



## Regeneron Reports Full Year and Fourth Quarter 2009 Financial and Operating Results

February 18, 2010

TARRYTOWN, N.Y., Feb 18, 2010 /PRNewswire via COMTEX News Network/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial and operating results for the full year and fourth quarter of 2009. The Company reported a net loss of \$67.8 million, or \$0.85 per share (basic and diluted), for the year ended December 31, 2009 compared with a net loss of \$79.1 million, or \$1.00 per share (basic and diluted), for the year ended December 31, 2008. The Company reported a net loss of \$36.5 million, or \$0.46 per share (basic and diluted), for the fourth quarter of 2009 compared with a net loss of \$29.5 million, or \$0.37 per share (basic and diluted), for the fourth quarter of 2008.

At December 31, 2009, cash, restricted cash, and marketable securities totaled \$390.0 million compared with \$527.5 million at December 31, 2008.

"Regeneron ended 2009 with many late-stage Phase 3 trials, a diversified pipeline, and a healthy balance sheet," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer. "Our eight drug candidates in development for 17 indications and our expanded antibody collaboration with sanofi-aventis position the Company for continued growth. 2010 should be especially eventful for Regeneron as we anticipate, among other clinical results, Phase 3 data from two of our four trials in gout and from our two studies in wet AMD (age-related macular degeneration), as well as potential interim news from our Phase 3 cancer program."

### Current Business Highlights

#### ARCALYST(R) (rilonacept) - CAPS

The Company shipped \$20.0 million of ARCALYST(R) (rilonacept) Injection for Subcutaneous Use to its distributors in 2009, including \$5.0 million in the fourth quarter, 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 in the United States. This compares to shipments of \$10.7 million in 2008, including \$4.0 million in the fourth quarter of 2008. 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. In October, rilonacept was approved under exceptional circumstances by the European Medicines Agency (EMA) for the treatment of CAPS with severe symptoms in adults and children aged 12 years and older. Rilonacept is not currently marketed in the European Union. ARCALYST is a fusion protein that blocks the cytokine interleukin-1 (IL-1).

#### Rilonacept - Gout

Rilonacept is in a Phase 3 clinical development program 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 nonsteroidal 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. PRE-SURGE 1 and SURGE are fully enrolled. The Company expects to report initial data from SURGE and PRE-SURGE 1 during the first half of 2010 and from PRE-SURGE 2 and RE-SURGE during the first half of 2011. Regeneron owns worldwide rights to rilonacept.

#### VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in the intraocular treatment of retinal diseases. VEGF Trap-Eye blocks vascular endothelial growth factor A (VEGF-A), a secreted protein which promotes the growth of blood vessels. It also binds other mediators of angiogenesis, including VEGF-B and Placental Growth Factor (PlGF). VEGF Trap-Eye is being developed by Regeneron in collaboration with Bayer HealthCare. Bayer HealthCare has rights to market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

Two Phase 3 studies (VIEW 1 and VIEW 2) evaluating VEGF Trap-Eye in patients with the neovascular form of age-related macular degeneration (wet AMD) are fully enrolled, and initial data from these studies are expected in late 2010. In addition, two Phase 3 studies (COPERNICUS and GALILEO) in central retinal vein occlusion (CRVO) are enrolling patients, and initial data are anticipated in early 2011.

In a separate press release issued today, Regeneron and Bayer HealthCare announced that in a Phase 2 study (called DA VINCI) in patients with clinically significant diabetic macular edema (DME), VEGF Trap-Eye achieved the primary study endpoint, a statistically significant improvement in visual acuity over 24 weeks compared to focal laser therapy, the standard of care in DME. VEGF Trap-Eye was generally well-tolerated, and no ocular or non-ocular drug-related serious adverse events were reported in the study.

#### Aflibercept (VEGF Trap) - Oncology

Aflibercept (VEGF Trap) is being developed worldwide by Regeneron and its collaborator, sanofi-aventis, for the potential treatment of solid tumors. Three Phase 3 trials 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. VITAL and VENICE are fully enrolled, and the VELOUR study is approximately 95 percent enrolled. Based on current enrollment and event rates, an interim analysis of VELOUR is expected to be conducted by an independent data monitoring committee (IDMC) in the second half of 2010. Final results from the VITAL study are anticipated in the first half of 2011 and from the VELOUR study in the second half of 2011.

