



## Regeneron Reports First Quarter 2010 Financial and Operating Results

April 29, 2010

TARRYTOWN, N.Y., April 29, 2010 /PRNewswire via COMTEX News Network/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial and operating results for the first quarter of 2010. The Company reported a net loss of \$30.5 million, or \$0.38 per share (basic and diluted), for the first quarter of 2010 compared with a net loss of \$15.4 million, or \$0.19 per share (basic and diluted), for the first quarter of 2009.

At March 31, 2010, cash, restricted cash, and marketable securities totaled \$413.5 million compared with \$390.0 million at December 31, 2009. During the first quarter of 2010, the Company received \$47.5 million from its landlord in connection with tenant improvement costs for new laboratory and office facilities that the Company leases in Tarrytown, New York. In addition, the Company received a \$20.0 million annual technology licensing payment from AstraZeneca during the first quarter of 2010, as described below.

### Current Business Highlights

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

The Company recognized \$9.9 million of net product sales of ARCALYST(R) (rilonacept) Injection for Subcutaneous Use in the first quarter of 2010, which included \$5.1 million of ARCALYST(R) (rilonacept) net product sales made during the quarter and \$4.8 million of previously deferred net product sales, as described below under "Financial Results." In the same quarter of 2009, the Company recognized \$3.9 million of ARCALYST(R) (rilonacept) net product sales. ARCALYST(R) (rilonacept) Injection for Subcutaneous Use 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(R) (rilonacept) is a fusion protein that blocks the cytokine interleukin-1 (IL-1). 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 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.

#### 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 second quarter 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, Regeneron and Bayer HealthCare are conducting two Phase 3 studies (COPERNICUS and GALILEO) in central retinal vein occlusion (CRVO). 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.

In February 2010, Regeneron and Bayer HealthCare announced results of a Phase 2 study (called DA VINCI) in patients with clinically significant diabetic macular edema (DME). In the study, VEGF Trap-Eye achieved the primary study endpoint of 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. 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.

#### 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 randomized, double-blind, Phase 3 trials, all of which are fully enrolled, 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. The third trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. Based on projected event rates, an interim analysis of VELOUR is expected to be conducted by an independent statistician and reviewed by an Independent Data Monitoring Committee (IDMC) in the second half of 2010. An IDMC is a body of independent clinical and statistical experts that meets periodically to evaluate data from the studies. 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 reviewed by an IDMC in mid-2011, with final results anticipated in 2012.

In addition, a randomized 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 fully enrolled, and initial data are anticipated in the second half of 2011.

### 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 and other pain indications.

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 enrolling patients.

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 \$103.5 million in the first quarter of 2010 from \$75.0 million in the same period of 2009. 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 ended March 31, 2010 and 2009 consisted of the following:

	Three months ended March 31,	
(In millions)	2010	2009
Collaboration revenue		
Sanofi-aventis	\$68.7	\$49.6
Bayer HealthCare	13.1	10.0
Total collaboration revenue	\$81.8	\$59.6

For the three months ended March 31, 2010 and 2009, collaboration revenue from sanofi-aventis consisted of the following:

	Three months ended March 31,	
(In millions)	2010	2009
Aflibercept:		
Regeneron expense reimbursement	\$4.9	\$5.4
Recognition of deferred revenue related to up-front payments	2.5	2.5
Total aflibercept	7.4	7.9

#### Antibody:

Regeneron expense reimbursement	59.3	38.4
Recognition of deferred revenue related to up-front payment	1.6	2.6
Recognition of revenue related to VelociGene(R) agreement	0.4	0.7
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Total antibody	61.3	41.7
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Total sanofi-aventis collaboration revenue	\$68.7	\$49.6
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Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased for the three months ended March 31, 2010, compared to 2009, primarily due to lower Company costs associated with internal research activities. 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 ended March 31, 2010, compared to the same periods in 2009, due to an increase in research activities under the companies' expanded collaboration, as described above, and increases in development activities for antibody candidates in clinical development.

For the three months ended March 31, 2010 and 2009, collaboration revenue from Bayer HealthCare consisted of the following:

	Three months ended March 31,	
	2010	2009
(In millions)	-----	-----
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Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$10.6	\$7.5
Recognition of deferred revenue related to up-front and milestone payments	2.5	2.5
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Total Bayer HealthCare collaboration revenue	\$13.1	\$10.0
	=====	=====

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 ended March 31, 2010, compared to the same period in 2009 due to higher costs incurred by the Company in connection with the collaboration's clinical development programs in wet AMD, DME, and CRVO. In 2010 and 2009, development expenses incurred by Regeneron and Bayer HealthCare under the VEGF Trap-Eye global development plan were shared equally.

