



Regeneron Reports Full Year and Fourth Quarter 2008 Financial and Operating Results

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Regeneron Reports Full Year and Fourth Quarter 2008 Financial and Operating Results TARRYTOWN, N.Y.--(BUSINESS WIRE)--Feb. 26, 2009-- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial and operating results for the full year and fourth quarter 2008. The Company reported a net loss of \$82.7 million, or \$1.05 per share (basic and diluted), for the year ended December 31, 2008 compared with a net loss of \$105.6 million, or \$1.59 per share (basic and diluted), for the same period in 2007. The Company reported a net loss of \$31.5 million, or \$0.40 per share (basic and diluted), for the fourth quarter of 2008 compared with a net loss of \$13.1 million, or \$0.19 per share (basic and diluted), for the fourth quarter of 2007. In the fourth quarter of 2007, in connection with the Company's VEGF Trap-Eye collaboration with Bayer HealthCare, the Company recognized a cumulative catch-up of revenue and expenses that reduced the net loss for the quarter by \$25.3 million, as described below.

At December 31, 2008, cash, restricted cash, and marketable securities totaled \$527.5 million compared with \$846.3 million at December 31, 2007. During 2008, the Company retired the full \$200 million of its 5.5 percent Convertible Senior Subordinated Notes.

Current Business Highlights

ARCALYST® (riloncept) – Inflammatory Diseases

The Company shipped \$10.7 million of ARCALYST® (riloncept) Injection for Subcutaneous Use to its distributors in 2008. In February 2008, the Company received marketing approval from the U.S. Food and Drug Administration (FDA) for ARCALYST 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, an interleukin-1 (IL-1) blocker, 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.

In March 2008, ARCALYST became available for prescription in the United States, and the Company transitioned the patients who participated in the CAPS pivotal study from clinical study drug to commercial supplies. The Company currently projects shipments of ARCALYST to its distributors to total approximately \$20-24 million in 2009.

The Company is in the process of initiating a Phase 3 clinical development program with ARCALYST 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. The Company plans 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.

Aflibercept (VEGF Trap) – Oncology

Regeneron and collaborator sanofi-aventis are enrolling patients in four Phase 3 trials that combine aflibercept, an anti-angiogenesis agent, 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. Each of the four Phase 3 trials is 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.

VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications. Regeneron and collaborator 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). Regeneron and Bayer HealthCare also initiated a Phase 2 study of VEGF Trap-Eye in patients with diabetic macular edema (DME) in late 2008.

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.), 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

Mylan Exhibit 1041

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. The VIEW 1 and VIEW 2 trials are expected to complete enrollment in 2009, and initial data are expected in late 2010.

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 up 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.

Monoclonal Antibodies

Regeneron and sanofi-aventis are collaborating on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *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 1 trial is in the process of being initiated for REGN421, an antibody to Delta-like ligand-4 (DlI4) that will be evaluated in oncology in patients with advanced malignancies. Over the course of the next several years, the Company and sanofi-aventis plan to advance an average of two to three new fully human antibodies into clinical development each year.

Financial Results

Revenues

Total revenues decreased to \$55.8 million in the fourth quarter of 2008 from \$64.7 million in the same quarter of 2007 and increased to \$238.5 million for the full year 2008 from \$125.0 million for the same period of 2007. The Company's revenue was comprised of contract research and development revenue, technology licensing revenue, and net product sales.

Contract Research and Development Revenue

Contract research and development revenue relates primarily to the Company's aflibercept and antibody collaborations with sanofi-aventis and the Company's VEGF Trap-Eye collaboration with Bayer HealthCare. Contract research and development revenue for the three months and years ended December 31, 2008 and 2007, consisted of the following:

<i>(In millions)</i>	Three months ended		Year ended	
	December 31,		December 31,	
	2008	2007	2008	2007
Contract research & development revenue				
Sanofi-aventis	\$37.6	\$17.2	\$154.0	\$51.7
Bayer HealthCare	3.0	35.9	31.2	35.9
Other	1.7	1.6	7.0	9.0
Total contract research & development revenue	\$42.3	\$54.7	\$192.2	\$96.6

For the three months and years ended December 31, 2008 and 2007, contract research and development revenue from sanofi-aventis consisted of the following:

<i>(In millions)</i>	Three months ended		Year ended	
	December 31,		December 31,	
	2008	2007	2008	2007
Aflibercept:				
Regeneron expense reimbursement	\$6.3	\$10.5	\$35.6	\$38.3
Recognition of deferred revenue related to up-front payments	2.5	2.1	8.8	8.8
Total aflibercept	8.8	12.6	44.4	47.1
Antibody:				
Regeneron expense reimbursement	25.5	3.7	97.9	3.7
Recognition of deferred revenue related to up-front payment	2.6	0.9	10.5	0.9
Other	0.7	—	1.2	—
Total antibody	28.8	4.6	109.6	4.6
Total sanofi-aventis contract research & development revenue	\$37.6	\$17.2	\$154.0	\$51.7

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased for the three months and year ended December 31, 2008, compared to the same periods in 2007, primarily due to lower costs related to manufacturing aflibercept clinical supplies.

