



Regeneron Reports Full Year and Fourth Quarter 2010 Financial and Operating Results

TARRYTOWN, N.Y., Feb. 17, 2011 /PRNewswire/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial results for the full year and fourth quarter of 2010 and provided an update on development programs and upcoming milestones.

"2010 was a very productive year for Regeneron as we reported positive Phase 3 results in four clinical trials: two with VEGF Trap-Eye in wet age-related macular degeneration, called wet AMD, one with VEGF Trap-Eye in central retinal vein occlusion, and one with ARCALYST® for the prevention of gout flares in patients initiating uric-acid lowering therapy," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron. "We expect regulatory applications to be filed in the first half of 2011 for marketing approval in the U.S. and Europe for VEGF Trap-Eye in wet AMD. We also look forward to reporting results from additional Phase 3 trials in central retinal vein occlusion and gout and from two Phase 3 trials with aflibercept in cancer."

"In anticipation of potential product approvals," Dr. Schleifer added, "we are continuing to build our commercialization capabilities. We are also advancing our earlier-stage pipeline which currently includes eight fully-human monoclonal antibodies in clinical development for the treatment of various diseases and conditions including elevated LDL cholesterol, rheumatoid arthritis, atopic dermatitis, and cancer. We anticipate Phase 2 data from some of these programs in 2011."

"We entered 2011 in a strong financial position to support our development and commercialization activities," commented Murray A. Goldberg, Chief Financial Officer, "with approximately \$627 million in cash and securities, following a successful public offering of Common Stock in October 2010."

Clinical Programs Update

VEGF Trap-Eye (aflibercept ophthalmic solution) — Ophthalmologic Diseases

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.

Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States. Bayer HealthCare LLC 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.

Phase 3 studies in wet age-related macular degeneration

In November 2010, Regeneron and Bayer Healthcare reported positive one-year data from 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).

Based on these results, Regeneron plans to submit a Biologics License Application to the Food and Drug Administration (FDA) for marketing approval in the U.S. in the first half of 2011. In addition, Bayer Healthcare intends to submit regulatory applications in the first half of 2011 for marketing approval in Europe.

In VIEW 1 and VIEW 2, VEGF Trap-Eye was administered either monthly or every two months, and compared to monthly doses of ranibizumab, which is the current standard of care in wet AMD. In these studies, all regimens of VEGF Trap-Eye including VEGF Trap-Eye dosed every two months successfully met the primary endpoint of non-inferiority compared to ranibizumab dosed every month. The primary endpoint was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. At least 94% of patients in every VEGF Trap-Eye group, including those dosed every two months, as well as those receiving ranibizumab dosed monthly, maintained visual acuity over 52 weeks.

Visual acuity was measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity. Maintenance of vision was defined as losing fewer than three lines (equivalent to 15 letters) on the ETDRS eye chart.

In VIEW 1 and VIEW 2, a generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. 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.

Phase 3 studies in central retinal vein occlusion

In December 2010, Regeneron and Bayer Healthcare reported positive initial results from the COPERNICUS study, the first of two Phase 3 studies evaluating VEGF Trap-Eye in central retinal vein occlusion (CRVO). Patients received six monthly intravitreal injections of either VEGF Trap-Eye at a dose of 2.0 milligrams (mg) or sham control injections. In COPERNICUS, VEGF Trap-Eye met the primary endpoint of a statistically significant improvement in vision at six months compared to sham injections. In this trial, 56.1% of patients receiving VEGF Trap-Eye gained at least 15 letters of vision from baseline, compared to 12.3% of patients receiving sham injections ($p < 0.0001$). Patients receiving VEGF Trap-Eye on average gained 17.3 letters of vision, compared to a mean loss of 4.0 letters with sham injections ($p < 0.001$), a secondary endpoint.

In the COPERNICUS study, VEGF Trap-Eye 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 VEGF Trap-Eye group were uncommon (3.5%) 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.

Initial results from GALILEO, the second of the two Phase 3 studies in CRVO, are expected in the first half of 2011.