#### 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 \$80.0 million in payments from AstraZeneca and \$60.0 million in payments from 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 by AstraZeneca or Astellas utilizing *VelocImmune(R)*.

#### 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. The Company had limited historical return experience for ARCALYST(R) (rilonacept) beginning with initial sales in 2008 through the end of 2009; therefore, ARCALYST(R) (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(R) (rilonacept). As a result, for the three months ended March 31, 2010, the Company recognized as revenue \$9.9 million of ARCALYST(R) (rilonacept) net product sales, which included \$5.1 million of ARCALYST(R) (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(R) (rilonacept) net product sales. There was no deferred ARCALYST(R) (rilonacept) net product sales revenue at March 31, 2010. At March 31, 2009, deferred ARCALYST(R) (rilonacept) net product sales revenue was \$4.2 million.

#### Expenses

Total operating expenses for the first quarter of 2010 were \$132.2 million, 44 percent higher than the same period in 2009. Average headcount increased to 1,087 for the first quarter of 2010 compared to 938 for the same period in 2009, due primarily to the Company's expanding 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 (Non-cash Compensation Expense) of \$8.8 million and \$7.7 million, in the first quarters of 2010 and 2009, respectively.

Research and development (R&D) expenses increased to \$117.5 million in the first quarter of 2010 from \$80.3 million in the comparable quarter of 2009. In the first quarter of 2010, the Company incurred higher R&D costs primarily related to additional R&D headcount; clinical development costs for VEGF Trap-Eye, rilonacept, and monoclonal antibodies; manufacturing clinical supplies of monoclonal antibodies and rilonacept; and research and other development activities associated with VEGF Trap-Eye and the Company's antibody programs. In addition, R&D expenses include cost-sharing of Bayer HealthCare's VEGF Trap-Eye development expenses, which increased in the first quarter of 2010 compared to the same period in 2009, primarily due to higher costs in connection with the Phase 3 VEGF Trap-Eye studies being conducted by Bayer HealthCare.

Selling, general, and administrative (SG&A) expenses increased to \$14.0 million in the first quarter of 2010 from \$11.4 million in the comparable quarter of 2009. In the first quarter of 2010, the Company incurred higher SG&A compensation expense due primarily to higher SG&A Non-cash Compensation Expense and additional SG&A headcount, higher recruitment costs, and higher SG&A facility-related costs.

#### 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 in 2010 compared to 2009.

Interest expense of \$2.1 million in the first quarter of 2010 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. These payments commenced in the third quarter of 2009.

#### Revision of Previously Issued Financial Statements

The Company has revised its financial statements for the three months ended March 31, 2009 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 March 31, 2009, and had no impact to the Company's business operations, existing capital resources, or the Company's ability to fund its operating needs. The revisions, and a description of the basis for the revisions, are more fully described in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2010.

#### **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, diseases of the eye (wet age-related macular degeneration and central retinal vein occlusion), and certain cancers. Additional therapeutic candidates 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](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. 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 collaboration agreement, including Regeneron's agreements with 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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(In thousands)

	December	
March 31,	31,	
2010	2009	
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#### ASSETS

Cash, restricted cash, and marketable securities	\$413,517	\$390,010	
Receivables	71,858	65,568	
Property, plant, and equipment, net	274,621	259,676	
Other assets	27,160	25,948	
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Total assets	\$787,156	\$741,202	
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#### LIABILITIES AND STOCKHOLDERS' EQUITY

Accounts payable, accrued expenses, and other liabilities	\$58,045	\$52,990	
Deferred revenue	185,941	182,428	
Facility lease obligations	156,899	109,022	
Stockholders' equity	386,271	396,762	
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Total liabilities and stockholders' equity	\$787,156	\$741,202	
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#### REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited) (In thousands, except per share data)

For the three months	
ended March 31,	
2010	2009
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	(Revised)*

#### Revenues

Collaboration revenue	\$81,758	\$59,608
Technology licensing	10,038	10,000
Net product sales	9,852	3,891
Contract research and other	1,886	1,482
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103,534	74,981	
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#### Expenses

Research and development	117,471	80,307
Selling, general, and administrative	14,005	11,420
Cost of goods sold	717	392
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132,193	92,119	
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Loss from operations	(28,659)	(17,138)
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Other income (expense)

Investment income	439	1,750
Interest expense	(2,084)	
	-----	
	(1,645)	1,750
	-----	-----
Net loss before income tax expense	(30,304)	(15,388)
Income tax expense	218	
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Net loss	\$(30,522)	\$(15,388)
	=====	=====
Net loss per share amounts, basic and diluted	\$(0.38)	\$(0.19)
Weighted average shares outstanding, basic and diluted	81,169	79,498

\* Revised as described in the paragraph of this press release titled "Revision of Previously Issued Financial Statements."