Based on projected event rates, an interim analysis of VENICE is expected to be conducted by an IDMC in mid-2011, with final results anticipated in 2012.

In addition, a Phase 2 study (AFFIRM) is evaluating aflibercept as a 1st line treatment for metastatic colorectal cancer in combination with FOLFOX (folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin). The AFFIRM study is approximately 75 percent enrolled.

### Monoclonal Antibodies

Since 2007, Regeneron and sanofi-aventis have collaborated on the discovery, development, and commercialization of fully human monoclonal antibodies generated by Regeneron using its *VelocImmune(R)* technology. During the fourth quarter of 2009, Regeneron and sanofi-aventis expanded and extended their collaboration with the objective to advance an average of four to five antibodies into clinical development each year between 2010 and 2017. There are five antibody candidates currently in development under the collaboration:

REGN475, an antibody to nerve growth factor (NGF), is being evaluated in Phase 2 studies in osteoarthritis of the knee, sciatic pain, vertebral fracture pain, chronic pancreatitis pain, and thermal injury pain.

REGN88, an antibody to the interleukin-6 receptor (IL-6R), has completed Phase 1 studies. A Phase 2/3 study of REGN88 in rheumatoid arthritis and a Phase 2 study in ankylosing spondylitis, a form of arthritis that primarily affects the spine, are open for enrollment.

REGN421, an antibody to Delta-like ligand-4 (Dl4), a novel anti-angiogenesis target, is in a Phase 1 study in patients with advanced malignancies.

REGN727, an antibody to PCSK9, a novel target for LDL cholesterol reduction, is in a Phase 1 study.

REGN668, an antibody to the interleukin-4 receptor (IL-4R), a target for allergic and immune conditions, is in a Phase 1 study.

### **Financial Results**

#### Revenues

Total revenues increased to \$96.8 million in the fourth quarter of 2009 from \$55.8 million in the same quarter of 2008 and increased to \$379.3 million for the full year 2009 from \$238.5 million for the full-year 2008. The Company's revenue was comprised of collaboration revenue, technology licensing revenue, net product sales, and contract research and other revenue.

#### *Collaboration Revenue*

Collaboration revenue relates to the Company's aflibercept and antibody collaborations with sanofi-aventis and the Company's VEGF Trap-Eye collaboration with Bayer HealthCare. Collaboration revenue for the three months and year ended December 31, 2009 and 2008 consisted of the following:

	Three months ended		Year ended	
	December 31,		December 31,	
(In millions)	2009	2008	2009	2008
Collaboration revenue				
Sanofi-aventis	\$68.2	\$37.6	\$247.2	\$154.0
Bayer HealthCare	12.4	3.0	67.3	31.2
Total collaboration revenue	\$80.6	\$40.6	\$314.5	\$185.2

For the three months and year ended December 31, 2009 and 2008, collaboration revenue from sanofi-aventis consisted of the following:

	Three months ended		Year ended	
	December 31,		December 31,	
(In millions)	2009	2008	2009	2008
Aflibercept:				
Regeneron expense reimbursement		\$5.0	\$6.3	\$26.6
Recognition of deferred revenue related to up-front payments	2.5	2.5	9.9	8.8
Total aflibercept	7.5	8.8	36.5	44.4

Antibody:	---	---	----	----
Regeneron expense reimbursement	58.2	25.5	198.1	97.9
Recognition of deferred revenue related to up-front payment	2.0	2.6	9.9	10.5
Recognition of revenue related to VelociGene(R) agreement	0.5	0.7	2.7	1.2
Total antibody	60.7	28.8	210.7	109.6
Total sanofi-aventis collaboration revenue	\$68.2	\$37.6	\$247.2	\$154.0
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Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased for the three months and year ended December 31, 2009, compared to 2008, primarily due to lower Company costs associated with internal research activities and lower costs related to manufacturing clinical drug supplies. Sanofi-aventis also incurs aflibercept development expenses directly, including costs related to the Phase 3 clinical trials sanofi-aventis is overseeing.

Sanofi-aventis' reimbursement of Regeneron's expenses under the antibody collaboration increased for the three months and year ended December 31, 2009, compared to the same periods in 2008, due to an increase in research activities and increases in development activities for antibody candidates in clinical development.

