturity. With respect to equity securities, this review process includes an evaluation of the Company's ability and intent to hold the securities until their full value can be recovered.

6. Inventory

Inventories as of March 31	, 2011 and December 31,	2010 consist of the following:
----------------------------	-------------------------	--------------------------------

REGENERON PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements (Unaudited)

(Unless otherwise noted, dollars in thousands, except per share data)

	March 31,	December 31,
	2011	2010
Raw materials	162	\$ 592
Work in process	3,634	699
Finished goods	85	132
	3,881	\$ 1,423

At March 31, 2011, \$0.1 million of inventories were included in prepaid expenses and other current assets and \$3.8 million of inventories were included in other assets. At December 31, 2010, inventories were included in prepaid expenses and other current assets.

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses as of March 31, 2011 and December 31, 2010 consist of the following:

	March 31,	December 31,
	2011	2010
Accounts payable	\$ 16,146	\$ 15.589
Accrued payroll and related costs	20,039	12,025
Accraed clinical trial expense	8,606	9.727
Accrued property, plant, and equipment costs	3,940	7,622
Other accrued expenses and liabilities	7,112	6441
Payable to Bayer HealthCare	2,759	2,254
		\$ 51,658

8. Income Taxes

For the three months ended March 31, 2011 and 2010, the Company incurred net losses for tax purposes and recognized a full valuation allowance against deferred tax assets. For the three months ended March 31, 2011, the Company recognized a \$0.2 million income tax benefit in connection with the net tax effect of the decrease in the Company's unrealized loss on "available-forsale" marketable securities, which is included in other comprehensive loss. For the three months ended March 31, 2010, no provision or benefit for income taxes was recorded.

9. Legal Matters

From time to time, the Company is a party to legal proceedings in the course of the Company's business. The Company does not expect any such current ordinary course legal proceedings to have a material adverse effect on the Company's business or financial condition. Legal costs associated with the Company's resolution of legal proceedings are expensed as incurred.

As previously reported, on November 19, 2010, the Company filed a complaint against Genentech, Inc. in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon the Company's submission to the FDA of a Biologics License Application ("BLA") for VEGF Trap-Eye for the treatment of wet AMD, the Company filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, the Company and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, the Company voluntarily dismissed its original complaint in favor of proceeding with its second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12(b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that the Company is entitled to the declaratory relief being sought by it, and asserting counterclaims that the Company's prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against the Company for damages, including for willful infringement, and other relief as the Court deems appropriate. The Company believes Genentech's counterclaims are without merit and intends to defend against them vigorously. As this matter is at a very early stage, at this time the Company is not able to predict the probability of the outcome or an estimate of loss, if any, related to this matter

REGENERON PHARMACEUTICALS, INC. Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

The Company has initiated patent-related actions against Genentech in Germany and the United Kingdom, and may initiate other actions in other countries outside the U.S.

10. Recently Issued Accounting Standards

Multiple-deliverable revenue arrangements

During the first quarter of 2011 the Company adopted amended authoritative guidance issued by the Financial Accounting Standards Board ("FASB") on multiple-deliverable revenue arrangements. The amended guidance provides greater ability to separate and allocate consideration to be received in a multiple-deliverable revenue arrangement by requiring the use of estimated selling prices to allocate the consideration, thereby eliminating the use of the residual method of allocation. The amended guidance also requires expanded qualitative and quantitative disclosures surrounding multiple-deliverable revenue arrangements. The Company is applying this amended guidance prospectively for new or materially modified arrangements, of which there were none during the three months ended March 31, 2011. The adoption of this guidance did not have a material impact on the Company's financial statements.

Milestone method of revenue recognition

During the first quarter of 2011, the Company adopted amended authoritative guidance issued by FASB codifying the milestone method of revenue recognition as an acceptable revenue recognition model when a milestone is deemed to be substantive. The Company has historically accounted for milestones under the milestone method; as such the adoption of this guidance did not have a material impact on the Company's financial statements.

In accordance with the Company's accounting policy for recognition of revenue in connection with collaboration agreements, as previously disclosed in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010, payments which are based on achieving a specific performance milestone, involving a degree of risk, are recognized as revenue when the milestone is achieved and the related payment is due and non-refundable, provided there is no future service obligation associated with that milestone. Substantive performance milestones typically consist of significant achievements in the development life-cycle of the related product candidate, such as completion of clinical trials, filing for approval with regulatory agencies, and receipt of approvals by regulatory agencies. In determining whether a payment is deemed to be a substantive performance milestone, the Company takes into consideration (i) the nature, timing, and value of significant achievements in the development life-cycle of the related development product candidate, (ii) the relative level of effort required to achieve the milestone, and (iii) the relative level of risk in achieving the milestone, taking into account the high degree of uncertainty in successfully advancing product candidates in a drug development program and in ultimately attaining an approved drug product. Payments for achieving milestones which are not considered substantive are accounted for as license payments and recognized over the related performance period.

REGENERON PHARMACEUTICALS, INC. Notes to Condensed Financial Statements (Unaudited) (Unless otherwise noted, dollars in thousands, except per share data)

The Company earns substantive performance milestone payments in connection with its collaboration agreements to develop and commercialize product candidates with the sanofi-aventis Group and Bayer HealthCare LLC. Descriptions of these collaboration agreements, including various financial terms and conditions, were provided in the Company's financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010. Under the Company's collaboration agreement with sanofi-aventis to jointly develop and commercialize ZALTRAPTM (affibercept), the Company may receive up to \$400 million in substantive milestone payments upon receipt of specified marketing approvals, including up to \$360 million in milestone payments related to the receipt of marketing approvals for up to eight ZALTRAPTM oncology and other indications in the U.S. or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five ZALTRAPTM oncology indications in Japan. Under the Company's global, strategic collaboration with sanofi-aventis to discover, develop, and commercialize fully human monoclonal antibodies, for each drug candidate identified under the collaboration's Discovery and Preclinical Development Agreement, sanofi-aventis has the option to license rights to the candidate under the collaboration's License and Collaboration Agreement and co-develop the drug candidate with the Company through product approval. Under certain defined circumstances, upon exercising its option to license rights to particular candidates, sanofi-aventis must make a \$10.0 million substantive milestone payment to the Company's VEGF Trap-Eye'), the Company is eligible to receive up to \$50 million in future substantive milestone payments related to marketing approvals of VEGF Trap-Eye'), the Company is eligible to receive up to \$50 million in future substantive milestone payments related to marketing approvals of VEGF Trap-Eye'), the Company is eligible to receive up to \$50 million in future sub

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion below contains forward-looking statements that involve risks and uncertainties relating to future events and the future financial performance of Regeneron Pharmaceuticals, Inc., and actual events or results may differ materially from these forward-looking statements. These statements concern, and these risks and uncertainties include, among other things, the nature, timing, and possible success and therapeutic applications of our product candidates and research programs now underway or planned, the likelihood and timing of possible regulatory approval and commercial launch of our late-stage product candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize its product and drug candidates, competing drugs that may be superior to our product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreements with the sanofi-aventis Group and Bayer HealthCare LLC, to be canceled or terminated without any product success, and risks associated with third-party intellectual property and pending or future litigation relating thereto. These statements are made by us based on management's current beliefs and judgment. In evaluating such statements, shareholders and potential investors should specifically consider the various factors identified under the caption "Risk Factors" which could cause actual events and results to differ materially from those indicated by such forward-looking statements. We do not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Overview

Regeneron Pharmaceuticals, Inc. is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical products for the treatment of serious medical conditions. We currently have one marketed product: ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available for prescription in the United States for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and children 12 and older.

We have 11 product candidates in clinical development, including three that are in late-stage (Phase 3) studies. All of these product candidates were discovered in our research laboratories. Our late-stage programs are VEGF Trap-Eye (affibercept ophthalmic solution), which is being developed using intraocular delivery for the treatment of serious eye diseases; ZALTRAPIM (affibercept), also known as VEGF Trap, which is being developed in oncology in collaboration with sanofi-aventis; and ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment. Our earlier stage clinical programs include the following fully human antibodies, which are being developed in collaboration with sanofiaventis:

- REGN727, an antibody to Proprotein Convertase Substilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;
- REGN88, an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis and ankylosing spondylitis;
- REGN668, an antibody to the interleukin-4 receptor (IL-4R), which is being developed in atopic dermatitis and eosinophilic asthma;
- REGN421, an antibody to Delta-like ligand-4 (Dll4), a novel angiogenesis target, which is being developed in oncology;
- REGN910, an antibody to Angiopoietin-2 (ANG2), another novel angiogenesis target, which is being developed in oncology;
- REGN475, an antibody to Nerve Growth Factor (NGF), which is being developed for the treatment of pain (currently on clinical hold); and
- REGN728 and REGN846, two antibodies in clinical development against undisclosed targets.

Our core business strategy is to maintain a strong foundation in basic scientific research and discovery-enabling technologies, to combine that foundation with our clinical development and manufacturing capabilities, and to continue to expand our commercialization capabilities in anticipation of possible regulatory approval and launch of one or more of our late-stage product candidates. Our long-term objective is to build a successful, integrated, multi-product biopharmaceutical company that provides patients and medical professionals with innovative options for preventing and treating human diseases.

We believe that our ability to develop product candidates is enhanced by the application of our *VelociSuite*TM technology platforms. Our discovery platforms are designed to identify specific proteins of therapeutic interest for a particular disease or cell type and validate these targets through high-throughput production of genetically modified mice using our *VelociGene*® technology to understand the role of these proteins in normal physiology, as well as in models of disease. Our human monoclonal antibody technology (*VelocImmune*®) and cell line expression technologies (*VelociMab*®) may then be utilized to discover and produce new product candidates directed against the disease target. Our antibody product candidates currently in clinical trials were developed using *VelocImmune*®. Under the terms of our antibody collaboration with sanofi-aventis, which was expanded during 2009, we plan to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017. We continue to invest in the development of enabling technologies to assist in our efforts to identify, develop, manufacture, and commercialize new product candidates.

Commercial Product:

ARCALYST® - CAPS

Net product sales of ARCALYST® (rilonacept) in the first quarter of 2011 were \$4.4 million. In the same quarter of 2010, net product sales of ARCALYST® were \$9.9 million, which included \$5.1 million of ARCALYST® net product sales made in the first quarter of 2010 and \$4.8 million of previously deferred net product sales, as described below under "Results of Operations."

ARCALYST® is a protein-based product designed to bind the interleukin-1 (called IL-1) cytokine and prevent its interaction with cell surface receptors. ARCALYST® is available for prescription in the U.S. for the treatment of CAPS, including FCAS and MWS in adults and children 12 and older. CAPS are a group of rare, inherited, auto-inflammatory conditions characterized by life-long, recurrent symptoms of rash, fever/chills, joint pain, eye redness/pain, and fatigue. Intermittent, disruptive exacerbations or flares can be triggered at any time by exposure to cooling temperatures, stress, exercise, or other unknown stimuli.

Clinical Programs:

1. VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye (aflibercept ophthalmic solution) is a specially purified and formulated form of VEGF Trap, which is being developed for use in intraocular applications. We, together with our ex-U.S. collaborator Bayer HealthCare, are evaluating VEGF Trap-Eye in Phase 3 programs in patients with the neovascular form of age-related macular degeneration (wet AMD), central retinal vein occlusion (CRVO), diabetic macular edema (DME), and choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia. Wet AMD, diabetic retinopathy (which includes DME), and retinal vein occlusion are three of the leading causes of adult blindness in the developed world. In these conditions, severe visual loss is caused by a combination of retinal edema and neovascular proliferation.

The Phase 3 trials in wet AMD, known as VIEW 1 and VIEW 2 (VEGF Trap: Investigation of Efficacy and Safety in Wet age-related macular degeneration), compared VEGF Trap-Eye and Lucentis® (ranibizumab injection), a registered trademark of Genentech, Inc. Lucentis® is an anti-angiogenic agent approved for use and the current standard of care in wet AMD. VIEW 1 was conducted in North America and VIEW 2 was conducted in Europe, Asia Pacific, Japan, and Latin America. The VIEW 1 and VIEW 2 trials both evaluated VEGF Trap-Eye doses of 0.5 milligrams (mg) and 2.0 mg at dosing intervals of four weeks and 2.0 mg at a dosing interval of eight weeks (following three initial monthly doses), compared with Lucentis® dosed according to its U.S. label, which specifies doses of 0.5 mg administered every four weeks over the first year. As-needed dosing (PRN) with both agents is being evaluated in the second year of the studies, although patients will be dosed no less frequently than every 12 weeks.

The primary endpoint of these non-inferiority studies was the proportion of patients treated with VEGF Trap-Eye who maintain visual acuity at the end of one year compared to patients dosed monthly with Lucentis. Visual acuity is defined as the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) chart, a standard research tool for measuring visual acuity. Maintenance of vision is defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS chart. Secondary endpoints included the mean change from baseline in visual acuity as measured by ETDRS, the proportion of patients who gained at least 15 letters of vision at week 52, and the amount of fluid under the retina.

We and Bayer HealthCare announced week 52 results from the VIEW 1 and VIEW 2 studies in November 2010. In these studies, all regimens of VEGF Trap-Eye, including VEGF Trap-Eye dosed every two months, successfully met the primary endpoint of statistical non-inferiority compared to Lucentis® dosed every month.

