

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, 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)

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) 847-7000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock - par value \$.001 per share	NASDAQ 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 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 pursuant to Rule 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 No

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.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the common stock held by non-affiliates of the registrant was approximately \$4,913,223,000, computed by reference to the closing sales price of the stock on NASDAQ on June 30, 2011, 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 10, 2012:

<u>Class of Common Stock</u>	<u>Number of Shares</u>
Class A Stock, \$.001 par value	2,109,512
Common Stock, \$.001 par value	91,779,465

DOCUMENTS INCORPORATED BY REFERENCE:

Specified portions of the Registrant's definitive proxy statement to be filed in connection with solicitation of proxies for its 2012 Annual Meeting of Shareholders are incorporated by reference into Part III of this Form 10-K. Exhibit index is located on pages 79 to 82 of this filing.

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 from these forward-looking statements. These statements concern, and these risks and uncertainties include, among other things, the success of our commercialization of EYLEA®, the nature, timing, and possible success of and therapeutic applications for 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 our product and drug candidates, competing drugs that may be superior to our product and drug candidates, uncertainty of market acceptance of 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 Sanofi 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.

General

Regeneron Pharmaceuticals, Inc. is a fully integrated biopharmaceutical company that discovers, invents, develops, manufactures, and commercializes medicines for the treatment of serious medical conditions. We currently have two marketed products:

- EYLEA® (aflibercept) Injection, known in the scientific literature as VEGF Trap-Eye, which is available in the United States for the treatment of neovascular age-related macular degeneration (wet AMD). Wet AMD is the leading cause of acquired blindness for people over the age of 65 in the United States and Europe; and
- ARCALYST® (rilonacept) Injection for Subcutaneous Use, which is available by 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 13 product candidates in clinical development, all of which were discovered in our research laboratories. Our Trap-based, late-stage programs are:

- EYLEA®, which is being developed for the treatment of additional serious eye diseases;
- ZALTRAP® (aflibercept), known in the scientific literature as VEGF Trap, which is being developed in oncology in collaboration with Sanofi; and
- ARCALYST®, which is being developed for the prevention of gout flares in patients initiating uric acid-lowering treatment.

Our antibody-based clinical programs include the following fully human monoclonal antibodies:

- Sarilumab (REGN88), an antibody to the interleukin-6 receptor (IL-6R), which is being developed in rheumatoid arthritis;
- REGN727, an antibody to Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9), which is being developed for low-density lipoprotein (LDL) cholesterol reduction;
- 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 (DlI4), 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);
- REGN728, an antibody in clinical development against an undisclosed target;
- REGN1033, an antibody in clinical development against an undisclosed target;
- REGN846, an antibody in clinical development against an undisclosed target, which is being developed in atopic dermatitis; and
- REGN1154, an antibody in clinical development against an undisclosed target.

With the exception of REGN475, REGN846, and REGN1154, which we are developing independently, all of these antibodies are being developed in collaboration with Sanofi.

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*[™] 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, which was expanded during 2009, we plan to advance a total of 20 to 30 candidates into clinical development over the life of the agreement. 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 Products:

***EYLEA*[®] (aflibercept) Injection – wet AMD**

In November 2011, we received U.S. marketing approval from the U.S. Food and Drug Administration (FDA) for EYLEA[®] Injection for the treatment of patients with wet AMD. The approval of EYLEA[®] was granted by the FDA under a Priority Review, a designation that is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. Net product sales of EYLEA[®] in 2011 were \$24.8 million.

EYLEA[®], known in the scientific literature as VEGF Trap-Eye, is a fusion protein locally administered in the eye that is designed to bind Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PlGF) proteins that are involved in the abnormal growth of new blood vessels. The abnormal growth of new blood vessels could leak blood and fluid, which causes disruption and dysfunction of the retina creating distortion and/or blind spots in central vision.

We are collaborating with Bayer HealthCare on the global development of EYLEA[®]. Bayer HealthCare has submitted applications for marketing authorization in the European Union, Japan, and other countries for wet AMD. Bayer HealthCare will market EYLEA[®] outside the United States, where the companies will share equally the profits from any future sales of EYLEA[®]. We maintain exclusive rights to EYLEA[®] in the United States and are entitled to all profits from any such sales.

***ARCALYST*[®] – CAPS**

Net product sales of ARCALYST[®] (riloncept) in 2011 were \$19.9 million. 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.”