Revenue under the antibody collaboration increased for the three months and year ended December 31, 2008 compared to the same periods in 2007 due to the initiation of the collaboration in November 2007.

For the three months and years ended December 31, 2008 and 2007, contract research and development revenue from Bayer HealthCare consisted of the following:

	Three months ended		Year ended	
	December 31,		December 31,	
<i>(In millions)</i>	2008	2007	2008	2007
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$0.5	\$20.0	\$18.8	\$20.0
Recognition of deferred revenue related to up-front and milestone payments	2.5	15.9	12.4	15.9
Total Bayer HealthCare contract research & development revenue	\$3.0	\$35.9	\$31.2	\$35.9

In connection with the Company's VEGF Trap-Eye collaboration with Bayer HealthCare, the Company received a \$75.0 million non-refundable, up-front payment in October 2006 and a \$20.0 million milestone payment in August 2007. Through September 30, 2007 all payments received from Bayer HealthCare, including the up-front and milestone payments and cost sharing reimbursements, were fully deferred and included in deferred revenue. In the fourth quarter of 2007, the Company commenced recognizing previously deferred payments from Bayer HealthCare and cost sharing of the Company's VEGF Trap-Eye development expenses in the Company's Statement of Operations through a cumulative catch-up. The \$75.0 million non-refundable, up-front license payment and \$20.0 million milestone payment are being recognized as contract research and development revenue over the related estimated performance period. In periods when the Company recognizes VEGF Trap-Eye development expenses that it 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, the Company recorded a cumulative catch-up of \$35.9 million of contract research and development revenue from Bayer HealthCare. In addition, in the fourth quarter of 2007, the Company recorded a cumulative catch-up of \$10.6 million of additional research and development expense related to the portion of Bayer HealthCare's 2007 VEGF Trap-Eye development expenses that the Company was obligated to reimburse.

Under the terms of the Bayer HealthCare collaboration, in 2008, the first \$70.0 million of agreed-upon VEGF Trap-Eye development expenses incurred by the Company and Bayer HealthCare under a global development plan were shared equally, and the Company was solely responsible for up to the next \$30.0 million. During the fourth quarter of 2008, Regeneron was solely responsible for most of the collaboration's VEGF Trap-Eye development expenses. As a result, in the fourth quarter of 2008, the portion of the Company's VEGF Trap-Eye development expenses that were reimbursable from Bayer HealthCare, and recognized as contract research and development revenue, amounted to only \$0.5 million.

Technology Licensing Revenue

Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that allow those companies to utilize *VelocImmune*[®] technology in their internal research programs to discover human monoclonal antibodies. Each company made \$20.0 million annual, non-refundable payments in each of 2007 and 2008 and agreed to make up to four additional annual payments of \$20.0 million, subject to the ability to terminate their agreements after making two such additional payments. Upon receipt, these payments are deferred and are recognized as revenue ratably over approximately the ensuing year of each agreement. Regeneron will also receive a mid-single-digit royalty on sales of any antibodies discovered utilizing *VelocImmune*.

Net Product Sales

The Company shipped \$10.7 million of ARCALYST[®] (rilonacept) to its distributors in 2008 and recorded \$3.5 million and \$6.3 million in product sales revenue for the three months and year ended December 31, 2008. 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. At December 31, 2008, \$4.0 million of ARCALYST net product sales was included in deferred revenue in the Company's financial statements.

Expenses

Total operating expenses for the fourth quarter of 2008 were \$90.4 million, 19 percent higher than the same period in 2007, and \$328.3 million for the full year 2008, 37 percent higher than for the same period of 2007. Average headcount increased to 903 for the fourth quarter of 2008 compared to 665 for the same period in 2007 and increased to 810 for the full year 2008 from 627 for the full year 2007, due primarily to the Company's expanding research and development activities principally in connection with the Company's antibody collaboration with sanofi-aventis.

Operating expenses included non-cash compensation expense related to employee stock option and restricted stock awards of \$7.8 million in the fourth quarter of 2008 and \$32.5 million for the full year of 2008, compared with \$7.5 million and \$28.1 million, respectively, for the same periods of 2007.