A generally favorable safety profile was observed for both VEGF Trap-Eye and Lucentis®. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies, with the most frequent events associated with the injection procedure, the underlying disease, and/or the aging process. The most frequent ocular adverse events were conjunctival hemorrhage, macular degeneration, eye pain, retinal hemorrhage, and vitreous floaters. The most frequent serious non-ocular adverse events were typical of those reported in this elderly population who receive intravitreal treatment for wet AMD; the most frequently reported events were falls, pneumonia, myocardial infarction, atrial fibrillation, breast cancer, and acute coronary syndrome. There were no notable differences among the study arms.

Based on these positive results, we submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in February 2011 for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011. Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe and other countries.

VEGF Trap-Eye is also in Phase 3 development for the treatment of CRVO, another cause of visual impairment. We are leading the COPERNICUS (Controlled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) study, and Bayer HealthCare is leading the GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study. Patients in both studies receive six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2.0 mg or sham control injections. The primary endpoint of both studies is improvement in visual acuity versus baseline after six months of treatment as measured by the ETDRS eye chart. At the end of the initial six months, patients are dosed on a PRN basis for another six months. All patients are eligible for rescue laser treatment.

We and Bayer HealthCare announced in December 2010 that in the COPERNICUS study, VEGF Trap-Eye met the primary endpoint of a statistically significant improvement in visual acuity at six months compared to sham injections. In the study, VEGF Trap-Eye was generally well tolerated. The most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were uncommon (3.5%), consisting of individual reports of corneal abrasion, endophalmitis, retinal vein occlusion, and reduced visual acuity, and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. There were no deaths among the 114 patients treated with VEGF Trap-Eye and two (2.7%) in the 73 patients treated with sham injections.

In April 2011, we and Bayer HealthCare announced that in the GALILEO study, VEGF Trap-Eye also met the primary endpoint of a statistically significant improvement in visual acuity at six months compared to sham injections. In this trial, 60.2% of patients receiving 2.0 mg of VEGF Trap-Eye monthly gained at least 15 letters of vision from baseline, compared to 22.1% of patients receiving sham injections (p<0.0001). Patients receiving 2.0 mg of VEGF Trap-Eye monthly gained, on average, 18 letters of vision compared to a mean gain of 3.3 letters with sham injections (p<0.0001), a secondary endpoint.

As in the COPERNICUS trial, VEGF Trap-Eye was generally well tolerated in the GALILEO study and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. Serious ocular adverse events in the VEGF Trap-Eye group were 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the VEGF Trap-Eye arm were eye pain, conjunctival hemorrhage, and elevated intraocular pressure. The most frequently reported adverse events in the control group were macular edema, eye irritation, and reduction of visual acuity. The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. The most frequent non-ocular adverse events were headache and nasopharyngitis. There were no deaths in the study.

Based on these positive results, we intend to submit a regulatory application for marketing approval for VEGF Trap-Eye in CRVO in the U.S. in the second half of 2011, and Bayer HealthCare is planning to submit regulatory applications in this indication in Europe in 2012.

In April 2011, we and Bayer Healthcare announced that Bayer Healthcare initiated a Phase 3 study outside the U.S. to evaluate the safety and efficacy of VEGF Trap-Eye in DME. The study, named VIVID-DME (VEGF Trap-Eye In Vision Inpairment Due to DME), has three study arms. In the first arm, patients will be treated every month with 2.0 mg of VEGF Trap-Eye. In the second arm, patients will be treated with 2.0 mg of VEGF Trap-Eye every two months after an initial phase of monthly injections. In the third arm, the comparator arm, patients will be treated with macular laser photocoagulation. The primary endpoint of the study is mean change in visual acuity from baseline as measured by the ETDRS eye chart. All patients will be followed for three years. We intend to commence a second Phase 3 study in DME, the VISTA-DME study (VEGF Trap-Eye: Investigation of Safety, Treatment effect, and Anatomic outcomes in DME), in the U.S., Canada, and other countries, later in 2011.

In January 2011, Regeneron and Bayer HealthCare initiated a Phase 3 trial in Asia in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of VEGF Trap-Eye in patients with CNV of the retina as a result of pathologic myopia. The study, which will enroll approximately 250 patients, has started in Japan and is scheduled to run until June 2013.

Collaboration with Bayer HealthCare

In October 2006, we entered into a license and collaboration agreement with Bayer HealthCare for the global development and commercialization outside the U.S. of VEGF Trap-Eye. Under the agreement, we and Bayer HealthCare collaborate on, and share the costs of, the development of VEGF Trap-Eye through an integrated global plan. Bayer HealthCare will market VEGF Trap-Eye outside the U.S., where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Commencing on the first commercial sale of VEGF Trap-Eye in a major market country outside the U.S., we will be obligated to reimburse Bayer HealthCare for 50% of the development costs that it has incurred under the agreement from our share of the collaboration profits. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the collaboration profits in the quarter unless we elect to reimburse Bayer HealthCare at a faster rate. Within the U.S., we retain exclusive commercialization rights to VEGF Trap-Eye and are entitled to all profits from any such sales. We have received \$60 million in development milestone payments and can earn up to \$50 million in future milestone payments related to marketing approvals of VEGF Trap-Eye in major market countries outside the U.S. We can also earn up to \$135 million in sales milestone payments if total annual sales of VEGF Trap-Eye outside the U.S. achieve certain specified levels starting at \$200 million.

2. ZALTRAPIM (also known as aflibercept or VEGF Trap) - Oncology

ZALTRAPTM (affibercept) is a protein-based product candidate designed to bind all forms of Vascular Endothelial Growth Factor-A (called VEGF-A), VEGF-B, and the related Placental Growth Factor (called PIGF), and prevent their interaction with cell surface receptors. VEGF-A (and to a lesser degree, PIGF) is required for the growth of new blood vessels (a process known as angiogenesis) that are needed for tumors to grow.

ZALTRAPTM is being developed globally in cancer indications in collaboration with sanofi-aventis. In April 2011, we and sanofi-aventis announced that the Phase 3 VELOUR trial evaluating ZALTRAPTM in combination with the FOLFIRI chemotherapy regimen [folinic acid (leucovorin), 5-fluorouracil, and irinotecan] versus a regimen of FOLFIRI plus placebo met its primary endpoint of improving overall survival (OS) in the second-line treatment of metastatic colorectal cancer (mCRC). Full results will be presented at an upcoming medical meeting. The most frequent adverse events reported with ZALTRAPTM in combination with FOLFIRI were diarrhea, asthenia/fatigue, stomatitis and ulceration, nausea, infection, hypertension, gastrointestinal and abdominal pains, vomiting, decreased appetite, decreased weight, epistaxis, alopecia, and dysphonia.

Based upon these positive findings, we and sanofi-aventis plan to submit regulatory applications for marketing approval of ZALTRAPTM for the second-line treatment of mCRC to the FDA and the European Medicines Agency (EMA) in the second half of 2011.

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In March 2011, we and sanofi-aventis announced results from the Phase 3 VITAL trial evaluating ZALTRAPTM for the second-line treatment of non-small cell lung cancer (NSCLC). The data showed that adding ZALTRAPTM to the chemotherapy drug docetaxel did not meet the pre-specified criteria for the primary endpoint of improvement in overall survival compared with a regimen of docetaxel plus placebo (HR=1.01, CI: 0.868 to 1.174). The addition of ZALTRAPTM to docetaxel demonstrated activity as measured by key secondary endpoints of the study: progression free survival (PFS) (HR=0.82, CI: 0.716 to 0.937) and an overall objective response rate (ORR) of 23.3% in the ZALTRAPTM arm compared to 8.9% in the placebo arm. Consistent with published literature reporting on combined cytotoxic and anti-VEGF therapy, the incidence of adverse events was higher in the ZALTRAPTM arm compared to placebo. The most frequent Grade 3/4 adverse events included fatigue, stomatitis, disease progression, and hypertension.

Another randomized, double-blind Phase 3 trial (VENICE), which is fully enrolled, is evaluating ZALTRAPTM as a first-line treatment for hormone-refractory metastatic prostate cancer in combination with docetaxel/prednisone. The VENICE trial is being monitored by an Independent Data Monitoring Committee (IDMC), a body of independent clinical and statistical experts. The IDMCs meet periodically to evaluate data from the trial and may recommend changes in study design or study discontinuation. Both interim and final analyses will be conducted when a prespecified number of events have occurred in this trial. Based on projected event rates, an interim analysis of the VENICE trial is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012.

In addition, a randomized Phase 2 study (AFFIRM) of ZALTRAPTM in first-line mCRC in combination with FOLFOX [folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin] is fully enrolled. Initial data from this study are anticipated in the second half of 2011.

ZALTRAPTM Collaboration with sanofi-aventis

We and sanofi-aventis globally collaborate on the development and commercialization of ZALTRAPTM. Under the terms of our September 2003 collaboration agreement, as amended, we and sanofi-aventis will share co-promotion rights and profits on sales, if any, of ZALTRAPTM outside of Japan for disease indications included in our collaboration. In Japan, we are entitled to a royalty of approximately 35% on annual sales of ZALTRAPTM, subject to certain potential adjustments. We may also receive up to \$400 million in milestone payments upon receipt of specified marketing approvals, including up to \$360 million related to the receipt of marketing approvals for up to eight ZALTRAPTM oncology and other indications in the U.S. or the European Union and up to \$40 million related to the receipt of marketing approvals for up to five oncology indications in Japan.

Under the ZALTRAPTM collaboration agreement, as amended, agreed upon worldwide development expenses incurred by both companies during the term of the agreement will be funded by sanofi-aventis. If the collaboration becomes profitable, we will be obligated to reimburse sanofi-aventis out of our share of ZALTRAPTM profits for 50% of the development expenses that they funded. The reimbursement payment in any quarter will equal 5% of the then outstanding repayment obligation, but never more than our share of the ZALTRAPTM profits in the quarter unless we elect to reimburse sanofi-aventis at a faster rate.

3. ARCALYST®- Inflammatory Diseases

ARCALYST® (rilonacept) is being developed for the prevention of gout flares in patients initiating uric acid-lowering therapy. Gout, a disease in which IL-1 may play an important role in pain and inflammation, is a very painful and common form of arthrits that results from high levels of uric acid, a bodily waste product normally excreted by the kidneys. The elevated uric acid can lead to formation of urate crystals in the joints of the toes, ankles, knees, wrists, fingers, and elbows. Uric acid-lowering therapy, most commonly allopurinol, is prescribed to eliminate the urate crystals and prevent them from reforming. Paradoxically, the initiation of uric acid-lowering therapy often triggers an increase in the frequency of gout attacks in the first several months of treatment, which may lead to discontinuation of therapy. The break up of the urate crystals can result in stimulation of inflammatory mediators, including IL-1, resulting in acute flares of joint pain and inflammation. These painful flares generally persist for at least five days.

We have been conducting a Phase 3 clinical development program with ARCALYST® in gout patients initiating uric acid-lowering therapy. The program consists of three studies: PRE-SURGE 1 (PRE-vention Study against URate-lowering drug-induced Gout Exacerbations), PRE-SURGE 2, and RE-SURGE (RE-view of Safety Utilizing Rilonacept in Gout Exacerbations).

In June 2010, we announced that results from PRE-SURGE 1, a North America-based double-blind, placebo-controlled study, showed that ARCALYST® prevented gout attacks, as measured by the primary study endpoint of the number of gout flares per patient over the 16 week treatment period. Patients initiating uric acid-lowering therapy who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, p<0.0001). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, p<0.0001).

All secondary endpoints of the study were highly positive (p<0.001 vs. placebo). Among these endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 88% (3.8% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 31.6% with placebo, p<0.001). In addition, treatment with ARCALYST® reduced the proportion of patients who experienced at least one gout flare during the study period by up to 65% (16.3% with ARCALYST® 160 mg, 18.8% with ARCALYST® 80 mg, and 46.8% with placebo, p<0.001).

A total of 241 patients were randomized in PRE-SURGE 1. ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Adverse events that occurred at a frequency of at least 5% in any study group were injection site reaction (19.8% with ARCALYST® 160 mg, 8.8% with ARCALYST® 80 mg, and 1.3% with placebo), upper respiratory tract infection (9.9% with ARCALYST® 160 mg, 8.8% with ARCALYST® 160 mg, 5.0% with ARCALYST® 160 mg, 5.0% with ARCALYST® 80 mg, and 2.5% with placebo), musculoskeletal pain/discomfort (6.2% with ARCALYST® 160 mg, 7.5% with ARCALYST® 80 mg, and 8.9% with placebo), and headache, (3.7% with ARCALYST® 160 mg, 6.3% with ARCALYST® 80 mg, and 1.3% with placebo).

In February 2011, we reported the results of PRE-SURGE 2 and RE-SURGE. In the PRE-SURGE 2 efficacy study in gout patients initiating allopurinol therapy, which was identical to PRE-SURGE 1 in design and analysis, 248 patients were randomized. ARCALYST® met the primary and all secondary study endpoints. The primary endpoint was the number of gout flares per patient over the 16-week treatment period. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of either 160 mg or 80 mg had a 72% decrease in mean number of gout flares compared to the placebo group (p<0.0001). Among secondary endpoints, treatment with ARCALYST® reduced the proportion of patients who experienced two or more flares during the study period by up to 82% (6.0% with ARCALYST® 160 mg, 8.5% with ARCALYST® 80 mg, and 32.9% with placebo, p \leq 0.001). In addition, treatment with ARCALYST® 80 mg, and 56.1% with placebo, p \leq 0.001).

ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. The most frequently reported adverse event was upper respiratory tract infection (15.5% with ARCALYST® 160 mg, 12.2% with ARCALYST® 80 mg, and 12.2% with placebo). Overall, the cumulative rate of infections was 27.4% in patients treated with ARCALYST® 160 mg, 28.0% in patients treated with ARCALYST® 80 mg, and 25.6% in patients treated with placebo. Injection site reactions were more commonly reported in patients treated with ARCALYST® (17.9% with ARCALYST® 160 mg, 12.2% with ARCALYST® 80 mg, and 1.2% with placebo). These results were consistent with those in PRE-SURGE 1.

We also announced that in the RE-SURGE study, which evaluated the safety of ARCALYST® versus placebo over 16 weeks, ARCALYST® was generally well tolerated, and the safety profile was consistent with that reported in the PRE-SURGE 1 and PRE-SURGE 2 studies. RE-SURGE evaluated 1,315 patients who were at risk for gout flares while initiating or continuing uric acid-lowering drug treatment. Other than injection site reactions, the incidence of treatment-emergent adverse events was generally well-balanced among the 985 patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg and the 330 patients who received placebo. Injection site reactions, usually considered mild, were reported more commonly with ARCALYST® (15.2%) than with placebo (3.3%). Overall, the cumulative rate of infections was 20.1% in patients treated with ARCALYST® and 19.1% in placebo patients. Serious infections were reported in 0.5% of patients treated with ARCALYST® and 0.9% of placebo patients. Deaths were reported for 0.3% of patients treated with ARCALYST® and 0.9% of placebo patients.

In the RE-SURGE study, ARCALYST® met all secondary endpoints, which evaluated efficacy, over the 16 week treatment period (p<0.0001). These included the number of gout flares per patient, the proportion of patients who experienced two or more flares, and the proportion of patients who experienced at least one gout flare during the study period.

Based on the results of the three Phase 3 studies, we plan to submit in mid-2011 a supplemental BLA for U.S. regulatory approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. We own worldwide rights to ARCALYST®.

4. REGN727 (PCSK9 Antibody) for LDL cholesterol reduction

Elevated LDL cholesterol ("bad cholesterol") level is a validated risk factor leading to cardiovascular disease. Statins are a class of drugs that lower LDL cholesterol by upregulating the expression of the LDL receptor (LDLR), which removes LDL from circulation. PCSK9 is a naturally occurring secreted protein that also modulates LDL cholesterol levels through its interaction with the LDL receptor. In a landmark study published in the New England Journal of Medicine in March 2006, patients with lower than normal PCSK9 levels due to a genetic abnormality not only had significantly lower levels of LDL cholesterol, but also a significant reduction in the risk of coronary heart disease. We used our VelocImmune® technology to generate a fully human monoclonal antibody inhibitor of PCSK9, called REGN727, that is intended to robustly lower LDL cholesterol.

In May 2010, we announced that in an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL cholesterol. Each dosing cohort consisted of six treated and two placebo patients. In July 2010, we presented additional data from this Phase 1 program. At the highest intravenous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than one month. At the highest subcutaneous dose tested, a single dose of REGN727 achieved a greater than 60% maximum mean reduction of LDL cholesterol from baseline that lasted for more than two weeks. No serious adverse events and no dose limiting toxicities have been reported.

In July 2010, we also presented the results of an interim efficacy analysis of a dose escalating, randomized, double-blind, placebo-controlled Phase 1 trial of subcutaneously delivered REGN727 in hyperlipidemic patients (familial hypercholesterolemia and non-familial hypercholesterolemia) on stable doses of statins whose LDL levels were greater than 100 milligrams per deciliter (mg/dL). At the highest dose tested at that time, in eleven patients, a single dose of REGN727 achieved an approximately 40% maximum mean additional reduction of LDL cholesterol from baseline. No serious adverse events and no dose limiting toxicities were reported.

In early 2011, we initiated Phase 2 studies of REGN727 in patients with hypercholesterolemia in combination with statin therapy. REGN727 is being developed in collaboration with sanofiaventis.

5. REGN88 (IL-6R Antibody) for inflammatory diseases

IL-6 is a key cytokine involved in the pathogenesis of rheumatoid arthritis, causing inflammation and joint destruction. A therapeutic antibody to IL-6R, Actemra® (tocilizumab), a registered trademark of Genentech, has been approved for the treatment of rheumatoid arthritis.

REGN88 is a fully human monoclonal antibody to IL-6R generated using our VelocImmune® technology that has completed Phase 1 studies, the results of which were presented at the annual meetings of the European League Against Rheumatism (EULAR) in June 2010 and the American College of Rheumatology in October 2010. REGN88 was well tolerated by patients with rheumatoid arthritis, and no dose-limiting toxicities were reported. Treatment with REGN88 resulted in dose-related reductions in biomarkers of inflammation. REGN88 is currently in a Phase 2/3 double-blind, placebo-controlled, dose-ranging study in patients with active rheumatoid arthritis and a Phase 2 double-blind, placebo-controlled, dose-ranging study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients, and initial Phase 2 results are expected in mid-2011. REGN88 is being developed in collaboration with sanofiavemis.

6. REGN668 (IL-4R Antibody) for allergic and immune conditions

IL-4R is required for signaling by the cytokines IL-4 and IL-13. Both of these cytokines are critical mediators of immune response, which, in turn, drives the formation of Immunoglobulin E (IgE) antibodies and the development of allergic responses, as well as the atopic state that underlies asthma and atopic dermatitis.

REGN668 is a fully human monoclonal antibody generated using our $VelocImmune^{\oplus}$ technology that is designed to bind to IL-4R. A Phase 1 trial of REGN668 in healthy volunteers has been completed. A Phase 1b study in patients with atopic dermatitis and a Phase 2 study in eosinophilic asthma are underway. REGN668 is being developed in collaboration with sanofi-aventis.

7. REGN421 (Dll4 Antibody) for advanced malignancies

In many clinical settings, positively or negatively regulating blood vessel growth could have important therapeutic benefits, as could the repair of damaged and leaky vessels. VEGF was the first growth factor shown to be specific for blood vessels, by virtue of having its receptor primarily expressed on blood vessel cells. In the December 21, 2006 issue of the journal *Nature*, we reported data from a preclinical study demonstrating that blocking an important cell signaling molecule, known as Dll4, inhibited the growth of experimental tumors by interfering with their ability to produce a functional blood supply. The inhibition of tumor growth was seen in a variety of tumor types, including those that were resistant to blockade of VEGF, suggesting a novel anti-angiogenesis therapeutic approach. Moreover, inhibition of tumor growth is enhanced by the combination of Dll4 and VEGF blockade in many preclinical tumor models.

REGN421 is a fully human monoclonal antibody to Dll4 generated using our VelocImmune® technology. REGN421, which is being developed in collaboration with sanofi-aventis, is in Phase 1 clinical development.

8. REGN910 (ANG2 Antibody) for oncology

In the fourth quarter of 2010, we initiated a Phase 1 study in an oncology setting of REGN910, an antibody that specifically blocks ANG2. The angiopoietins, which were discovered at Regeneron, are ligands for the endothelial cell receptor Tie2 and are essential for vascular development and angiogenesis. Unlike other family members, ANG2 is strongly upregulated by endothelial cells at sites of angiogenesis and vascular remodeling, including tumors. REGN910 is a fully human monoclonal antibody generated using our *VelocImmune* technology, which is being developed for cancer indications in collaboration with sanofi-aventis.

9. REGN475 (NGF Antibody) for pain

REGN475 is a fully human monoclonal antibody to NGF, generated using our *VelocImmune*® technology, which is designed to block pain sensitization in neurons. Preclinical experiments indicate that REGN475 specifically binds to and blocks NGF activity and does not bind to or block cell signaling for closely related neurotrophins such as NT-3, NT-4, or BDNF.

In May 2010, we announced positive results from an interim analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial in 217 patients with osteoarthritis of the knee. In July 2010, we presented additional results from this trial through 16 weeks.

In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients. REGN475 is being developed in collaboration with sanofi-aventis.

10. REGN728 and REGN846

In the fourth quarter of 2010, clinical trials began with two additional fully human monoclonal antibodies generated using our *VelocImmune®* technology that are part of the sanofi-aventis collaboration, REGN728 and REGN846. The targets of these antibodies have not been disclosed.

Research and Development Technologies:

Many proteins that are either on the surface of or secreted by cells play important roles in biology and disease. One way that a cell communicates with other cells is by releasing specific signaling proteins, either locally or into the bloodstream. These proteins have distinct functions and are classified into different "families" of molecules, such as peptide hormones, growth factors, and cytokines. All of these secreted (or signaling) proteins travel to and are recognized by another set of proteins, called "receptors," which reside on the surface of responding cells. These secreted proteins impact many critical cellular and biological processes, causing diverse effects ranging from the regulation of growth of particular cell types to inflammation mediated by white blood cells. Secreted proteins can at times be overactive and thus result in a variety of diseases. In these disease settings, blocking the action of specific secreted proteins can have clinical benefit. In other cases, proteins on the cell-surface can mediate the interaction between cells, such as the processes that give rise to inflammation and autoimmunity.

Our scientists have developed two different technologies to design protein therapeutics to block the action of specific cell surface or secreted proteins. The first technology, termed the "Trap" technology, was used to generate our first approved product, ARCALYST®, as well as ZALTRAP™ and VEGF Trap-Eye, all of which are in Phase 3 clinical trials. These novel "Traps" are composed of fusions between two distinct receptor components and the constant region of an antibody molecule called the "Fc region", resulting in high affinity product candidates. $VelociSuite^{TM}$ is our second technology platform; it is used for discovering, developing, and producing fully human monoclonal antibodies that can address both secreted and cell-surface targets.

VelociSuiteTM

VelociSuiteTM consists of VelocImmune®, VelociGene®, VelociMouse®, and VelociMab®. The VelocImmune® mouse platform is utilized to produce fully human monoclonal antibodies. VelocImmune® was generated by exploiting our VelociGene® technology (see below), in a process in which six megabases of mouse immune gene loci were replaced, or "humanized," with corresponding human immune gene loci. VelocImmune® mice can be used to generate efficiently fully human monoclonal antibodies to targets of therapeutic interest. VelocImmune® and our entire VelociSuiteTM offer the potential to increase the speed and efficiency through which human monoclonal antibody therapeutics may be discovered and validated, thereby improving the overall efficiency of our early stage drug development activities. We are utilizing the VelocImmune® technology to produce our next generation of drug candidates for preclinical and clinical development.

Our VelociGene® platform allows custom and precise manipulation of very large sequences of DNA to produce highly customized alterations of a specified target gene, or genes, and accelerates the production of knock-out and transgenic expression models without using either positive/negative selection or isogenic DNA. In producing knock-out models, a color or fluorescent marker may be substituted in place of the actual gene sequence, allowing for high-resolution visualization of precisely where the gene is active in the body during normal body functioning as well as in disease processes. For the optimization of preclinical development and pharmacology programs, VelociGene® offers the opportunity to humanize targets by replacing the mouse gene with the human homolog. Thus, VelociGene® allows scientists to rapidly identify the physical and biological effects of deleting or over-expressing the target gene, as well as to characterize and test potential therapeutic molecules.

Our *VelociMouse®* technology platform allows for the direct and immediate generation of genetically altered mice from embryonic stem cells (ES cells), thereby avoiding the lengthy process involved in generating and breeding knockout mice from chimeras. Mice generated through this method are normal and healthy and exhibit a 100% germ-line transmission. Furthermore, mice developed using our *VelociMouse®* technology are suitable for direct phenotyping or other studies. We have also developed our *VelociMab®* platform for the rapid screening of antibodies and rapid generation of expression cell lines for our Traps and our *Velocimmune®* human monoclonal antibodies.

Antibody Collaboration and License Agreements

sanofi-aventis. In November 2007, we and sanofi-aventis entered into a global, strategic collaboration to discover, develop, and commercialize fully human monoclonal antibodies. The collaboration is governed by a Discovery and Preclinical Development Agreement and a License and Collaboration Agreement. In connection with the execution of the discovery agreement in 2007, we received a non-refundable, up-front payment of \$85.0 million from sanofi-aventis. Pursuant to the collaboration, sanofi-aventis is funding our research to identify and validate potential drug discovery targets and develop fully human monoclonal antibodies against these targets. We lead the design and conduct of research activities under the collaboration, including target identification and validation, antibody development, research and preclinical activities through filing of an Investigational New Drug Application (IND) or its equivalent, toxicology studies, and manufacture of preclinical and clinical supplies.

For each drug candidate identified through discovery research under the discovery agreement, sanofi-aventis has the option to license rights to the candidate under the license agreement. If it elects to do so, sanofi-aventis will co-develop the drug candidate with us through product approval. Development costs for the drug candidate are shared between the companies, with sanofi-aventis generally funding these costs up front, except that following receipt of the first positive Phase 3 trial results for a co-developed drug candidate, subsequent Phase 3 trial-related costs for that drug candidate are shared 80% by sanofi-aventis and 20% by us. We are generally responsible for reimbursing sanofi-aventis for half of the total development costs for all collaboration antibody products from our share of profits from commercialization of collaboration products to the extent they are sufficient for this purpose. However, we are not required to apply more than 10% of our share of the profits from collaboration products in any calendar quarter towards reimbursing sanofi-aventis for these development costs.

