Regeneron Reports Third Quarter 2009 Financial and Operating Results

November 3, 2009

TARRYTOWN, N.Y., Nov 03, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN)today announced financial and operating results for the third quarter of 2009. The Company reported a net loss of $1.0 million, or $0.01 per share (basic and diluted), for the third quarter of 2009 compared with a net loss of $19.1 million, or $0.24 per share (basic and diluted), for the third quarter of 2008. The Company reported a net loss of $31.3 million, or $0.39 per share (basic and diluted), for the nine months ended September 30, 2009 compared with a net loss of $49.6 million, or $0.63 per share (basic and diluted), for the same period in 2008. During the third quarter of 2009, the Company recognized as revenue a $20.0 million milestone payment from Bayer HealthCare, as described below.

At September 30, 2009, cash, restricted cash, and marketable securities totaled $438.6 million compared with $527.5 million at December 31, 2008.

Current Business Highlights

ARCALYST(R) (rilonacept) - Inflammatory Diseases

The Company shipped $5.3 million of ARCALYST(R) (rilonacept) Injection for Subcutaneous Use to its U.S. distributors during the third quarter of 2009, compared to $4.3 million in the same quarter of 2008. Shipments during the first nine months of 2009 were $15.0 million compared to $6.7 million for the same period of 2008. ARCALYST, an interleukin-1 (IL-1) blocker, was approved in the United States in February 2008 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. The Company currently projects shipments of ARCALYST to its U.S. distributors to total approximately $20 million in 2009. In October 2009, rilonacept was approved under exceptional circumstances by the European Medicines Agency (EMEA) for the treatment of CAPS with severe symptoms in adults and children aged 12 years and older.

ARCALYST is in a Phase 3 clinical development program for the treatment of gout. The program includes four clinical trials, all of which are currently enrolling patients. Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) are evaluating ARCALYST 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 ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The fourth Phase 3 trial is a placebo-controlled safety study (RE-SURGE). The Company expects to report initial data from the Phase 3 program in the first half of 2010. Regeneron owns worldwide rights to ARCALYST (rilonacept).

Aflibercept (VEGF Trap) - Oncology

Aflibercept, an anti-angiogenic protein product candidate designed to bind all forms of vascular endothelial growth factor A (VEGF-A), is being developed worldwide by Regeneron and its collaborator, sanofi-aventis. At the end of the third quarter of 2009, more than 80 percent of the planned number of patients were enrolled in each of three Phase 3 trials that 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. Analyses of the data from these studies will be conducted when a prespecified number of events have occurred in each trial. Based on current enrollment and event rates, an interim analysis of the Phase 3 study in colorectal cancer is expected to be conducted by an independent data monitoring committee (IDMC) in the second half of 2010. Complete results from this study in colorectal cancer and from the study in non-small cell lung cancer are anticipated in the first half of 2011. Based on the current enrollment and number of events, an interim analysis of the prostate study is expected to be conducted by an IDMC in mid-2011, with complete results anticipated in 2012. In addition, a Phase 2 study (AFFIRM) is being conducted of aflibercept in 1st line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin.

In September 2009, as previously reported, a fourth Phase 3 trial (VANILLA) that was evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine was discontinued at the recommendation of an IDMC. As part of a planned interim efficacy analysis, the Committee determined that the addition of aflibercept to gemcitabine would be unable to demonstrate a statistically significant improvement in the primary endpoint of overall survival compared to placebo plus gemcitabine in this study. The types and frequencies of adverse events reported on the combination arm with aflibercept were generally as anticipated.

VEGF Trap-Eye - Ophthalmologic Diseases

VEGF Trap-Eye, a specially purified and formulated form of VEGF Trap for use in intraocular treatment of retinal disease, is being developed by Regeneron and its collaborator, Bayer HealthCare. 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 now fully enrolled, and we expect initial data from this program to be reported in late 2010. A Phase 2 study (called DA VINCI) of VEGF Trap-Eye for the treatment of the Diabetic Macular Edema (DME) is also fully enrolled, with data expected during the first half of 2010. Additionally, two Phase 3 studies in Central Retinal Vein Occlusion (CRVO) are enrolling patients; data from the first of these studies are anticipated to be available in the first half of 2011.