For the three months and year ended December 31, 2009 and 2008, collaboration revenue from Bayer HealthCare consisted of the following:

(In millions)	Three months ended		Year ended	
	December 31,	December 31,	December 31,	December 31,
	2009	2008	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$9.9	\$0.5	\$37.4	\$18.8
Substantive performance milestone payment	20.0			
Recognition of deferred revenue related to up-front and other milestone payments	2.5	2.5	9.9	12.4
Total Bayer HealthCare collaboration revenue	\$12.4	\$3.0	\$67.3	\$31.2
	=====	=====	=====	=====

In periods when the Company recognizes VEGF Trap-Eye development expenses that the Company incurs under the collaboration with Bayer HealthCare, the Company also recognizes, as contract research and development revenue, the portion of those VEGF Trap-Eye development expenses that is reimbursable by Bayer HealthCare. Cost-sharing of the Company's VEGF Trap-Eye development expenses with Bayer HealthCare increased for the three months and year ended December 31, 2009, compared to the same periods in 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 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, which reduced the amount of cost-sharing revenue the Company 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 the collaboration's clinical development programs in wet AMD, DME, and CRVO. In July 2009, the Company 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, which was recognized as collaboration revenue for the year ended December 31, 2009.

#### Technology Licensing Revenue

Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that allow those companies to utilize *VelocImmune(R)* technology in their internal research programs to discover human monoclonal antibodies. Each company is required to make six \$20.0 million annual, non-refundable payments, subject to the ability to terminate their agreements after making a total of four such payments. To date, the Company has received \$60.0 million in payments from each of AstraZeneca and Astellas under these agreements. Upon receipt, these payments are deferred and

recognized as revenue ratably over 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

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. For the three months and year ended December 31, 2009, the Company recognized as revenue \$5.0 million and \$18.4 million of ARCALYST(R) (rilonacept) net product sales, respectively, for which the right of return no longer exists and rebates can be reasonably estimated, compared to \$3.5 million and \$6.3 million for three months and year ended December 31, 2008. At December 31, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled \$4.8 million and \$4.0 million, respectively.

#### Expenses

Total operating expenses for the fourth quarter of 2009 were \$136.2 million, 54 percent higher than the same period in 2008, and \$453.4 million for the full year 2009, 40 percent higher than the same period in 2008. Average headcount increased to 1,020 for the fourth quarter of 2009 from 903 in the same period of 2008 and increased to 980 for the full year 2009 from 810 in the same period of 2008, due primarily to expanded research and development activities, principally in connection with the sanofi-aventis antibody collaboration. Operating expenses included non-cash compensation expense related to employee stock option and restricted stock awards of \$8.7 million in the fourth quarter of 2009 and \$31.3 million for the full year of 2009, compared with \$7.8 million and \$32.5 million, respectively, for the same periods of 2008.

Research and development (R&D) expenses increased to \$118.8 million in the fourth quarter of 2009 from \$74.6 million in the comparable quarter of 2008, and to \$398.8 million for the full year 2009 from \$274.9 million in 2008. In the fourth quarter and full year of 2009, the Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for rilonacept, VEGF Trap-Eye, and monoclonal antibodies, research and preclinical development costs associated with the antibody programs, and facility-related costs to support expanded R&D activities.

Selling, general, and administrative (SG&A) expenses increased to \$17.0 million in the fourth quarter of 2009 from \$13.2 million in the comparable quarter of 2008, and to \$52.9 million for the full year 2009 from \$48.9 million in 2008. In the fourth quarter and for the full year of 2009, the Company incurred higher compensation expense, higher patent-related costs, higher facility-related costs due primarily to increases in administrative headcount, and higher patient assistance costs related to ARCALYST(R) (rilonacept). These increases were partially offset by lower marketing costs, lower recruitment costs, and lower professional fees related to various corporate matters.

#### Other Income and Expense

Investment income decreased to \$0.6 million in the fourth quarter of 2009 from \$2.6 million in the comparable quarter of 2008 and to \$4.5 million for the full year 2009 compared to \$18.2 million for the full year 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in 2009 compared to 2008.