Sanofi-aventis will lead commercialization activities for products developed under the license agreement, subject to our right to co-promote such products. The parties will equally share profits and losses from sales within the U.S. The parties will share profits outside the U.S. on a sliding scale based on sales starting at 65% (sanofi-aventis)/35% (us) and ending at 55% (sanofi-aventis)/45% (us), and will share losses outside the U.S. at 55% (sanofi-aventis)/45% (us). In addition to profit sharing, we are entitled to receive up to \$250 million in sales milestone payments, with milestone payments commencing after aggregate annual sales outside the U.S. exceed \$1.0 billion on a rolling 12-month basis.

In November 2009, we and sanofi-aventis amended these agreements to expand and extend our antibody collaboration. The goal of the expanded collaboration is to advance an average of four to five new antibody product candidates into clinical development each year, for an anticipated total of 30-40 candidates from 2010 through 2017.

Under the amended discovery agreement, sanofi-aventis agreed to fund up to \$160 million per year of our antibody discovery activities over the period from 2010-2017, subject to a one-time option for sanofi-aventis to adjust the maximum reimbursement amount down to \$120 million per year commencing in 2014 if over the prior two years certain specified criteria were not satisfied. Sanofi-aventis has an option to extend the discovery program for up to an additional three years after 2017 for further antibody development and preclinical activities. Pursuant to the collaboration, sanofi-aventis is also obligated to fund up to \$30 million of agreed-upon costs we incur to expand our manufacturing capacity at our Rensselaer, New York facilities.

In 2010, as we scaled up our capacity to conduct antibody discovery activities, sanofi-aventis funded \$137.7 million of our preclinical research under the expanded collaboration. The balance between that amount and \$160 million, or \$22.3 million, has been added to the funding otherwise available to us in 2011-2012 under the amended discovery agreement.

From the collaboration's inception in November 2007 through March 31, 2011, sanofi-aventis has funded a total of \$354.8 million of our costs under the discovery agreement and a total of \$294.1 million of our development costs under the license agreement, or a total of \$648.9 million in funding for our antibody research and development activities during this period.

In August 2008, we entered into an agreement with sanofi-aventis to use our VelociGene® platform to supply sanofi-aventis with genetically modified mammalian models of gene function and disease. Under this agreement, sanofi-aventis is required to pay us a minimum of \$21.5 million for the term of the agreement, which extends through December 2012, for knock-out and transgenic models of gene function for target genes identified by sanofi-aventis. Sanofi-aventis will use these models for its internal research programs that are outside of the scope of our antibody collaboration.

Astellas Pharma Inc. In March 2007, we entered into a six-year, non-exclusive license agreement with Astellas Pharma Inc. to allow Astellas to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, Astellas made a \$20.0 million annual, non-refundable payment to us in each of the second quarters of 2007, 2008, 2009, and 2010. In July 2010, the license agreement with Astellas was amended and extended through June 2023. Under the terms of the amended agreement, Astellas made a \$165.0 million up-front payment to us in August 2010. In addition, Astellas will make a \$130.0 million second payment to us in June 2018 unless the license agreement has been terminated prior to that date. Astellas has the right to terminate the agreement at any time by providing 90 days' advance written notice. Under certain limited circumstances, such as our material breach of the agreement, Astellas may terminate the agreement and receive a refund of a portion of its up-front payment or, if such termination occurs after June 2018, a portion of its second payment, to us under the July 2010 amendment to the agreement. We are entitled to receive a mid-single-digit royalty on any future sales of antibody products discovered by Astellas using our VelocImmune® technology.

AstraZeneca UK Limited. In February 2007, we entered into a six-year, non-exclusive license agreement with AstraZeneca UK Limited to allow AstraZeneca to utilize our VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of the agreement, AstraZeneca made a \$20.0 million annual, non-refundable payment to us in each of the first quarters of 2007, 2008, 2009, and 2010. In November 2010, as permitted by the agreement, MedImmune Limited (as successor by novation from AstraZeneca) gave written notice of voluntary termination of the agreement, effective in February 2011, thereby canceling its obligation to make either of the final two annual payments. We remain entitled to receive a midsingle-digit royalty on any future sales of antibody products discovered by MedImmune using our VelocImmune® technology.

Royalty Agreement with Novartis Pharma AG

Under a June 2009 agreement with Novartis (that replaced a previous collaboration and license agreement), we receive royalties on worldwide sales of Novartis' canakinumab, a fully human anti-interleukin-IL1B antibody. The royalty rates in the agreement start at 4% and reach 15% when annual sales exceed \$1.5 billion. Canakinumab is marketed for the treatment of CAPS, has completed Phase 3 development for gout, and is in earlier stage development for atherosclerosis and other inflammatory diseases. While our royalties under this agreement could be significant if canakinumab is approved and successfully commercialized for additional disease indications, to date these royalties have been minimal. Accordingly, we are unable to predict whether these royalties will ever contribute materially to our results of operations or financial condition.

National Institutes of Health Grant

In September 2006, we were awarded a five-year grant from the National Institutes of Health (NIH) as part of the NIH's Knockout Mouse Project. The goal of the Knockout Mouse Project is to build a comprehensive and broadly available resource of knockout mice to accelerate the understanding of gene function and human diseases. Under the NIH grant, as amended, we have received \$22.6 million from the grant's inception through March 31, 2011 and are entitled to receive an additional \$2.7 million through the remaining term of the grant.

Research Programs

Our preclinical research programs are in the areas of oncology and angiogenesis, ophthalmology, metabolic and related diseases, muscle diseases and disorders, inflammation and immune diseases, bone and cartilage, pain, cardiovascular diseases, and infectious diseases.

General:

Developing and commercializing new medicines entails significant risk and expense. Since inception we have not generated any significant sales or profits from the commercialization of ARCALYST® or any of our other product candidates. Before significant revenues from the commercialization of ARCALYST® or our other product candidates can be realized, we (or our collaborators) must overcome a number of hurdles which include successfully completing research and development and obtaining regulatory approval from the FDA and regulatory authorities in other countries. In addition, the biotechnology and pharmaceutical industries are rapidly evolving and highly competitive, and new developments may render our products and technologies uncompetitive or obsolete.

From inception on January 8, 1988 through March 31, 2011, we had a cumulative loss of \$1.1 billion, principally related to our research and development activities. We expect to continue to incur substantial expenses related to our research and development activities, a significant portion of which we expect to be reimbursed by our collaborators. We submitted a BLA to the FDA in February 2011 for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review, Under Priority Review, the target date for an FDA decision on the VEGF Trap-Eye BLA is August 20, 2011. Bayer HealthCare intends to submit regulatory applications in the first half of 2011 for marketing approval of VEGF Trap-Eye in wet AMD in Europe and other countries. We plan to submit a BLA to the FDA in the second half of 2011 for marketing approval of VEGF Trap-Eye in CRVO in Europe in 2012. We also plan to submit a supplemental BLA to the FDA in mid-2011 for marketing approval in the U.S. of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy. We and sanofi-aventis plan to submit regulatory applications for marketing approval of ZALTRAP™ for the second-line treatment of mCRC to the FDA and the EMA in the second half of 2011. We expect to incur substantial costs to prepare for potential commercialization of these late-stage product candidates and, if one or more of these product candidates receive regulatory approval, to fund the launch of the product (s). Thus, we expect to continue to incur substantial operating losses over at least the next few years related primarily to our research and development and commercialization activities. Also, our research and development activities outside our collaborations, the costs of which are not reimbursed, may expand and require additional resources. Our losses may fluctuate from quarter to quarter and will depend on, among other factors, the scope and progress of our research and

The planning, execution, and results of our clinical programs are significant factors that can affect our operating and financial results. In our clinical programs, key events in 2011 to date were, and plans for the next 12 months are, as follows:

		2011-12114118
Clinical Program	2011 Events to Date	(next 12 months)
VEGF Trap–Eye	 Submitted a BLA to the U.S. FDA for the treatment of wet AMD FDA accepted BLA for wet AMD and granted our request for Priority Review Reported positive six-month results in the Phase 3 GALILEO trial in CRVO Bayer Healthcare initiated a Phase 3 trial in DME outside the U.S. Initiated a Phase 3 trial in Asia in CNV of the retina as a result of pathologic myopia 	 Target date for FDA decision on VEGF Trap-Eye BLA is August 20, 2011 Report two-year data from VIEW 1 and VIEW 2 in wet AMD, and one-year data from COPERNICUS and GALILEO in CRVO in the second half of 2011 Submit a BLA to the FDA for the treatment of CRVO in the second half of 2011 Initiate a second DME Phase 3 trial in the U.S. in the second half of 2011
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2011-12 Plans

Clinical Program	2011 Events to Date	2011-12 Plans (next 12 months)
ZALTRAPIM	 Reported positive results in the Phase 3 VELOUR trial in mCRC Reported results for the VITAL trial in NSCLC 	Submit a BLA to the FDA for the treatment of mCRC in the second half of 2011 IDMC review of interim results for the Phase 3 VENICE trial in prostate cancer in mid-2011 Report initial results in the Phase 2 AFFIRM trial in colorectal cancer in the second half of 2011
ARCALYST®	 Reported positive results from two Phase 3 studies for the prevention of gout flares (PRE-SURGE 2 and RESURGE) 	Submit a supplemental BLA to the FDA for the prevention of gout flares in mid-2011
REGN727 (PCSK9 Antibody)	• Initiated Phase 2 studies for LDL cholesterol reduction	Report initial data from the Phase 2 program for LDL cholesterol reduction
REGN88 (IL-6R Antibody)	 Continued patient enrollment in studies in rheumatoid arthritis and ankylosing spondylitis 	Report initial Phase 2 data in rheumatoid arthritis and ankylosing spondylitis
REGN668 (IL-4R Antibody)	• Initiated Phase 1b study in atopic dermatitis and Phase 2 proof of concept study in eosinophilic asthma	• Initiate Phase 2 program in atopic dermatitis
REGN421 (Dll4 Antibody)	Continued patient enrollment in Phase 1 program	Initiate a Phase 1b program in advanced malignancies
REGN910 (ANG2 Antibody)	Continued patient enrollment in Phase 1 program	
REGN475 (NGF Antibody)	On clinical hold	
REGN728 (target not disclosed)	Continued patient enrollment in Phase 1 program	
REGN846 (target not disclosed)	Continued patient enrollment in Phase 1 program	
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Results of Operations

Three Months Ended March 31, 2011 and 2010

Net Loss

Regeneron reported a net loss of \$43.4 million, or \$0.49 per share (basic and diluted), for the first quarter of 2011, compared to a net loss of \$30.5 million, or \$0.38 per share (basic and diluted) for the first quarter of 2010. The increase in our net loss in 2011 was principally due to higher research and development expenses and higher selling, general, and administrative expenses, partly offset by higher collaboration revenue in connection with our antibody collaboration with sanofi-aventis.

Revenues

Revenues for the three months ended March 31, 2011 and 2010 consist of the following:

(In millions)	2011	2	010
Collaboration revenue			
Sanofi-aventis	\$ 85.3	\$	68.7
Baver HealthCare	12.5		111
Total collaboration revenue	97.8		81.8
Technology licensing revenue	79		100
Net product sales	4.4		9.9
Contract research and other revenue	2.1		13
Total revenue	\$ 112.2	\$	103.5

 $Sano fi-avent is\ Collaboration\ Revenue$

The collaboration revenue we earned from sanofi-aventis, as detailed below, consisted primarily of reimbursement for research and development expenses and recognition of revenue related to non-refundable up-front payments of \$105.0 million related to the ZALTRAPTM collaboration and \$85.0 million related to the antibody collaboration.

	Three m	onths ei	aded
Sanofi-aventis Collaboration Revenue	Ma	rch 31,	
(In millions)	2011	20	010
ZALTRAPM			
Regeneron expense reimbursement	\$ 7.2	\$	4.9
Recognition of deferred revenue related to ap-front per monts	2.5		22.5
Total ZALTRAPIM	9.7		7.4
Antibody			
Regeneron expense reimbursement	73.2		59.3
Recognition of deferred revenue related to up-front and other provincins	2.0		1.6
Recognition of revenue related to VelociGene® agreement	0.4		0.4
Total antibody	356		613
Total sanofi-aventis collaboration revenue	\$ 85.3	\$	68.7

Sanofi-aventis' reimbursement of our ZALTRAPTM expenses increased in the first quarter of 2011 compared to same period in 2010, primarily due to higher costs related to manufacturing ZALTRAPTM clinical supplies. As of March 31, 2011, \$30.1 million of the original \$105.0 million of up-front payments related to ZALTRAPTM was deferred and will be recognized as revenue in future periods.

In the first quarter of 2011, sanofi-aventis' reimbursement of our antibody expenses consisted of \$42.1 million under the discovery agreement and \$31.1 million of development costs under the license agreement, compared to \$26.7 million and \$32.6 million, respectively, in the first quarter of 2010. The higher reimbursement amount under the discovery agreement in the first quarter of 2011, compared to the same period in 2010, was primarily due to an increase in our antibody discovery activities.

Recognition of deferred revenue related to sanofi-aventis' \$85.0 million up-front payment and other payments increased in the first quarter of 2011 compared to the same period in 2010. In connection with the November 2009 amendment of the discovery agreement, sanofi-aventis is funding up to \$30 million of agreed-upon costs incurred by us to expand our manufacturing capacity at our Rensselaer, New York facilities. Revenue related to these payments for such funding from sanofi-aventis is deferred and recognized as collaboration revenue prospectively over the related performance period in conjunction with the recognition of the original \$85.0 million up-front payment. As of March 31, 2011, \$23.9 million of such funding from sanofi-aventis was received or receivable, compared to \$5.1 million as of March 31, 2010, as a result, we recognized more deferred revenue in the first quarter of 2011 than in the same quarter of 2010. As of March 31, 2011, \$78.3 million of the sanofi-aventis payments was deferred and will be recognized as revenue in future periods.