Phase 2 study in diabetic macular edema

In December 2010, Regeneron and Bayer Healthcare reported 52-week results from a Phase 2 study (DA VINCI) comparing treatment with VEGF Trap-Eye to focal laser therapy, the current standard of care, in patients with clinically significant diabetic macular edema (DME). The DME data showed that previously reported visual acuity gains achieved with VEGF Trap-Eye treatment over 24 weeks, the primary endpoint of the study, were maintained or numerically improved up to completion of the study at week 52 in all VEGF Trap-Eye study groups, including the group receiving a 2.0 mg dose every other month. At week 52, all VEGF Trap-Eye dose groups reported mean gains in visual acuity of 9.7 to 13.1 letters, compared to a mean loss of 1.3 letters for patients receiving focal laser therapy ($p < 0.01$ for each VEGF Trap-Eye group versus focal laser).

In DA VINCI, VEGF Trap-Eye was generally well tolerated. The most common adverse events reported were those typically associated with intravitreal injections or the underlying disease. The most frequent ocular adverse events reported among patients receiving VEGF Trap-Eye included conjunctival hemorrhage, eye pain, ocular redness (hyperemia), and increased intraocular pressure. There were no non-ocular serious adverse events judged by investigators to be drug-related during the first six months of the study and one during the second six months.

Based on these positive results, Regeneron and Bayer Healthcare are discussing plans to initiate Phase 3 studies of VEGF Trap-Eye in DME.

Phase 3 study in choroidal neovascularisation

In January 2011, Regeneron and Bayer HealthCare announced a new Phase 3 clinical trial in Asia in collaboration with the Singapore Eye Research Institute (SERI) investigating the efficacy and safety of VEGF Trap-Eye in patients with choroidal neovascularisation (CNV) of the retina as a result of pathologic myopia.

ARCALYST® (riloncept) — Gout

ARCALYST® is a fusion protein that blocks the cytokine interleukin-1 (IL-1). ARCALYST® is currently 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. 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® 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. Patients who received ARCALYST® at a weekly, self-administered, subcutaneous dose of 160 mg had an 80% decrease in mean number of gout flares compared to the placebo group over the 16 week treatment period (0.21 flares vs. 1.06 flares, $p < 0.0001$). Patients who received ARCALYST® at a weekly dose of 80 mg had a 73% decrease compared to the placebo group (0.29 flares vs. 1.06 flares, $p < 0.0001$).

ARCALYST® was generally well tolerated with no reported drug-related serious adverse events. Injection site reaction, generally considered mild, was the most commonly reported adverse event with ARCALYST®.

Two other studies are ongoing 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® 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 in the first quarter of 2011. Regeneron owns worldwide rights to ARCALYST®.

Aflibercept (VEGF Trap) — Oncology

Aflibercept, also known as VEGF Trap, is a fusion protein that is designed to bind VEGF-A and PLGF, proteins that are involved in the abnormal growth of new blood vessels in solid tumors.

Aflibercept is being developed worldwide by Regeneron and its collaborator, the sanofi-aventis Group, 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.

Final results from the VITAL and VELOUR studies are anticipated in the first half of 2011. Based on projected event rates, an interim analysis of the VENICE study is expected to be conducted by an Independent Data Monitoring Committee 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*® 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 eight antibody candidates are currently in clinical development under the collaboration:

REGN727, an antibody to Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9), a novel target for LDL cholesterol ("bad cholesterol") reduction, has been evaluated 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. Phase 2 studies have been initiated in patients with hypercholesterolemia.

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, and initial Phase 2 results are expected in 2011.

REGN421, an antibody to Delta-like ligand-4 (DII4), a novel 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. A Phase 1b study in patients with atopic dermatitis is underway and a Phase 2 study in asthma is planned.

REGN910, an antibody to angiopoietin-2 (ANG2), a novel angiogenesis target, is in a Phase 1 study in oncology.

REGN475, an antibody to nerve growth factor (NGF), has completed a Phase 2 trial in osteoarthritis of the knee. In December 2010, the Company was informed by the FDA that a case confirmed as avascular necrosis of a joint was seen in another company's anti-NGF program. The FDA believes this case, which follows previously-reported cases of joint replacements in patients on an anti-NGF drug candidate being developed by another pharmaceutical company, provides evidence to suggest a class-effect and has placed REGN475 on clinical hold. There are currently no ongoing trials with REGN475 that are either enrolling or treating patients.

REGN728 and REGN846, whose targets remain undisclosed, have entered clinical development.

Financial Results

The Company's total revenues increased to \$133.7 million in the fourth quarter of 2010 from \$96.8 million in the same quarter of 2009 and to \$459.1 million for the full year 2010 from \$379.3 million for the full year 2009. The increases were primarily due to higher collaboration revenue in 2010 in connection with the Company's antibody collaboration with sanofi-aventis. In addition, the increase in the fourth quarter of 2010 was partly due to the recognition of \$20.0 million in substantive milestone payments from Bayer HealthCare.