Research and development (R&D) expenses increased to \$76.3 million in the fourth quarter of 2008 from \$64.8 million in the comparable quarter of 2007, and to \$278.0 million for the full year 2008 from \$201.6 million for the same period of 2007. In the fourth quarter and for the full year of 2008, the Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for ARCALYST and REGN88, research and preclinical development costs associated with our antibody programs, and facility-related costs to support the Company's expanded R&D activities. In addition, for the full year of 2008, the Company incurred higher R&D costs related to clinical development of VEGF Trap-Eye and manufacturing supplies of our drug product candidates, especially our monoclonal antibodies. Also, as described above, commencing in the fourth quarter of 2007, the Company began recognizing as additional R&D expense, the portion of Bayer HealthCare's VEGF Trap-Eye development expenses that the Company is obligated to reimburse.

Selling, general, and administrative (SG&A) expenses increased to \$13.5 million in the fourth quarter of 2008 from \$11.4 million in the comparable quarter of 2007, and to \$49.4 million for the full year 2008 from \$37.9 million for the full year 2007. In 2008, the Company incurred \$5.2 million of selling expenses related to ARCALYST[®] (rilonacept) for the treatment of CAPS. In addition, the Company incurred higher compensation expense and recruitment costs associated with expanding the Company's SG&A headcount, higher professional fees related to various general corporate matters, and higher SG&A facility related costs.

Other Income and Expense

Investment income increased to \$2.6 million in the fourth quarter of 2008 from \$1.5 million in the comparable quarter of 2007, and decreased to \$18.2 million for the full year 2008 from \$20.9 million for the full year 2007. For the full year 2008, investment income decreased primarily due to lower yields on our cash and marketable securities. The Company recognized charges of \$0.2 million and \$5.1 million for the fourth quarters of 2008 and 2007, respectively, and \$2.5 million and \$5.9 million for the full year 2008 and 2007, respectively, related to certain marketable securities that were determined to be other-than-temporarily impaired. For the full year 2008, these charges were partially offset by realized gains of \$1.2 million on sales of marketable securities during the year.

During the second and third quarters of 2008, the Company repurchased \$82.5 million in principal amount of its 5.5 percent Convertible Senior Subordinated Notes. In connection with the repurchased notes, the Company recognized a \$0.9 million loss on early extinguishment of debt. The remaining \$117.5 million of these notes were repaid in full upon their maturity in October 2008.

Income Tax Expense

In the fourth quarter of 2008, the Company recognized a \$0.7 million income tax benefit, resulting from a provision in the Housing Assistance Tax Act of 2008 that allowed the Company to claim a refund for certain unused pre-2006 research tax credits. For the full year 2008, income tax expense was \$2.4 million and consisted primarily of alternative minimum tax, which resulted from 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.

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 clinical trials for the potential treatment of cancer, eye diseases, inflammatory diseases, and pain, and has preclinical programs in other diseases and disorders. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks 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 collaboration agreement, including Regeneron's 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, 2008. 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.

REGENERON PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS (Unaudited) (In thousands)

	December 31, 2008	December 31, 2007
ASSETS		
Cash, restricted cash, and marketable securities	\$527,461	\$846,279
Receivables	35,212	18,320
Property, plant, and equipment, net	87,853	58,304
Other assets	19,512	13,355
Total assets	\$670,038	\$936,258
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	\$41,261	\$39,232
Deferred revenue	209,925	236,759
Notes payable		200,000
Stockholders' equity	418,852	460,267
Total liabilities and stockholders' equity	\$670,038	\$936,258

REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited) (In thousands, except per share data)

	For the three months ended December 31,		For the year ended December 31,	
	2008	2007	2008	2007
Revenues				
Contract research and development	\$42,294	\$54,730	\$192,208	\$96,603
Technology licensing	10,000	10,000	40,000	28,421
Net product sales	3,543		6,249	
	55,837	64,730	238,457	125,024
Expenses				
Research and development	76,314	64,825	278,016	201,613
Selling, general, and administrative	13,491	11,439	49,348	37,865
Cost of goods sold	631		923	
	90,436	76,264	328,287	239,478
Loss from operations	(34,599)	(11,534)	(89,830)	(114,454)
Other income (expense)				
Investment income	2,648	1,473	18,161	20,897
Interest expense	(295)	(3,010)	(7,752)	(12,043)
Loss on early extinguishment of debt			(938)	
	2,353	(1,537)	9,471	8,854
Net loss before income tax expense	(32,246)	(13,071)	(80,359)	(105,600)
Income tax expense (benefit)	(728)		2,351	
Net loss	\$ (31,518)	\$ (13,071)	\$ (82,710)	\$ (105,600)
Net loss per share amounts, basic and diluted	\$ (0.40)	\$ (0.19)	\$ (1.05)	\$ (1.59)
Weighted average shares outstanding, basic and diluted	79,190	67,754	78,827	66,334

Source: Regeneron Pharmaceuticals, Inc.

Regeneron Pharmaceuticals, Inc.

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