In August 2008, we entered into a separate VelociGene® agreement with sanofi-aventis. In both the three months ended March 31, 2011 and 2010, we recognized \$0.4 million in revenue related to this agreement.

Bayer HealthCare Collaboration Revenue

The collaboration revenue we earned from Bayer HealthCare, as detailed below, consisted of cost sharing of Regeneron VEGF Trap-Eye development expenses and recognition of revenue related to a non-refundable \$75.0 million up-front payment received in October 2006 and a \$20.0 million milestone payment received in August 2007 (which, for the purpose of revenue recognition, was not considered substantive).

	Three mor	ths ended
Bayer HealthCare Collaboration Revenue	Marc	h 31,
(In millions) Cost-sharing of Regeneron VEGF Trap-Fye development expenses Recognition of deferred revenue related to up-front and other milestone	2011 \$ 100	2010 \$ 10.6
payments Total Bayer HealthCare collaboration revenus	2.5	2.5

Cost-sharing of our VEGF Trap-Eye development expenses with Bayer HealthCare decreased slightly in the first quarter of 2011 compared to the same period in 2010. In the first quarter of 2011, we incurred lower clinical development costs in connection with our Phase 3 VIEW 1 trial in wet AMD and our Phase 2 DA VINCI trial in DME, partly offset by higher internal costs in connection with regulatory filings in wet AMD. In connection with the recognition of deferred revenue related to the \$75.0 million up-front payment and \$20.0 million milestone payment received in August 2007, as of March 31, 2011, \$44.5 million of these payments was deferred and will be recognized as revenue in future periods.

Technology Licensing Revenue

In connection with our VelocImmune® license agreement with Astellas, the \$20.0 million non-refundable payment received in the second quarter of 2010 was deferred upon receipt and is being recognized as revenue ratably over the ensuing year. In addition, in connection with the amendment and extension of our license agreement with Astellas, in August 2010, we received a \$165.0 million up-front payment, which was deferred upon receipt and will be recognized as revenue ratably over a seven-year period beginning in mid-2011. In connection with our VelocImmune® license agreement with AstraZeneca, the \$20.0 million non-refundable payment received in the first quarter of 2010 was deferred upon receipt and recognized as revenue ratably over the final year of the agreement. In the first quarter of 2011 and 2010, we recognized \$7.9 million and \$10.0 million, respectively, of technology licensing revenue related to these agreements. As of March 31, 2011, \$168.7 million of technology licensing payments received from Astellas was deferred and will be recognized as revenue in future periods.

Net Product Sales

For the three months ended March 31, 2011 and 2010, we recognized as revenue \$4.4 million and \$9.9 million, respectively, of ARCALYST® net product sales. We had limited historical return experience for ARCALYST® beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST® net product sales were deferred until the right of return no longer existed and rebates could be reasonably estimated. Effective in the first quarter of 2010, we determined that we had accumulated sufficient historical data to reasonably estimate both product returns and rebates of ARCALYST®. As a result, \$4.8 million of previously deferred ARCALYST® net product sales were recognized as revenue in the first quarter of 2010. At March 31, 2011 and 2010, there was no deferred revenue related to ARCALYST® net product sales.

Contract Research and Other Revenue

Contract research and other revenue for the three months ended March 31, 2011 and 2010 included \$1.0 million and \$1.1 million, respectively, recognized in connection with our five-year grant from the NIH, which we were awarded in September 2006 as part of the NIH's Knockout Mouse Project.

Expenses

Total operating expenses increased to \$153.2 million in the first quarter of 2011 from \$132.4 million in the first quarter of 2010. Our average headcount in the first quarter of 2011 increased to 1,432 from 1,087 in the same period of 2010 principally as a result of our expanding research and development activities, which were primarily attributable to our antibody collaboration with sanofi-aventis.

Operating expenses in the first quarter of 2011 and 2010 included a total of \$14.8 million and \$8.8 million, respectively, of non-cash compensation expense related to employee stock option and restricted stock awards (Non-cash Compensation Expense), as detailed below:

	For the three months ended March 31, 2011		
	Expenses before		
	inclusion of Non-cash	Non-cash	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported
Research and development	\$ 1216	\$ 78	\$ 129.4
Selling, general, and administrative	16.4	7.0	23.4
Cost of goods sold	0.4		0.4
Total operating expenses	\$ 138.4	\$ 14.8	\$ 153.2
	For the three months ended March 31, 2010		
	Expenses before		_
	inclusion of Non-cash	Non-cash	
Expenses	Compensation	Compensation	Expenses as
(In millions)	Expense	Expense	Reported
Research and development	\$ 112.5	\$ 50	5 1173
Selling, general, and administrative	10.4	3.8	14.2
Cost of goods sold	p. 7		67
Total operating expenses	\$ 123.6	\$ 8.8	\$ 132.4

The increase in total Non-cash Compensation Expense in the first quarter of 2011 was primarily attributable to (i) the recognition of higher expense in the first quarter of 2011 in connection with previously granted performance-based stock options that we estimate will vest, (ii) the higher fair market value of our Common Stock on the date of our annual employee option grants made in December 2010 compared to recent prior years, and (iii) the recognition of higher expense related to grants of restricted stock in December 2010.

Research and Development Expenses

Research and development expenses increased to \$129.4 million in the first quarter of 2011 from \$117.5 million in the same period of 2010. The following table summarizes the major categories of our research and development expenses for the three months ended March 31, 2011 and 2010:

	For the three months ended		
Research and Development Expenses	March 31,		Increase
(In millions)	2011	2010	(Decrease)
Payroll and benefits (1)	\$ 42.6	177.7	\$ 14.9
Clinical trial expenses	19.0	32.2	(13.2)
Climical manufacturing costs (2)	22.2	20,0	2.2
Research and other development costs	15.3	12.8	2.5
Occupancy and other operating costs	14.0	12.0	2.0
Cost-sharing of Bayer HealthCare VEGF Trap-			
Eye development expenses (3)	16,3	12.8	3.5
Total research and development expenses	§ 129.4	117.5	\$ 119

- (1) Includes \$6.9 million and \$4.3 million of Non-cash Compensation Expense for the three months ended March 31, 2011 and 2010, respectively.
- (2) Represents the full cost of manufacturing drug for use in research, preclinical development, and clinical trials, including related payroll and benefits, Non-cash Compensation Expense, manufacturing materials and supplies, depreciation, and occupancy costs of our Rensselaer manufacturing facility. Includes \$0.9 million and \$0.7 million of Non-cash Compensation Expense for the three months ended March 31, 2011 and 2010, respectively.
- (3) Under our collaboration with Bayer HealthCare, in periods when Bayer HealthCare incurs VEGF Trap-Eye development expenses, we also recognize, as additional research and development expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Bayer HealthCare provides us with estimated VEGF Trap-Eye development expenses for the most recent fiscal quarter. Bayer HealthCare's estimate is reconciled to its actual expenses for such quarter in the subsequent fiscal quarter and our portion of its VEGF Trap-Eye development expenses that we are obligated to reimburse is adjusted accordingly.

Payroll and benefits increased principally due to the increase in employee headcount, as described above. Clinical trial expenses decreased due primarily to lower costs related to our Phase 3 clinical development program for ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, our Phase 3 VIEW 1 trial of VEGF Trap-Eye in wet AMD and our Phase 2 DA VINCI trial in DME, and our clinical development program for NGF, which is currently on clinical hold. Clinical manufacturing costs increased due to higher facility-related costs in connection with the expansion of our manufacturing capacity at our Rensselaer facility and higher costs related to manufacturing ZALTRAPTM clinical supplies, partly offset by lower costs related to manufacturing ARCALYST® clinical supplies. Research and other development costs increased primarily due to higher costs associated with filing our BLA for VEGF Trap-Eye in wet AMD. Occupancy and other operating costs increased principally in connection with our higher headcount, expanded research and development activities, and new and expanded leased laboratory and office facilities in Tarrytown, New York. Cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses increased primarily due to higher costs in connection with Bayer HealthCare's Phase 3 trial in DME, which was initiated in the first quarter of 2011.

We prepare estimates of research and development costs for projects in clinical development, which include direct costs and allocations of certain costs such as indirect labor, Non-cash Compensation Expense, and manufacturing and other costs related to activities that benefit multiple projects, and, under our collaboration with Bayer HealthCare, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that we are obligated to reimburse. Our estimates of research and development costs for clinical development programs are shown below:

	For the three months		
Project Costs	ended March 31,		Increase
(In millions)	2011	2010	(Decrease)
ARCALYST*	. 89	\$ 20.1	\$ (112)
VEGF Trap-Eye	39.6	33.6	6.0
ZALIRAPPA	6.4	1.9	2.5
REGN88	6.7	4.9	1.8
REGN727	7.1	\$ 7	19
Other antibody candidates in clinical development	12.6	18.9	(6.3)
Other research programs & unallocated costs	48.1	30.9	172
Total research and development expenses	129.4	\$ 117.5	\$ 11.9

Drug development and approval in the U.S. is a multi-step process regulated by the FDA. The process begins with discovery and preclinical evaluation, leading up to the submission of an IND to the FDA which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phases 1, 2, and 3. The most significant costs in clinical development are in Phase 3 clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase 3 clinical trials for a biological product, a BLA must be submitted to, and accepted by, the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase 3B and 4 studies. Phase 3B studies are initiated and either completed or substantially completed while the BLA is under FDA review. These studies are conducted under an IND. Phase 4 studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. In addition, as discovery research, preclinical development, and clinical programs progress, opportunities to expand development of drug candidates into new disease indications can emerge. We may elect to add such new disease indications to our development efforts (with the approval of our collaborator for joint development programs), thereby extending the period in which we will be developing a product. For example, we, and our collaborators where applicable, continue to explore further development of ARCALYST®, ZALTRAPTM, and VEGF Trap-Eye in different disease indications.

There are numerous uncertainties associated with drug development, including uncertainties related to safety and efficacy data from each phase of drug development, uncertainties related to the enrollment and performance of clinical trials, changes in regulatory requirements, changes in the competitive landscape affecting a product candidate, and other risks and uncertainties described in Part II, Item IA, "Risk Factors" under "Risks Related to the Development and Approval of Our Product Candidates," "Risks Related to Commercialization of Products," and "Regulatory and Litigation Risks." The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business.

For these reasons and due to the variability in the costs necessary to develop a pharmaceutical product and the uncertainties related to future indications to be studied, the estimated cost and scope of the projects, and our ultimate ability to obtain governmental approval for commercialization, accurate and meaningful estimates of the total cost to bring our product candidates to market are not available. Similarly, we are currently unable to reasonably estimate if our product candidates will generate material product revenues and net cash inflows. In 2008, we received FDA approval for ARCALYST® for the treatment of CAPS, a group of rare, inherited auto-inflammatory diseases that affect a very small group of people. We currently do not expect to generate material product revenues and net cash inflows from the sale of ARCALYST® for the treatment of CAPS.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased to \$23.4 million in the first quarter of 2011 from \$14.2 million in the same period of 2010 due primarily to increases in compensation expense principally in connection with higher headcount in the first quarter of 2011, higher market research costs primarily in connection with VEGF Trap-Eye, higher legal expenses in connection with patent-related litigation with Genentech, and an increase in Non-cash Compensation Expense for the reasons described above.

Cost of Goods Sold

Cost of goods sold in the first quarter of 2011 and 2010 was \$0.4 million and \$0.7 million, respectively, and consisted primarily of royalties and other period costs related to ARCALYST® commercial supplies.

Other Income and Expense

Investment income increased to \$1.0 million in the first quarter of 2011 from \$0.4 million in the same period of 2010, due primarily to higher yields on, and higher average balances of, cash and marketable securities.

Interest expense increased to \$3.7 million in the first quarter of 2011 from \$2.1 million in the same period of 2010. Interest expense is primarily attributable to the imputed interest portion of payments to our landlord, commencing in the third quarter of 2009, to lease newly constructed laboratory and office facilities in Tarrytown, New York. In February 2011, we began occupying an additional new building in Tarrytown and, therefore, began recognizing interest expense on the related payments to our landlord.

Liquidity and Capital Resources

Since our inception in 1988, we have financed our operations primarily through offerings of our equity securities, a private placement of convertible debt (which was repurchased or repaid in 2008), purchases of our equity securities by our collaborators, including sanofi-aventis, revenue earned under our past and present research and development agreements, including our agreements with sanofi-aventis and Bayer HealthCare, our past contract manufacturing agreements, our technology licensing agreements, ARCALYST® product revenue, and investment income.

Three months ended March 31, 2011 and 2010

At March 31, 2011, we had \$607.6 million in cash, cash equivalents, and marketable securities (including \$7.5 million of restricted cash and marketable securities) compared with \$626.9 million at December 31, 2010 (including \$7.5 million of restricted cash and marketable securities). In January 2011, we received, from Bayer HealthCare, a \$10.0 million milestone payment, which was earned in 2010, in connection with the COPERNICUS study of VEGF Trap-Eye in CRVO.