During October 2009, 24-month results of the extension stage of the Phase 2 study of VEGF Trap-Eye in wet AMD (CLEAR-IT 2) were presented at the 2009 American Academy of Ophthalmology meeting. After receiving VEGF Trap-Eye for one year, the 117 patients who elected to enter the extension stage were dosed on a 2.0 mg PRN basis, irrespective of the dose at which they were treated earlier in the study. On a combined basis, for

these 117 patients, the mean gain in visual acuity was 7.3 letters (p<0.0001 versus baseline) at the three-month primary endpoint of the original Phase 2 study, 8.4 letters (p<0.0001 versus baseline) at one year, and 6.1 letters (p<0.0001 versus baseline) at month 12 of the extension study. Thus, after 24 months of dosing with VEGF Trap-Eye in the Phase 2 study, patients continued to maintain a highly significant improvement in visual acuity versus baseline, while receiving, on average, only 4.6 injections over the 21-month PRN dosing phase that extended from month three to month 24. The most common adverse events were those typically associated with intravitreal injection.

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.

Monoclonal Antibodies

During the third quarter of 2009, REGN475, an antibody to Nerve Growth Factor (NGF), a novel target for pain, began a dose ranging study in osteoarthritis of the knee. Trial results are expected during the first half of 2010. A Phase 1 study of REGN475 in healthy volunteers is also continuing, and Phase 1 studies are in progress with REGN88, an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis, and REGN421, an antibody to Delta-like ligand-4 (Dll4) that is being studied in patients with advanced malignancies. REGN475, REGN88, and REGN421 are fully human monoclonal antibodies generated by Regeneron using the *VelocImmune(R)* technology and developed within the Company's human antibody collaboration with sanofi-aventis. Regeneron and sanofi-aventis expect to enter two more human monoclonal antibodies into clinical development this year and to advance an average of two to three into clinical development each year thereafter over the next several years.

Financial Results

Revenues

Total revenues increased to $117.5 million in the third quarter of 2009 from $65.6 million in the same quarter of 2008 and increased to $282.5 million for the first nine months of 2009 from $182.6 million for the same period of 2008. The Company's revenue was comprised of contract research and development revenue, a 2009 research progress payment, 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 and nine months ended September 30, 2009 and 2008 consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	2009	2008	2009	2008
Contract research & development revenue				
Sanofi-aventis	$68.5	$42.0	$178.9	$116.3
Bayer HealthCare	12.2	9.0	34.9	28.2
Other	1.8	1.9	5.3	5.4
Total contract research & development revenue	$82.5	$52.9	$219.1	$149.9

For the three and nine months ended September 30, 2009 and 2008, contract research and development revenue from sanofi-aventis consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	2009	2008	2009	2008
Aflibercept:				
Regeneron expense reimbursement	$7.0	$7.3	$21.6	$29.3
Recognition of deferred revenue related to up-front payments	2.5	2.1	7.4	6.2
Total aflibercept	9.5	9.4	29.0	35.5
Antibody:				
Regeneron expense reimbursement	55.7	29.5	139.8	72.4
Recognition of deferred revenue related to up-front payment	2.6	2.6	7.9	7.9
Recognition of revenue related to VelociGene((R))				

agreement	0.7	0.5	2.2	0.5
Total antibody	59.0	32.6	149.9	80.8
Total sanofi-aventis contract research & development revenue	$68.5	$42.0	$178.9	$116.3

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased for the three and nine months ended September 30, 2009, compared to the same periods in 2008, primarily due to lower Company costs associated with internal research activities and, for the nine months ended September 30, 2009, 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 in the oncology program.

Sanofi-aventis' reimbursement of Regeneron's expenses under the antibody collaboration increased for the three and nine months ended September 30, 2009, compared to the same periods in 2008, due to an increase in research activities conducted under the collaboration's discovery agreement and increases in development activities for antibody candidates, including REGN88, REGN421, and REGN475, under the collaboration's license agreement.