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 by 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. EYLEA[®] – Ophthalmologic Diseases

We, together with our ex-U.S. collaborator Bayer HealthCare, are evaluating EYLEA[®] in Phase 3 programs in patients with central retinal vein occlusion (CRVO), diabetic macular edema (DME), and choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia. We plan on initiating a Phase 3 study in branch retinal vein occlusion (BRVO) in the first quarter of 2012. 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 EYLEA[®] and Lucentis[®] (ranibizumab injection), a registered trademark of Genentech, Inc. Lucentis[®] is an anti-VEGF 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 EYLEA[®] 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. The primary endpoint of these non-inferiority studies was the proportion of patients treated with EYLEA[®] 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 EYLEA[®], including EYLEA[®] 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 EYLEA[®] 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 FDA in February 2011 for marketing approval of EYLEA[®] in wet AMD in the United States. In April 2011, the FDA accepted the BLA for filing and granted our request for Priority Review. In June 2011, the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA unanimously recommended that the FDA approve our BLA. In 2011, Bayer HealthCare submitted regulatory applications for marketing approval of EYLEA[®] in wet AMD in the European Union, Japan, and other countries. In November 2011, we received U.S. marketing approval from the FDA for EYLEA[®] Injection for the treatment of patients with wet AMD.

In December 2011, we and Bayer HealthCare announced Year 2 results from the VIEW 1 and VIEW 2 studies. In the second year of the studies, patients were treated with the same dose per injection as in the first year and were evaluated monthly to determine need for retreatment. Patients were treated at least every 12 weeks. All Year 2 analyses were considered exploratory. In an integrated analysis of the VIEW 1 and VIEW 2 studies, the visual acuity gain from baseline in the EYLEA[®] 2.0 mg every eight week group at week 96 was 7.6 letters compared to 8.4 letters at week 52, with an average of 11.2 injections over two years and 4.2 injections during the second year. The visual acuity gain from baseline in the monthly Lucentis[®] group at week 96 was 7.9 letters compared to 8.7 letters at week 52, with an average of 16.5 injections over two years and 4.7 injections during the second year. The results of each of the VIEW 1 and VIEW 2 studies were consistent with the integrated analysis.

The overall fewer average number of injections in the second year in the EYLEA[®] 2.0 mg every eight week group compared to the Lucentis[®] group (4.2 versus 4.7; nominal $p < 0.0001$) was driven by the fact that fewer patients needed more intense therapy in the EYLEA[®] group and those patients required fewer injections.

The proportion of patients who required frequent injections (six or more) during Year 2 was lower in the EYLEA[®] 2.0 mg every eight week group compared to the Lucentis[®] group (15.9% versus 26.5%). In the 25% of patients who required the most intense therapy (the greatest number of injections), patients in the EYLEA[®] 2.0 mg every eight week group required an average of 1.4 fewer injections in Year 2 compared to the Lucentis[®] group (6.6 versus 8.0). In the 25% of patients in each group who had the fewest number of injections in Year 2, the average number of injections was similar (approximately 3 for both groups, corresponding to the protocol-mandated minimum number of injections).

A generally favorable safety profile was observed for both EYLEA[®] and Lucentis[®]. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies. The most frequent ocular adverse events (greater than 10% of patients for the overall study population) were conjunctival hemorrhage, eye pain, retinal hemorrhage, and visual acuity reduced. 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 (greater than 1% of patients for the overall study population) were falls, pneumonia, myocardial infarction and atrial fibrillation. There were no notable differences among the study arms. The incidence of arterial thrombotic events as defined by the "Anti-Platelet Trialists" group criteria was 3.2% of patients for Lucentis[®] and 3.3% of patients in the combined EYLEA[®] groups.

In the fourth quarter of 2011, we and Bayer HealthCare initiated a Phase 3 trial, known as SIGHT, evaluating the efficacy and safety of EYLEA[®] in the neovascular form of wet AMD in China. EYLEA[®] will be evaluated for its effect on improving and maintaining vision when dosed as an intravitreal injection on a schedule of 2.0 mg every two months (following three initial monthly doses), as compared with Photodynamic Therapy (PDT) with verteporfin. After assessment of the primary endpoint at week 28, all patients, including those on PDT, will receive EYLEA[®] treatment until the end of the study at week 52. The trial will include approximately 300 patients and will be the largest retinal trial conducted in China. The SIGHT trial is being led by Bayer HealthCare.

EYLEA[®] was also in Phase 3 clinical studies for the treatment of CRVO, another cause of visual impairment. We led 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 led the GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) study. Patients in both studies received six monthly intravitreal injections of either EYLEA[®] at a dose of 2.0 mg or sham control injections. The primary endpoint of both studies was 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 were dosed on an as-needed (PRN) basis for another six months. All patients were eligible for rescue laser treatment. In the COPERNICUS study, patients who were randomized to sham injections in the first six months were eligible to cross over to EYLEA[®] PRN dosing in the second six months.