Cash Used in Operating Activities

Net cash used in operating activities was \$10.6 million in the first quarter of 2011 and \$9.6 million in the first quarter of 2010. Our net losses of \$43.4 million in the first quarter of 2011 and \$30.5 million in the first quarter of 2010 included \$14.8 million and \$8.8 million, respectively, of Non-cash Compensation Expense. Our net losses also included depreciation and amortization of \$7.0 million and \$4.2 million in the first quarter of 2011 and 2010, respectively.

At March 31, 2011, accounts receivable decreased by \$5.0 million, compared to end-of-year 2010, primarily due to the receipt of the \$10.0 million milestone payment in January 2011 from Bayer HealthCare, as discussed above. Our deferred revenue at March 31, 2011 decreased by \$10.3 million, compared to end-of-year 2010, primarily due to the amortization of previously received and deferred \$20.0 million payments under our license agreements with AstraZeneca and Astellas. Accounts payable, accrued expenses, and other liabilities increased by \$13.6 million at March 31, 2011, compared to end-of-year 2010, primarily in connection with higher liabilities for payroll-related expenses.

At March 31, 2010, accounts receivable increased by \$6.3 million, compared to end-of-year 2009, primarily due to a higher receivable balance related to our antibody collaboration with sanofi-aventis. At March 31, 2010, accounts payable, accrued expenses, and other liabilities increased by \$12.6 million, compared to end-of-year 2009, primarily in connection with our expanded levels of activities and expenditures, including higher liabilities for clinical-related expenses and payroll and related costs.

Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$20.3 million in the first quarter of 2011, compared with net cash used in investing activities of \$136.4 million in the first quarter of 2010. In the first quarter of 2011, sales or maturities of marketable securities exceeded purchases by \$42.5 million, whereas in the first quarter of 2010, purchases of marketable securities exceeded sales or maturities by \$113.7 million. Capital expenditures in the first quarter of 2011 and 2010 included costs in connection with expanding our manufacturing capacity at our Rensselaer, New York facilities and tenant improvements and related costs in connection with our December 2006 Tarrytown, New York lease.

Cash Provided by Financing Activities

Net cash provided by financing activities was \$13.0 million in the first quarter of 2011 and \$56.2 million in the first quarter of 2010. In the first quarter of 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs for our new Tarrytown facilities, which we recognized as additional facility lease obligations since we are deemed to own these facilities in accordance with FASB authoritative guidance. In addition, proceeds from issuances of Common Stock in connection with exercises of employee stock options were \$13.3 million in the first quarter of 2011 and \$9.2 million in the first quarter of 2010.

Fair Value of Marketable Securities

At March 31, 2011 and December 31 2010, we held marketable securities whose aggregate fair value totaled \$471.7 million and \$513.9 million, respectively. The composition of our portfolio of marketable securities on these dates was as follows:

	March 31, 2011		December 31, 201	
Investment type	Fair Value	Percent	Fair Value	Percent
Orresponded				
U.S. government agency securities	\$ 385.4	82%	\$ 434.4	85%
U.S. government-guaranteed corporate bunds	55.4	12%	644	13%
Municipal bonds	17.4	4%		
Equity securities	4.6	196	36	194
U.S. government guaranteed collateralized mortgage				
obligations	1.6		2.1	
Other			1.6	
Mortgage-backed securities	0.3	···	1.1	
Total immistrated marketable securities	464.7	99%	506.8	99%
Restricted				
U.S. government agency securities	7.0	1%	7.1	1%
Total marketable securities	<u>\$ 4717</u>	100%	\$ 513.9	100%

In addition, at March 31, 2011 and December 31, 2010, we had \$135.9 million and \$113.0 million, respectively, of cash, cash equivalents, and restricted cash, primarily held in money market funds that invest in U.S. government securities.

Capital Expenditures:

Our cash expenditures for property, plant, and equipment totaled \$22.2 million and \$22.7 million for the first three months of 2011 and 2010, respectively. In February 2010, we received \$47.5 million from our landlord in connection with tenant improvement costs in Tarrytown. In addition, sanofi-aventis has funded \$0.5 million and \$4.6 million, respectively, of agreed-upon capital expenditures incurred by us during the first quarters of 2011 and 2010 to expand our manufacturing capacity at our Rensselaer facilities, which was either received or receivable at March 31, 2011 and 2010.

We expect to incur capital expenditures of approximately \$50 to \$65 million during the remainder of 2011 primarily in connection with tenant improvements at our leased Tarrytown facilities, capital improvements at our Rensselaer, New York manufacturing facilities, and purchases of equipment. We expect to be reimbursed for a portion of these capital expenditures for our Rensselaer facilities by sanofi-aventis, with the remaining amount to be funded by our existing capital resources.

Funding Requirements:

We expect to continue to incur substantial funding requirements for research and development activities (including preclinical and clinical testing). As described above, expenses that we incur in connection with our ZALTRAPTM and antibodies collaborations are, generally, fully funded by sanofi-aventis. In addition, as described above, we and Bayer HealthCare share agreed-upon development expenses that both companies incur in connection with our VEGF Trap-Eye collaboration. After taking into account anticipated reimbursements from our collaborators, we currently estimate that approximately 30-40% of our funding requirements for 2011 will be directed toward technology development, basic research and early preclinical activities, and the preclinical and clinical development of our product candidates (principally, for ARCALYST® and VEGF Trap-Eye). For 2011, we also currently estimate that approximately 15-25% of our funding requirements will be directed toward the planned commercialization of our late-stage product candidates; approximately 20-30% of our funding requirements will be applied to capital expenditures (as described above); and the remainder of our funding requirements will be used for general corporate purposes.

The amount we need to fund operations will depend on various factors, including the potential regulatory approval and commercialization of our product candidates and the timing thereof, the status of competitive products, the success of our research and development programs, the potential future need to expand our professional and support staff and facilities, the status of patents and other intellectual property rights (and pending or future litigation related thereto), the delay or failure of a clinical trial of any of our potential drug candidates, and the continuation, extent, and success of our collaborations with sanofi-aventis and Bayer HealthCare. Clinical trial costs are dependent, among other things, on the size and duration of trials, fees charged for services provided by clinical trial investigators and other third parties, the costs for manufacturing the product candidate for use in the trials, and for supplies, laboratory tests, and other expenses. The amount of funding that will be required for our clinical programs depends upon the results of our research and preclinical programs and early-stage clinical trials, regulatory requirements, the duration and results of clinical trials underway and of additional clinical trials that we decide to initiate, and the various factors that affect the cost of each trial as described above. Our commercialization costs over approximately the next few years will depend on, among other things, whether or not our late-stage product candidates receive regulatory approval, the market potential for such product candidates, and the commercialization terms of our collaboration agreements, if applicable (whereby some or all commercialization costs may be shared with our collaborators). Currently, we are required to pay royalties on product sales of ARCALYST® for the treatment of CAPS. In the future, if we are able to successfully develop, market, and sell ARCALYST® for other indications or certain of our product candidates, we may be required to pay royalties or share

We expect that expenses related to the filing, prosecution, defense, and enforcement of patents and other intellectual property will continue to be substantial.

We believe that our existing capital resources, including funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013. However, this is a forward-looking statement based on our current operating plan, and there may be a change in projected revenues or expenses that would lead to our capital being consumed significantly before such time. For example, in connection with preparing to commercialize and launch potential products that are not licensed to a third party, we could incur substantial premarketing and commercialization expenses that could lead us to consume our cash at a faster rate. If there is insufficient capital to fund all of our planned operations and activities, we anticipate that we would (i) seek sources of additional capital through collaborative arrangements and/or additional public or private financing, including debt and equity financing and/or (ii) prioritize available capital to fund selected preclinical and clinical development programs and/or preparations for the potential commercialization of our late-stage product candidates, or license selected products.

Other than letters of credits totaling \$3.8 million, including the \$3.4 million letter of credit issued in connection with our lease for facilities in Tarrytown, New York, we have no off-balance sheet arrangements. In addition, we do not guarantee the obligations of any other entity. As of March 31, 2011, we had \$0.7 million of financing available under a capital equipment lease line. Aside from this lease line, we had no other established banking arrangements through which we could obtain short-term financing or a line of credit. In October 2010, we filed a shelf registration statement on Form \$-3\$ registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Factors influencing the availability of additional financing include our progress in product development and commercialization, investor perception of our prospects, and the general condition of the financial markets. We may not be able to secure the necessary funding through new collaborative arrangements or additional public or private offerings. If we cannot raise adequate funds to satisfy our capital requirements, we may have to delay, scale-back, or eliminate certain of our research and development activities or future operations. This could materially harm our business.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our earnings and cash flows are subject to fluctuations due to changes in interest rates, principally in connection with our investments in marketable securities, which consist primarily of direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. Government securities. We do not believe we are materially exposed to changes in interest rates. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We estimate that a one percent unfavorable change in interest rates would have resulted in approximately a \$5.5 million and \$1.6 million decrease in the fair value of our investment portfolio at March 31, 2011 and 2010, respectively. The increase in interest rate risk year over year is due primarily to higher balances of marketable debt securities with maturities in excess of one year that we held at March 31, 2011 compared to the same period of 2010.

Credit Quality Risk

We have an investment policy that includes guidelines on acceptable investment securities, minimum credit quality, maturity parameters, and concentration and diversification. Nonetheless, deterioration of the credit quality of an investment security subsequent to purchase may subject us to the risk of not being able to recover the full principal value of the security. We recognized an other-than-temporary impairment charge related to a marketable security of \$0.1 million in the first quarter of 2010. During the first quarter of 2011, we did not recognize any other-than-temporary impairment charges.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our chief executive officer and chief financial officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Based on this evaluation, our chief executive officer and chief financial officer each concluded that, as of the end of such period, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II, OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we are a party to legal proceedings in the course of our business. We do not expect any such current ordinary course legal proceedings to have a material adverse effect on our business or financial condition.

As previously reported, on November 19, 2010, we filed a complaint against Genentech in the U.S. District Court for the Southern District of New York seeking a declaratory judgment that no activities relating to VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. On January 12, 2011, Genentech filed a motion to dismiss the complaint, arguing that the lawsuit was premature and thus the Court lacked subject matter jurisdiction. Upon our submission to the FDA of a BLA for VEGF Trap-Eye for the treatment of wet AMD, we filed a second complaint against Genentech in the same court seeking the same declaratory relief. On April 7, 2011, we and Genentech entered into a Joint Stipulation, which was approved and executed by the Court on April 11, 2011. Pursuant to the Joint Stipulation, we voluntarily dismissed our original complaint in favor of proceeding with our second complaint, and Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the second complaint for lack of subject matter jurisdiction or otherwise under Rule 12 (b) of the Federal Rules of Civil Procedure. On April 25, 2011, Genentech filed an answer to the second complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. We believe Genentech's counterclaims are without merit and intend to defend against them vigorously.

We have initiated patent-related actions against Genentech in Germany and the United Kingdom, and may initiate other actions in other countries outside the U.S.

ITEM 1A. RISK FACTORS

We operate in an environment that involves a number of significant risks and uncertainties. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, operating results, financial condition, and cash flows. The risks described below include forward-looking statements, and actual events and our actual results may differ materially from these forward-looking statements. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business operations. Furthermore, additional risks and uncertainties are described under other captions in this report and should also be considered by our investors.

Risks Related to Our Financial Results and Need for Additional Financing

We have had a history of operating losses and we may never achieve profitability. If we continue to incur operating losses, we may be unable to continue our operations.

From inception on January 8, 1988 through March 31, 2011, we had a cumulative loss of \$1.1 billion. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. In the absence of substantial revenue from the sale of products or other sources, the amount, timing, nature or source of which cannot be predicted, our losses will continue as we conduct our research and development activities.

We may need additional funding in the future, which may not be available to us, and which may force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We will need to expend substantial resources for research and development, including costs associated with clinical testing of our product candidates, and to prepare for potential commercialization of our late-stage product candidates and, if one or more of those product candidates receive(s) regulatory approval, to fund the launch of those product(s). We believe our existing capital resources, together with funding we are entitled to receive under our collaboration agreements, will enable us to meet operating needs through at least 2013; however, one or more of our collaboration agreements may terminate, our projected revenue may decrease, or our expenses may increase, which could result in our capital being consumed significantly before that time. Our expenses may increase for many reasons, including expenses in connection with the potential commercial launch of our late-stage product candidates, expenses related to clinical trials testing ARCALYST® or VEGF Trap-Eye, and expenses related to the potential requirement for us to fund 20% of Phase 3 clinical trial costs for any of our antibody product candidates pursuant to the terms of our collaboration with sanofi-aventis.

We may require additional financing in the future and we may not be able to raise additional funds. If we are able to obtain additional financing through the sale of equity or convertible debt securities, such sales may be dilutive to our shareholders. Debt financing arrangements may require us to pledge certain assets or enter into covenants that would restrict our business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our shareholders. In October 2010, we filed a shelf registration statement on Form S-3 registering the sale, in one or more offerings, of an indeterminate amount of equity or debt securities, together or separately. Our October 2010 public offering of approximately 6.3 million shares of Common Stock was completed under this shelf registration statement; however, there is no assurance that we will be able to complete any additional offerings of securities. Should we require and be unable to raise sufficient funds to complete the development of our product candidates and also to successfully commercialize our late-stage product candidates if they obtain regulatory approval, we may face delay, reduction, or elimination of our research and development or preclinical programs, and even if regulatory approval is obtained for such product candidates, they may never be successfully launched or become profitable, in which case our business, financial condition, or results of operations may be materially harmed.

