



Regeneron Reports Third Quarter 2010 Financial Results and Business Highlights

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TARRYTOWN, N.Y., Oct 28, 2010 /PRNewswire via COMTEX News Network/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial results for the third quarter of 2010 and provided current business highlights.

Current Business Highlights

Public Offering of Common Stock

In October 2010, the Company completed a public offering of 6,325,000 shares of Common Stock and received net proceeds of approximately \$174.7 million.

Extension of Technology Licensing Agreement with Astellas

In July 2010, Astellas Pharma extended through 2023 the non-exclusive license agreement that allows Astellas to utilize Regeneron's *VelocImmune*(R) technology in its internal research programs to discover fully human monoclonal antibody product candidates. Astellas made a \$165.0 million up-front payment to the Company in August 2010 and will make another \$130.0 million payment in June 2018 unless it terminates the agreement prior to that date. Upon commercialization of any antibody products discovered utilizing *VelocImmune*(R), Astellas will pay the Company a mid-single-digit royalty on product sales.

VEGF Trap-Eye - Ophthalmologic Diseases

Initial data from two Phase 3 studies (VIEW 1 and VIEW 2) evaluating VEGF Trap-Eye (aflibercept ophthalmic solution) in patients with the neovascular form of age-related macular degeneration (wet AMD) are expected in the fourth quarter of 2010. In addition, two Phase 3 studies (COPERNICUS and GALILEO) of VEGF Trap-Eye in central retinal vein occlusion (CRVO) are fully enrolled, and initial data from these studies are anticipated in the first half of 2011. One-year results from a Phase 2 study (DA VINCI) in patients with clinically significant diabetic macular edema (DME) will be available in the fourth quarter of 2010. In February 2010, the Company reported a statistically significant improvement in visual acuity compared to focal laser therapy over the initial 24 weeks of treatment, the primary endpoint of the study.

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.

ARCALYST(R) (rilonacept) - CAPS

Net product sales of ARCALYST(R) Injection for Subcutaneous Use in the third quarter of 2010 were \$4.9 million, compared to \$5.0 million during the same period of 2009. The Company recognized \$20.0 million of net product sales during the first nine months of 2010, which included \$15.2 million of ARCALYST(R) net product sales made during the first nine months of 2010 and \$4.8 million of previously deferred net product sales. In the first nine months of 2009, the Company recognized \$13.4 million of ARCALYST(R) net product sales.

ARCALYST(R) 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) 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.

ARCALYST(R) (rilonacept) - Gout

ARCALYST(R) is in a Phase 3 clinical development program for the prevention of gout flares in patients initiating uric acid-lowering therapy. In June 2010, the Company announced positive efficacy and safety results from a Phase 3 study (PRE-SURGE 1) in gout patients initiating allopurinol therapy to lower their uric acid levels. There are two other ongoing studies in the Phase 3 program. The global PRE-SURGE 2 study, which has a similar trial design as PRE-SURGE 1, is evaluating the number of gout flares per patient over the first 16 weeks of initiation of allopurinol therapy. The global RE-SURGE study is evaluating the safety of ARCALYST(R) versus placebo over 16 weeks in patients who are at risk for gout flares because they are taking uric acid-lowering drug treatment. PRE-SURGE 2 and RE-SURGE are fully enrolled, and the Company expects to have initial data from both studies by early 2011. Regeneron owns worldwide rights to ARCALYST(R).

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 (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 castration-resistant prostate cancer in combination with docetaxel/prednisone.

In September 2010, Regeneron and sanofi-aventis announced that, following a planned interim analysis, the Independent Data Monitoring Committee (IDMC) for the VELOUR study recommended that the study continue to completion as planned, with no modifications due to efficacy or safety concerns. An IDMC is a body of independent clinical and statistical experts that meets periodically to evaluate study data.

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

In addition, a randomized Phase 2 study (AFFIRM) 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. The following antibody candidates are being developed under the collaboration:

REGN727, an antibody to PCSK9, a novel target for LDL cholesterol reduction, is in Phase 1 studies using both intravenous and subcutaneous routes of administration. REGN727 is being studied as a single agent and in combination with statin therapy. A Phase 2 program is expected to begin in the first half of 2011.

REGN88, an antibody to the interleukin-6 receptor (IL-6R), is in a Phase 2/3 study in rheumatoid arthritis and a Phase 2 study in ankylosing spondylitis, a form of arthritis that primarily affects the spine. Both studies are enrolling patients.

REGN421, an antibody to Delta-like ligand-4 (DII4), a novel anti-angiogenesis target, is in a Phase 1 study in patients with advanced malignancies.

REGN668, an antibody to the interleukin-4 receptor (IL-4R), a target for allergic and immune conditions, has completed Phase 1 testing in healthy volunteers and will be entering a Phase 2 study in patients with atopic dermatitis in the fourth quarter of 2010.