Net product sales of ARCALYST® in the fourth quarter of 2010 were \$5.3 million, compared to \$5.0 million during the same period of 2009. The Company recognized \$25.3 million of net product sales for the full year 2010, which included \$20.5 million of ARCALYST® net product sales made during 2010 and \$4.8 million of previously deferred net product sales. In 2009, the Company recognized \$18.4 million of ARCALYST® net product sales.

The Company's total operating expenses increased to \$146.5 million in the fourth quarter of 2010 from \$136.2 million in the same quarter of 2009, and to \$556.5 million for the full year 2010 from \$453.4 million for the full year 2009. The increases were primarily due to higher research and development expenses arising from the Company's expanding research and development activities in 2010 and related higher employee headcount, principally in connection with the sanofi-aventis antibody collaboration. Research and development expenses for the full year 2010 rose to \$489.2 million from \$398.8 million in 2009.

The Company had a net loss of \$14.6 million, or \$0.17 per share (basic and diluted), for the fourth quarter of 2010 compared with a net loss of \$36.5 million, or \$0.46 per share (basic and diluted), for the fourth quarter of 2009. The Company had a net loss of \$104.5 million, or \$1.26 per share (basic and diluted), for the full year 2010 compared with a net loss of \$67.8 million, or \$0.85 per share (basic and diluted), for the full year 2009.

In October 2010, the Company completed a public offering of 6,325,000 shares of Common Stock and received net proceeds of \$174.8 million. At December 31, 2010, cash and marketable securities totaled \$626.9 million (including \$7.5 million of restricted cash and marketable securities) compared with \$390.0 million (including \$1.6 million of restricted cash) at 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® (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 and actual events or results may differ materially from these forward-looking statements. These risks and uncertainties 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, 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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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	December 31, 2010	December 31, 2009
ASSETS		
Cash, restricted cash, and marketable securities	626,939	\$390,010

Receivables	93,112	65,568
Property, plant, and equipment, net	347,450	259,676
Other assets	21,931	25,948
	<u> </u>	<u> </u>
Total assets	<u>\$1,089,432</u>	<u>\$741,202</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Accounts payable, accrued expenses, and other liabilities	\$61,008	\$52,990
Deferred revenue	340,579	182,428
Facility lease obligations	160,030	109,022
Stockholders' equity	527,815	396,762
	<u> </u>	<u> </u>
Total liabilities and stockholders' equity	<u>\$1,089,432</u>	<u>\$741,202</u>

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

	For the three months		For the year	
	ended December 31,		ended December 31,	
	2010	2009	2010	2009
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Revenues				
Collaboration revenue	\$117,047	\$80,582	\$386,725	\$314,457
Technology licensing	10,038	10,013	40,150	40,013
Net product sales	5,269	5,000	25,254	18,364
Contract research and other	1,321	1,205	6,945	6,434
	<u>133,675</u>	<u>96,800</u>	<u>459,074</u>	<u>379,268</u>
Expenses				
Research and development	125,212	118,790	489,252	398,762
Selling, general, and administrative	20,641	17,031	65,201	52,923
Cost of goods sold	599	387	2,093	1,686
	<u>146,452</u>	<u>136,208</u>	<u>556,546</u>	<u>453,371</u>
Loss from operations	<u>(12,777)</u>	<u>(39,408)</u>	<u>(97,472)</u>	<u>(74,103)</u>
Other income (expense)				
Investment income	638	553	2,122	4,488
Interest expense	(2,458)	(1,756)	(9,118)	(2,337)
	<u>(1,820)</u>	<u>(1,203)</u>	<u>(6,996)</u>	<u>2,151</u>
Net loss before income tax benefit	<u>(14,597)</u>	<u>(40,611)</u>	<u>(104,468)</u>	<u>(71,952)</u>
Income tax benefit		<u>(4,122)</u>		<u>(4,122)</u>
Net loss	<u>\$ (14,597)</u>	<u>\$ (36,489)</u>	<u>\$ (104,468)</u>	<u>\$ (67,830)</u>
Net loss per share amounts, basic and diluted	\$ (0.17)	\$ (0.46)	\$ (1.26)	\$ (0.85)
Weighted average shares outstanding, basic and diluted	87,405	80,137	82,926	79,782

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