The value of our investment portfolio, which includes cash, cash equivalents, and marketable securities, is influenced by varying economic and market conditions. A decrease in the value of an asset in our investment portfolio or a default by the issuer may result in our inability to recover the principal we invested and/or a recognition of a loss charged against income

As of March 31, 2011, our cash, cash equivalents, and marketable securities totaled \$607.6 million (including \$7.5 million of restricted cash and marketable securities) and represented 57% of our total assets. We have invested our excess cash primarily in direct obligations of the U.S. government and its agencies, other debt securities guaranteed by the U.S. government, and money market funds that invest in U.S. government securities. We consider assets classified as marketable securities to be "available-for-sale," as defined by FASB authoritative guidance. Marketable securities totaled \$464.7 million at March 31, 2011, are carried at fair value, and the unrealized gains and losses are included in other accumulated comprehensive income (loss) as a separate component of stockholders' equity. If the decline in the value of a security in our investment portfolio is deemed to be other-than-temporary, we write down the security of the total value and recognized a loss which may be fully charged against income. For example, we recognized an other-than-temporary impairment charge related to a marketable security of \$0.1 million in 2010. The current economic environment and the volatility of securities markets increase the risk that we may not recover the principal we invested and/or there may be further declines in the market value of securities in our investment portfolio. As a result, we may incur additional charges against income in future periods for other-than-temporary impairments or realized losses upon a security's sale or maturity, and such amounts may be material.

Risks Related to the Development and Approval of Our Product Candidates

We believe that a significant portion of the value attributed to our company by investors is based on the commercial potential of VEGF Trap-Eye for the treatment of wet AMD and other ophthalmologic diseases, which has not yet been approved by the FDA or by regulatory authorities in countries outside the U.S. If there are material delays in obtaining marketing approval for VEGF Trap-Eye, or such approval is not obtained, our business, results of operations, and financial condition will be materially harmed.

The FDA has substantial discretion in deciding whether or not VEGF Trap-Eye should be granted approval in the U.S. based on the benefits and risks of VEGF Trap-Eye in treating the particular ophthalmologic diseases in which it is being studied in clinical trials. Analogous regulatory authorities in countries outside the U.S. have similar discretion as to approval of VEGF Trap-Eye in those countries. In February 2011, we submitted a BLA for VEGF Trap-Eye for the treatment of wet AMD to the FDA. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Under Priority Review, the target date for an FDA decision on the BLA is August 20, 2011. However, the FDA is not under any legal obligation to complete its review of the BLA or to render a decision within this timeframe, and it is not unusual for the FDA's review of and/or rendering a decision with respect to a BLA that has been granted Priority Review to extend beyond the initial target date. For instance, the FDA may request additional clinical or other data or impose other conditions that must be met in order to secure final approval of our BLA. Even if such data and information are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. The granting of Priority Review designation for our BLA does not change the standards for approval and does not ensure that VEGF Trap-Eye for the treatment of wet AMD will be approved.

Whether VEGF Trap-Eye is approved by the FDA for the treatment of wet AMD, and the timing thereof, will depend on many factors, including the following:

- whether or not the FDA determines that the evidence gathered in well-controlled clinical trials, other clinical trials and nonclinical studies of VEGF Trap-Eye demonstrates that it is safe and effective as a treatment for wet AMD;
- whether or not the FDA is satisfied that the manufacturing facilities, processes, and controls for VEGF Trap-Eye are adequate, that the labeling is satisfactory and that plans for post-marketing studies, safety monitoring, and risk evaluation and management are sufficient; and
- the timing and nature of the FDA's comments and questions, or those of any advisers to the FDA if the FDA seeks external advice, regarding our BLA for VEGF Trap-Eye for the
 treatment of wet AMD, the time required to respond to any such comments and questions and to obtain final labeling, and any other delays that may be associated with the BLA review
 process.

If we experience material delays in obtaining marketing approval for VEGF Trap-Eye for wet AMD in the U.S., we will not receive product revenues during the delay, which would negatively affect our business, results of operations, and financial condition. Such delays may also increase the challenge of competitive products as doctors and patients continue to use existing therapies. If we do not obtain approval to market VEGF Trap-Eye for wet AMD in the U.S., or if there are material delays in obtaining such approval, our business and financial position will be materially harmed.

If we do not obtain regulatory approval for our product candidates, we will not be able to market or sell them, which would materially and negatively impact our business and prospects.

We cannot sell or market products without regulatory approval. If we do not obtain and maintain regulatory approval for our product candidates, including ARCALYST® for the treatment of diseases other than CAPS, VEGF Trap-Eye for the treatment of ophthalmologic diseases, and/or ZALTRAP™ for one or more oncology indications, the value of our company and our results of operations will be materially harmed. As with our BLA for VEGF Trap-Eye for the treatment of wet AMD, we cannot predict as to whether or when our other product candidates, including ZALTRAP™ for second-line treatment of mCRC, VEGF Trap-Eye for CRVO and DME, and ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering therapy, will receive regulatory approval. If we are unable to obtain such approval(s), or if we are materially delayed in doing so, our business and prospects would be materially harmed.

Obtaining and maintaining regulatory approval for drug products is costly, time-consuming, and highly uncertain.

In the U.S., we must obtain and maintain approval from the FDA for each drug we intend to sell. Obtaining FDA approval is typically a lengthy and expensive process, and approval is highly uncertain. Foreign governments also regulate drugs distributed in their country and approval in any country is likely to be a lengthy and expensive process, and approval is highly uncertain. Except for FDA approval of ARCALYST®, and the EMA approval of rilonacept, for the treatment of CAPS, none of our product candidates has ever received regulatory approval to be marketed and sold in the U.S. or any other country. We may never receive regulatory approval for any of our current or future product candidates.

The FDA enforces Good Clinical Practices (GCPs) and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators, and trial sites. If we or any of the third parties conducting our clinical studies are determined to have failed to fully comply with GCPs, the study protocol or applicable regulations, the clinical data generated in those studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, require us to incur additional costs and could substantially harm our business.

Before approving a new drug or biologic product, the FDA requires that the facilities at which the product will be manufactured be in compliance with current Good Manufacturing Practices, or cGMP, requirements. Manufacturing product candidates in compliance with these regulatory requirements is complex, time-consuming, and expensive. To be successful, our products must be manufactured for development, and following approval in commercial quantities, in compliance with regulatory requirements, and at competitive costs. If we or any of our product collaborators or third-party manufacturers, product packagers, or labelers are unable to maintain regulatory compliance, the FDA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug or biologic product, or revocation of a pre-existing approval. As a result, our business, financial condition, and results of operations may be materially harmed.

In addition to the FDA and other regulatory agency regulations in the U.S., we are subject to a variety of foreign regulatory requirements governing human clinical trials, manufacturing, marketing and approval of drugs, and commercial sale and distribution of drugs in foreign countries. The foreign regulatory approval process includes all of the risks associated with FDA approval as well as country specific regulations. Whether or not we obtain FDA approval for a product in the U.S., we must obtain approval of the product by the comparable regulatory authorities in foreign countries before we can conduct clinical trials of or market that product or any other product in those countries.

Clinical trials required for our product candidates are expensive and time-consuming, and their outcome is highly uncertain. If any of our drug trials are delayed or yield unfavorable results, regulatory approval for our product candidates may be delayed or become unobtainable.

As described above, we must conduct extensive testing of our product candidates before we can obtain regulatory approval to market and sell them. We need to conduct both preclinical animal testing and human clinical trials. Conducting these trials is a lengthy, time-consuming, and expensive process. These tests and trials may not achieve favorable results for many reasons, including, among others, failure of the product candidate to demonstrate safety or efficacy, the development of serious or life-threatening adverse events (or side effects) caused by or connected with exposure to the product candidate, difficulty in enrolling and maintaining subjects in the clinical trial, lack of sufficient supplies of the product candidate or comparator drug, and the failure of clinical investigators, trial monitors, contractors, consultants, or trial subjects to comply with the trial plan, protocol, or applicable regulations related to GCPs. A clinical trial may fail because it did not include a sufficient number of patients to detect the endpoint being measured or reach statistical significance. A clinical trial may also fail because the dose(s) of the investigational drug included in the trial were either too low or too high to determine the optimal effect of the investigational drug in the disease setting.

We will need to reevaluate any drug candidate that does not test favorably and either conduct new trials, which are expensive and time consuming, or abandon the drug development program. The failure of clinical trials to demonstrate the safety and effectiveness of our clinical candidates for the desired indication(s) would preclude the successful development of those candidates for such indication(s), in which event our business, financial condition, and results of operations may be materially harmed.

Successful development of our current and future product candidates is uncertain.

Only a small minority of all research and development programs ultimately result in commercially successful drugs. We are testing ZALTRAPTM and VEGF Trap-Eye in a number of late-stage clinical trials. Clinical trials may not demonstrate statistically sufficient effectiveness and safety to obtain the requisite regulatory approvals for these product candidates. In a number of instances, we have terminated the development of product candidates due to a lack of or only modest effectiveness. Moreover, even if we obtain positive results from preclinical or clinical trials, we may not achieve the same success in future trials. Many companies in the biopharmaceutical industry, including Regeneron, have suffered significant setbacks in clinical trials, even after promising results have been obtained in earlier trials.

In April 2011 we announced that our Phase 3 VELOUR trial of ZALTRAPTM met its primary endpoint of improving overall survival in the second-line treatment of mCRC, and that based upon these positive results, we and sanofi-aventis plan to submit regulatory applications for marketing approval to the FDA and EMA in the second half of 2011. However, we can give no assurance as to whether or when such applications, if submitted, will be approved. ZALTRAPTM is also in a Phase 3 clinical trial in combination with a standard chemotherapy regimen for the treatment of first-line androgen independent prostate cancer. We do not have proof of concept data from early-stage, double-blind, controlled clinical trials that ZALTRAPTM will be safe or effective in this cancer setting. In March 2010, Genentech announced that a Phase 3 trial of its VEGF antagonist, Avastin® (Bevacizumab Injection), in combination with chemotherapy in men with prostate cancer, did not meet its primary endpoint. This trial had a very similar design to our ongoing Phase 3 trial of ZALTRAPTM in prostate cancer.

We are testing VEGF Trap-Eye in Phase 3 trials for the treatment of wet AMD, the treatment of CRVO, and the treatment of DME. As described above, in February 2011, we submitted a BLA to the FDA for marketing approval of VEGF Trap-Eye in wet AMD in the U.S. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. Although we reported positive Phase 3 trial results with VEGF Trap-Eye in wet AMD after one year of treatment, the Phase 3 trials will continue for an additional year and there is a risk that the results from the second year of the studies could differ from the previously reported results; such difference could delay or preclude regulatory approval or, if regulatory approval has been granted, result in the revocation of such approval. We also reported positive Phase 3 trial results with VEGF Trap-Eye in CRVO after six months of treatment. The trials are continuing and there is a risk that the one-year results from the studies could differ from the previously reported results, and such final results could delay or preclude regulatory approval. We also reported positive results of a Phase 2 trial in the treatment of DME and that we have initiated a Phase 3 program in that indication. A number of other potential new drugs and biologics which showed promising results in Phase 1 and 2 clinical trials subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals, and this could occur with respect to subsequent clinical trials of VEGF Trap-Eye for the treatment of DME.

Based on the results of three Phase 3 studies, we plan to submit a supplemental BLA to the FDA seeking approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering drug therapy. However, there can be no assurance as to if or when the FDA will grant such approval.

Many of our clinical trials are conducted under the oversight of IDMCs. These independent oversight bodies are made up of external experts who review the progress of ongoing clinical trials, including available safety and efficacy data, and make recommendations concerning a trial's continuation, modification, or termination based on interim, unblinded data. Any of our ongoing clinical trials may be discontinued or amended in response to recommendations made by responsible IDMCs based on their review of such interim trial results. For example, in September 2009, a Phase 3 trial that was evaluating ZALTRAPTM as a first-line treatment for metastic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC after a planned analysis of interim efficacy data determined that the trial would not meet its efficacy endpoint. The recommended termination of any of our ongoing late-stage clinical trials by an IDMC could negatively impact the future development of our product candidate(s), and our business may be materially harmed.

We are studying our antibody candidates in a wide variety of indications in early stage clinical trials. Many of these trials are exploratory studies designed to evaluate the safety profile of these compounds and to identify what diseases and uses, if any, are best suited for these product candidates. These early stage product candidates may not demonstrate the requisite efficacy and/or safety profile to support continued development for some or all of the indications that are being, or are planned to be, studied, which would diminish our clinical "pipeline" and could negatively affect our future prospects and the value of our company.

Serious complications or side effects have occurred, and may continue to occur, in connection with the use of our approved product and in clinical trials of some of our product candidates which could cause our regulatory approval to be revoked or otherwise negatively affected or lead to delay or discontinuation of development of our product candidates which could severely harm our business.

During the conduct of clinical trials, patients report changes in their health, including illnesses, injuries, and discomforts, to their study doctor. Often, it is not possible to determine whether or not the drug candidate being studied caused these conditions. Various illnesses, injuries, and discomforts have been reported from time-to-time during clinical trials of our product candidates. It is possible that as we test our drug candidates in larger, longer, and more extensive clinical programs, illnesses, injuries, and discomforts that were observed in earlier trials, as well as conditions that did not occur or went undetected in smaller previous trials, will be reported by patients. Many times, side effects are only detectable after investigational drugs are tested in large scale, Phase 3 clinical trials or, in some cases, after they are made available to patients after approval. If additional clinical experience indicates that any of our product candidates has many side effects or causes serious or life-threatening side effects, the development of the product candidate may fail or be delayed, which would severely harm our business.