REGN475, an antibody to nerve growth factor (NGF), is being evaluated in Phase 2 studies in osteoarthritis of the knee and other pain indications. At the request of the FDA, another pharmaceutical company has suspended its anti-NGF antibody clinical program in osteoarthritis and certain other chronic pain indications. Regeneron has responded to FDA requests for information about patients in the Company's REGN475 clinical trials. REGN475 is currently not on clinical hold, and the Company's Phase 2 trials in patients with vertebral fracture pain and chronic pancreatitis pain are ongoing. The Company's Phase 2 trial in osteoarthritis of the knee has been completed.

REGN910 is an antibody to angiopoietin-2 (ANG2), a novel angiogenesis target. An Investigational New Drug Application (IND) for REGN910 in the oncology setting is expected to be filed by the end of 2010.

We plan to initiate clinical trials with two additional antibodies by the end of the year, REGN846 and REGN728.

Financial Results

The Company's total revenues decreased to \$106.0 million in the third quarter of 2010 from \$117.5 million in the same quarter of 2009, primarily due to the receipt of a \$20.0 million substantive milestone payment from Bayer HealthCare in the third quarter of 2009, partly offset by higher collaboration revenue in the third quarter of 2010 in connection with the Company's antibody collaboration with sanofi-aventis. Total revenues increased to \$325.4 million for the first nine months of 2010 from \$282.5 million for the same period of 2009, primarily due to higher collaboration revenue in 2010 in connection with the Company's antibody collaboration with sanofi-aventis, partly offset by the receipt of the \$20.0 million substantive milestone payment from Bayer HealthCare in 2009.

The Company's total operating expenses increased to \$138.1 million in the third quarter of 2010 from \$118.7 million in the same quarter of 2009, and to \$410.1 million for the first nine months of 2010 from \$317.2 million for the same period of 2009, primarily due to higher research and development expenses in connection with the Company's higher employee headcount and expanding

research and development activities in 2010, principally in connection with the sanofi-aventis antibody collaboration.

The Company had a net loss of \$33.9 million, or \$0.41 per share (basic and diluted), for the third quarter of 2010 compared with a net loss of \$1.0 million, or \$0.01 per share (basic and diluted), for the third quarter of 2009. The Company had a net loss of \$89.9 million, or \$1.10 per share (basic and diluted), for the nine months ended September 30, 2010 compared with a net loss of \$31.3 million, or \$0.39 per share (basic and diluted), for the same period in 2009.

At September 30, 2010, cash, restricted cash, and marketable securities totaled \$520.4 million compared with \$390.0 million at December 31, 2009. Cash, restricted cash, and marketable securities at the end of the third quarter of 2010 included the \$165.0 million up-front payment received in August 2010 from Astellas, as described above. Regeneron currently estimates that year-end 2010 cash, restricted cash, and marketable securities, including the net proceeds of the Company's public offering, as described above, will total \$600 - \$620 million.

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 developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

This news release 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 September 30, 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.

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

	September 30, 2010 ----	December 31, 2009 ----
ASSETS ☐		
Cash, restricted cash, and marketable securities	\$520,409	\$390,010
Receivables	82,287	65,568
Property, plant, and equipment, net	318,498	259,676
Other assets	21,239	25,948
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Total assets	\$942,433	\$741,202
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LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses, and other liabilities	\$80,265	\$52,990
Deferred revenue	355,088	182,428

Facility lease obligations	159,016	109,022
Stockholders' equity	348,064	396,762
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Total liabilities and stockholders' equity	\$942,433	\$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 September 30,		For the nine months ended September 30,	
	2010	2009	2010	2009
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Revenues □				
Collaboration revenue	\$89,344	\$100,689	\$269,678	\$233,875
Technology licensing	10,037	10,000	30,112	30,000
Net product sales	4,936	4,973	19,985	13,364
Contract research and other	1,662	1,793	5,624	5,229
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	105,979	117,455	325,399	282,468
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Expenses □				
Research and development	122,043	105,434	364,040	279,972
Selling, general, and administrative	15,658	12,840	44,560	35,892
Cost of goods sold	372	472	1,494	1,299
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	138,073	118,746	410,094	317,163
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Loss from operations	(32,094)	(1,291)	(84,695)	(34,695)
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Other income (expense)				
Investment income	453	857	1,484	3,935
Interest expense	(2,234)	(581)	(6,660)	(581)
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	(1,781)	276	(5,176)	3,354
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Net loss	\$ (33,875)	\$ (1,015)	\$ (89,871)	\$ (31,341)
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Net loss per share amounts, basic and diluted	\$ (0.41)	\$ (0.01)	\$ (1.10)	\$ (0.39)
Weighted average shares outstanding, basic and diluted	81,638	79,866	81,433	79,663

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