In December 2010, we and Bayer HealthCare announced that in the COPERNICUS study, EYLEA[®] demonstrated a statistically significant improvement in visual acuity at six months compared to sham injections, the primary endpoint of the study. In this study, 56.1% of patients receiving EYLEA[®] gained at least 15 letters of vision from baseline, compared to 12.3% of patients receiving sham injections ($p < 0.0001$). In the study, EYLEA[®] 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 EYLEA[®] group were uncommon (3.5%), consisting of individual reports of corneal abrasion, endophthalmitis, 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 EYLEA[®] and two (2.7%) in the 73 patients treated with sham injections.

The one-year COPERNICUS results showed that 55.3% of patients receiving EYLEA[®] dosed monthly for 24 weeks, then on a PRN basis (guided by anatomic and visual acuity monitoring) over the next 28 weeks, gained at least 15 letters from baseline on an ETDRS eye chart compared to 30.1% of patients who received sham injections for the first 24 weeks followed by EYLEA[®] PRN from week 24 to week 52 ($p = 0.0006$). In terms of gain in visual acuity from baseline to week 52, patients receiving EYLEA[®] monthly for 24 weeks followed by EYLEA[®] PRN gained, on average, 16.2 letters of vision compared to a mean gain of 3.8 letters for patients who switched at week 24 from sham to EYLEA[®] PRN ($p < 0.0001$). These results demonstrate that the benefits achieved with monthly EYLEA[®] treatment through week 24 were maintained out to week 52. At week 24, patients receiving EYLEA[®] had a mean gain of 17.3 letters, while patients receiving sham had a mean loss of 4.0 letters ($p < 0.0001$). Patients who received EYLEA[®] monthly followed by EYLEA[®] PRN, were administered a mean of 2.7 EYLEA[®] injections from week 24 to 52, while patients who switched from sham to EYLEA[®] PRN received a mean of 3.9 EYLEA[®] injections. EYLEA[®] was generally well tolerated in the study. At week 52, the most frequently reported adverse events in patients who went from monthly EYLEA[®] to EYLEA[®] PRN were reduction of visual acuity, conjunctival hemorrhage, eye pain, and intraocular pressure increased. The most frequently reported adverse events in patients who switched from sham to EYLEA[®] PRN were reduction of visual acuity, conjunctival hemorrhage, intraocular pressure increased, and retinal hemorrhage. At week 52, 5.3% of patients receiving EYLEA[®] who switched to EYLEA[®] PRN and 16.2% of patients who switched from sham to EYLEA[®] PRN reported at least one ocular serious adverse event.

In April 2011, we and Bayer HealthCare announced that in the GALILEO study, EYLEA[®] also demonstrated a statistically significant improvement in visual acuity at six months compared to sham injections, the primary endpoint of the study. In this trial, 60.2% of patients receiving 2.0 mg of EYLEA[®] 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 EYLEA[®] 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, EYLEA[®] 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 EYLEA[®] group were 2.9% and were more frequent in the control group (8.8%). The most frequently reported adverse events overall in the EYLEA[®] 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 reduced 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.

The one-year GALILEO results showed that 60.2% of patients receiving EYLEA[®] dosed monthly for 24 weeks, then on a PRN basis (guided by anatomic and visual acuity monitoring) over the next 28 weeks, gained at least 15 letters from baseline on an ETDRS eye chart compared to 32.4% of patients receiving sham injections ($p = 0.0004$). In terms of gain in visual acuity from baseline to week 52, patients receiving EYLEA[®] gained, on average, 16.9 letters of vision compared to a mean gain of 3.8 letters for patients receiving sham injections ($p < 0.0001$). These results demonstrate that the benefits achieved with monthly EYLEA[®] treatment through week 24 were maintained out to week 52. At week 24, patients receiving EYLEA[®] had a mean gain of 18 letters compared to a mean gain of 3.3 letters for patients with sham injections ($p < 0.0001$). Patients treated with EYLEA[®] received an average of 2.5 EYLEA[®] injections from week 24 to week 52. EYLEA[®] was generally well tolerated in the study. At week 52, the most frequently reported adverse events overall in the EYLEA[®] arm were macular edema, elevated intraocular pressure, eye pain, conjunctival hemorrhage, and retinal hemorrhage. The most frequently reported adverse events in the sham group were macular edema, retinal hemorrhage, retinal vascular disorder, reduction of visual acuity and eye irritation. At week 52, 9.6% of patients in the EYLEA[®] arm and 8.8% of patients in the sham arm presented with at least one ocular serious adverse event.

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