ZALTRAPTM is being studied for the potential treatment of certain types of cancer and our VEGF Trap-Eye candidate is being studied in diseases of the eye. There are many potential safety concerns associated with significant blockade of VEGF that may limit our ability to successfully develop ZALTRAPTM and VEGF Trap-Eye. These serious and potentially life-threatening risks, based on clinical and preclinical experience of VEGF inhibitors, include bleeding, intestinal perforation, hypertension, proteinuria, congestive heart failure, heart attack, and stroke. In addition, patients given infusions of any protein, including VEGF Trap delivered through intravenous administration, may develop severe hypersensitivity reactions or infusion reactions. Other VEGF blockers have reported side effects that became evident only after large scale trials or after marketing approval when large numbers of patients were treated. There are risks inherent in the intravitreal administration of drugs like VEGF Trap-Eye, which can cause injury to the eye and other complications. These and other complications or side effects could harm the development of ZALTRAPTM for the treatment of cancer or VEGF Trap-Eye for the treatment of diseases of the eye.

As more patients begin to use ARCALYST® if it receives approval for the prevention of gout flares in patients initiating uric acid-lowering therapy, and to the extent it is tested in new disease settings, new risks and side effects associated with ARCALYST® may be discovered, and risks previously viewed as inconsequential could be determined to be significant. Like cytokine antagonists such as Ilaris® (canakinumab), a registered trademark of Novartis, Kineret® (anakinra), a registered trademark of Biovitmm AB, Enbrel® (etanercept), a registered trademark of Amgen, Inc. and Pfizer Inc., and Remicade® (infliximab) a registered trademark of Centocor Ortho Biotech, ARCALYST® affects the immune defense system of the body by blocking some of its functions. Therefore, ARCALYST® may interfere with the body's ability to fight infections. Treatment with Kineret®, a medication that works through the inhibition of IL-1, has been associated with an increased risk of serious infections, and serious, life threatening infections have been reported in patients taking ARCALYST®. These or other complications or side effects could cause regulatory authorities to revoke approvals of ARCALYST® for the treatment of CAPS or deny the approval of ARCALYST® for the prevention of gout flares in patients initiating uric acid-lowering treatment or other disease settings. Alternatively, we may be required to conduct additional clinical trials, make changes in the labeling of our product, or limit or abandon our efforts to develop ARCALYST® in new disease settings. Any such side effects may also result in a reduction, or even the elimination, of sales of ARCALYST® in approved indications.

We are studying REGN475, a fully human monoclonal antibody to NGF, in a variety of pain indications, including osteoarthritis of the knee. In December 2010, we were informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

ARCALYST® and our product candidates in development are recombinant proteins that could cause an immune response, resulting in the creation of harmful or neutralizing antibodies against the therapeutic protein.

In addition to the safety, efficacy, manufacturing, and regulatory hurdles faced by our product candidates, the administration of recombinant proteins frequently causes an immune response, resulting in the creation of antibodies against the therapeutic protein. The antibodies can have no effect or can totally neutralize the effectiveness of the protein, or require that higher doses be used to obtain a therapeutic effect. In some cases, the antibody can cross react with the patient's own proteins, resulting in an "auto-immune" type disease. Whether antibodies will be created can often not be predicted from preclinical or clinical experiments, and their detection or appearance is often delayed, so that there can be no assurance that neutralizing antibodies will not be detected at a later date, in some cases even after pivotal clinical trials have been completed. Antibodies directed against the receptor domains of ARCALYST® were detected in patients with CAPS after treatment with ARCALYST®. Nineteen of 55 subjects (35%) who received ARCALYST® for at least 6 weeks tested positive for treatment-emerging binding antibodies on at least one occasion. To date, no side effects related to antibodies were observed in these subjects and there were no observed effects on drug efficacy or drug levels. It is possible that as we continue to test ZALTRAPTM and VEGF Trap-Eye with more sensitive assays in different patient populations, we will find that subjects given ZALTRAPTM and VEGF Trap-Eye develop antibodies to these product candidates, and may also experience side effects related to the antibodies, which could adversely impact the development of such candidates.

We may be unable to formulate or manufacture our product candidates in a way that is suitable for clinical or commercial use.

Changes in product formulations and manufacturing processes may be required as product candidates progress in clinical development and are ultimately commercialized. If we are unable to continue to develop suitable product formulations or manufacturing processes to support large scale clinical testing of our product candidates, including our antibody candidates, we may be unable to supply necessary materials for our clinical trials, which would delay the development of our product candidates. Similarly, if we are unable to supply sufficient quantities of our product or develop product formulations suitable for commercial use, we will not be able to successfully commercialize our product candidates.

Risks Related to Intellectual Property

If we cannot protect the confidentiality of our trade secrets or our patents are insufficient to protect our proprietary rights, our business and competitive position will be harmed.

Our business requires using sensitive and proprietary technology and other information that we protect as trade secrets. We seek to prevent improper disclosure of these trade secrets through confidentiality agreements. If our trade secrets are improperly exposed, either by our own employees or our collaborators, it would help our competitors and adversely affect our business. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biotechnology companies, including our company, involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. Our patents may be challenged, invalidated, or circumvented. Patent applications filed outside the U.S. may be challenged by third parties who file an opposition. Such opposition proceedings are increasingly common in the European Union and are costly to defend. We have pending patent applications in the European Patent Office and it is likely that we will need to defend patent applications from third-party challengers from time to time in the future. Our patent rights may not provide us with a proprietary position or competitive advantages against competitors. Furthermore, even if the outcome is favorable to us, the enforcement of our intellectual property rights can be extremely expensive and time consuming.

We may be restricted in our development, manufacturing, and/or commercialization activities by, and could be subject to damage awards if we are found to have infringed, third-party patents or other proprietary rights, and the costs and expenses of ongoing patent litigation have been and will likely continue to be significant.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Other parties may allege that they have blocking patents to our products in clinical development, either because they claim to hold proprietary rights to the composition of a product or the way it is manufactured or used. Moreover, other parties may allege that they have blocking patents to antibody products made using our *VelocImmune*® technology, either because of the way the antibodies are discovered or produced or because of a proprietary position covering an antibody or the antibody's target.

We are aware of patents and pending applications owned by Genentech that claim certain chimeric VEGF receptors. We do not believe that ZALTRAPTM or VEGF Trap-Eye infringes any valid claim in these patents or patent applications. As described above under Item 1 ("Legal Proceedings"), in November 2010, we commenced a lawsuit against Genentech in the U.S. District Court for the Southern District of New York, seeking a declaratory judgment that no activities relating to the Regeneron VEGF Trap infringe any valid claim of certain Genentech patents referred to as the Davis-Smyth patents. In April 2011, we and Genentech entered into a Joint Stipulation whereby Genentech agreed that it would not seek to transfer the case to another judicial district or move to dismiss the case for lack of subject matter jurisdiction. On April 25, 2011, Genentech filed an answer to our complaint, denying that we are entitled to the declaratory relief being sought by us, and asserting counterclaims that our prior or planned activities relating to VEGF Trap have infringed or will infringe one or more claims of the Davis-Smyth patents. In its answer, Genentech requests a judgment against us for damages, including for willful infringement, and other relief as the Court deems appropriate. We believe Genentech's counterclaims are without merit and intend to defend against them vigorously. However, it is possible that there could be an adverse determination or judgment in this litigation that would materially harm our business by requiring us to seek a license, which may not be available, or precluding the manufacture, further development, or sale of ZALTRAPTM or VEGF Trap-Eye, or resulting in a damage award. In addition, irrespective of the outcome of this litigation, we have incurred and will likely continue to incur significant costs and expenses associated with this matter, which has negatively affected, and will likely continue to negatively affect, our results of operations. We have initiated patent-related actions against Genentech in

We are aware of patents and pending applications owned by Roche that claim antibodies to IL-6R and methods of treating rheumatoid arthritis with such antibodies. We are developing REGN88, an antibody to IL-6R, for the treatment of rheumatoid arthritis. Although we do not believe that REGN88 infringes any valid claim in these patents or patent applications, Roche could initiate a lawsuit for patent infringement and assert its patents are valid and cover REGN88.

We are aware of a U.S. patent jointly owned by Genentech and City of Hope relating to the production of recombinant antibodies in host cells. We currently produce our antibody product candidates using recombinant antibodies from host cells and may choose to produce additional antibody product candidates in this manner. Neither ARCALYST®, ZALTRAP™, nor VEGF Trap-Eye are recombinant antibodies. If any of our antibody product candidates are produced in a manner subject to valid claims in the Genentech patent, then we may need to obtain a license from Genentech, should one be available. Genentech has licensed this patent to several different companies under confidential license agreements. If we desire a license for any of our antibody product candidates and are unable to obtain a license on commercially reasonable terms or at all, we may be restricted in our ability to use Genentech's techniques to make recombinant antibodies in or to import them into the U.S.

Further, we are aware of a number of other third-party patent applications that, if granted with claims as currently drafted, may cover our current or planned activities. We cannot assure you that our products and/or actions in manufacturing and selling our product candidates will not infringe such patents.

Any patent holders could sue us for damages and seek to prevent us from manufacturing, selling, or developing our drug candidates, and a court may find that we are infringing validly issued patents of third parties. In the event that the manufacture, use, or sale of any of our clinical candidates infringes on the patents or violates other proprietary rights of third parties, we may be prevented from pursuing product development, manufacturing, and commercialization of our drugs and may be required to pay costly damages. Such a result may materially harm our business, financial condition, and results of operations. Legal disputes are likely to be costly and time consuming to defend.

We seek to obtain licenses to patents when, in our judgment, such licenses are needed. If any licenses are required, we may not be able to obtain such licenses on commercially reasonable terms, if at all. The failure to obtain any such license could prevent us from developing or commercializing any one or more of our product candidates, which could severely harm our business.

Risks Related to Manufacturing and Supply

We have limited manufacturing capacity, and we rely on contract manufacturers for fill and finish, which could result in our being unable to successfully commercialize our products if they receive regulatory approval and to continue to develop our clinical candidates.

Our manufacturing facility is likely to be inadequate to produce sufficient commercial quantities of all of our late-stage products if they receive regulatory approval. We intend to rely on our corporate collaborators, as well as contract manufacturers, to produce commercial quantities of drug material needed for commercialization of our products to the extent such quantities are not manufactured at our own facility. We rely entirely on third-party manufacturers for filling and finishing services. Generally, in order for third parties to perform any step in the manufacturing and supply chain, we must transfer technology to the third party which can be time consuming and may not be successfully accomplished without considerable cost and expense, or at all. We will have to depend on these third parties to perform effectively on a timely basis and to comply with regulatory requirements. If for any reason they are unable to do so, and as a result we are unable to manufacture and supply sufficient commercial quantities of our products on acceptable terms, or if we should encounter delays or other difficulties in our relationships with our corporate collaborators or third-party manufacturers or other vendors in our supply chain which adversely affect the timely manufacture and supply of our products, our business, financial condition, and results of operations may be materially harmed.

We also must expand our own manufacturing capacity to support the planned growth of our clinical pipeline. Moreover, we will need to expand our manufacturing capacity to supply commercial quantities of the active pharmaceutical ingredients for our product candidates if they are approved for marketing. This will require substantial additional expenditures, and we will need to hire and train significant numbers of employees and managerial personnel to staff our facility. Start-up costs can be large and scale-up entails significant risks related to process development and manufacturing yields. The FDA and analogous foreign regulatory authorities must determine that our manufacturing facilities comply, or continue to comply, with cGMP requirements for both clinical and commercial production and license them, or continue to license them, accordingly. We may not successfully expand or establish sufficient manufacturing capabilities or manufacture our products economically or in compliance with cGMPs and other regulatory requirements, and we and our collaborators may not be able to build or procure additional capacity in the requirements of our clinical demand for VEGF-Trap-Eye, ZALTRAPTM, or our other late-stage product candidates if they receive regulatory approval, and to continue to meet the requirements of our clinical programs. This would interfere with our efforts to successfully commercialize VEGF Trap-Eye, ZALTRAPTM, and our other late-stage product candidates if they receive regulatory approval and could also delay our clinical development programs. As a result, our business, financial condition, and results of operations may be materially harmed.

We may also be unable to obtain key raw materials and supplies for the manufacture of ARCALYST® and our product candidates. In addition, we may face difficulties in developing or acquiring production technology and managerial personnel to manufacture sufficient quantities of our product candidates at reasonable costs and in compliance with applicable quality assurance and environmental regulations and governmental permitting requirements.

Our ability to manufacture our products may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe third-party patents.

Our ability to manufacture ARCALYST®, and our late-stage product candidates, including VEGF Trap-Eye and ZALTRAP™ in our Rensselaer, New York facilities, or to utilize third-party contract manufacturers to produce our products or perform fill/finish services, depends on our and their ability to operate without infringing the patents or other intellectual property rights of third parties. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of our products which could materially harm our business, operations and prospects.

If any of our clinical programs are delayed or discontinued, we may face costs related to the unused capacity at our manufacturing facilities and those of our third-party contract manufacturers performing fill/finish services.

We have large-scale manufacturing operations in Rensselaer, New York. We use our facilities to produce bulk product for clinical and preclinical candidates for ourselves and our collaborations. If our clinical candidates are discontinued, or their clinical development is delayed, we may have to absorb one hundred percent of related overhead costs and inefficiencies, as well as similar costs of third-party contract manufacturers performing fill/finish services for us.