Interest expense increased to \$1.8 million in the fourth quarter of 2009 from \$0.3 million in the comparable quarter of 2008, and decreased to \$2.3 million for the full year 2009 from \$7.8 million for the full year 2008. Interest expense in 2009 was attributable to the imputed interest portion of the Company's payments to its landlord to lease newly constructed laboratory and office facilities in Tarrytown, New York, which commenced in the third quarter of 2009. Interest expense in 2008 was attributable to the Company's 5.5 percent Convertible Senior Subordinated Notes; no Notes were outstanding in 2009. During the first nine months 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 (Benefit) Expense

In the fourth quarter of 2009, the Company recognized a \$4.1 million income tax benefit, consisting primarily of (i) \$2.7 million from a provision in the Worker, Homeownership, and Business Assistance Act of 2009 that allows the Company to claim a refund of the U.S. federal alternative minimum tax that the Company paid in 2008 and (ii) \$0.7 million 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.

In 2008, the Company 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, the Company incurred and paid income tax expense of \$3.1 million, which related 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 the Company to claim a refund for a portion of its unused pre-2006 research tax credits.

#### Revision of Previously Issued Financial Statements

The Company has revised its financial statements at December 31, 2008 and for the three months and year ended December 31, 2008 in connection with the application of authoritative guidance issued by the Financial Accounting Standards Board (FASB) to the Company's December 2006 lease, as amended, of laboratory and office facilities in Tarrytown, New York. The revisions consisted entirely of non-cash adjustments, primarily to the Company's balance sheet at December 31, 2008, and had no impact to the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs, including the development of its product candidates. The revisions, and a description of the basis for the revisions, are more fully described in the Company's Annual Report on Form 10-K for the year ended December 31, 2009.

#### **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(R) (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, age-related macular degeneration, and certain cancers. Additional therapeutic candidates are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at [www.regeneron.com](http://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 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 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, 2009. 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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REGENERON PHARMACEUTICALS, INC.  
CONDENSED BALANCE SHEETS (Unaudited)  
(In thousands)

December 31, December 31,  
2009 2008

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(Revised)\*

ASSETS

Cash, restricted cash, and marketable securities	\$390,010	\$527,461	
Receivables	65,568	35,212	
Property, plant, and equipment, net	259,676	142,035	
Other assets	25,948	19,512	
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Total assets	\$741,202	\$724,220	
	=====	=====	

LIABILITIES AND STOCKHOLDERS' EQUITY

Accounts payable, accrued expenses, and other liabilities	\$52,990	\$38,599	
Deferred revenue	182,428	209,925	
Facility lease obligations	109,022	54,182	
Stockholders' equity	396,762	421,514	
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Total liabilities and stockholders' equity	\$741,202	\$724,220	
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\* Revised as described in the paragraph of this press release titled "Revision of Previously Issued Financial Statements."

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,	
	2009	2008	2009	2008
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	(Revised)*		(Revised)*	

Revenues

Collaboration revenue	\$80,582	\$40,584	\$314,457	\$185,138
Technology licensing	10,013	10,000	40,013	40,000
Net product sales	5,000	3,543	18,364	6,249
Contract research and other	1,205	1,710	6,434	7,070
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	96,800	55,837	379,268	238,457
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Expenses

Research and development	118,790	74,568	398,762	274,903
Selling, general, and administrative	17,031	13,228	52,923	48,880
Cost of goods sold	387	631	1,686	923
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	136,208	88,427	453,371	324,706
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Loss from operations	(39,408)	(32,590)	(74,103)	(86,249)
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Other income (expense)

Investment income	553	2,648	4,488	18,161
Interest expense	(1,756)	(295)	(2,337)	(7,752)
Loss on early extinguishment of debt			(938)	
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	(1,203)	2,353	2,151	9,471
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Net loss before income tax

(benefit) expense	(40,611)	(30,237)	(71,952)	(76,778)
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Income tax (benefit) expense	(4,122)	(728)	(4,122)	2,351
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Net loss	\$(36,489)	\$(29,509)	\$(67,830)	\$(79,129)
	=====	=====	=====	=====

Net loss per share amounts,

basic and diluted	\$(0.46)	\$(0.37)	\$(0.85)	\$(1.00)
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Weighted average shares

outstanding, basic and diluted	80,137	79,190	79,782	78,827
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\* Revised as described in the paragraph of this press release titled "Revision of Previously Issued Financial Statements."

SOURCE Regeneron Pharmaceuticals, Inc.

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