For the three and nine months ended September 30, 2009 and 2008, contract research and development revenue from Bayer HealthCare consisted of the following:

	Three months ended September 30,		Nine months ended September 30,	
(In millions)	2009	2008	2009	2008
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$9.7	$5.7	$27.5	$18.3
Recognition of deferred revenue related to up-front and non-substantive milestone payments	2.5	3.3	7.4	9.9
Total Bayer HealthCare contract research & development revenue	$12.2	$9.0	$34.9	$28.2

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. The Company incurred higher VEGF Trap-Eye development expenses under the collaboration for the three and nine months ended September 30, 2009, compared to the same period in 2008, primarily in connection with the collaboration's clinical development programs in wet AMD, DME, and CRVO.

Research Progress Payment

In July 2009, the Company received a $20.0 million substantive 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. The payment was recognized in revenues as a research progress payment for the three and nine months ended September 30, 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 and nine months ended September 30, 2009, the Company recognized as revenue $5.0 million and $13.4 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 $2.7 million for three and nine months ended September 30, 2008. At September 30, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled $5.0 million and $3.8 million, respectively.

Expenses

Total operating expenses for the third quarter of 2009 were $118.7 million, 42 percent higher than the same period in 2008, and $317.2 million for the first nine months of 2009, 34 percent higher than the same period in 2008. Average headcount increased to 998 in the third quarter of 2009 from 851 in the same period of 2008 and increased to 967 for the first nine months of 2009 from 778 in the same period of 2008, 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 of $7.5 million in the third quarter of 2009 and $22.6 million for the first nine months of 2009, compared with $8.2 million and $24.7 million, respectively, for the same periods of 2008.

Research and development (R&D) expenses increased to $105.4 million in the third quarter of 2009 from $72.1 million in the comparable quarter of 2008, and to $280.0 million in the first nine months of 2009 from $200.3 million in the same period of 2008. In the third quarter and first nine months of 2009, the Company incurred higher R&D costs primarily related to additional R&D headcount, clinical development costs for ARCALYST, 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 $12.8 million in the third quarter of 2009 from $11.1 million in the comparable quarter of 2008, and to $35.9 million in the first nine months of 2009 from $35.7 million in the same period of 2008. In the third quarter and for the first nine months of 2009, the Company incurred higher compensation and facility-related expenses due primarily to increases in administrative headcount to support the expanded research and development activities, higher patent-related costs, and higher expenses related to ARCALYST(R) (rilonacept), partially offset by lower market research costs related to various programs and a decrease in recruitment costs for administrative headcount.

Other Income and Expense

Investment income decreased to $0.9 million in the third quarter of 2009 from $3.7 million in the comparable quarter of 2008 and to $3.9 million in the first nine months of 2009 compared to $15.5 million in the first nine months of 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 decreased to $0.6 million in the third quarter of 2009 from $1.8 million in the comparable quarter of 2008, and to $0.6 million in the first nine months of 2009 from $7.5 million in the same period of 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 Expense

In the third quarter of 2008, the Company incurred and paid income tax expense, consisting primarily of alternative minimum tax, of $3.1 million, which resulted from the utilization of certain net operating loss carry-forwards for tax purposes that would otherwise have expired over the next several years.

Revision of Previously Issued Financial Statements

The Company has revised its financial statements at December 31, 2008 and for the three and nine months ended September 30, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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 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 and Form 10-Q for the quarter ended September 30, 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)

	September 30, 2009	December 31, 2008
		(Revised)*
ASSETS		
Cash, restricted cash, and marketable securities	$438,596	$527,461
Receivables	67,766	35,212
Property, plant, and equipment, net	215,169	142,035
Other assets	20,661	19,512
Total assets	$742,192	$724,220
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$55,291	$36,168
Deferred revenue	198,546	209,925
Facility lease obligation	62,571	54,182
Other long-term liabilities	3,341	2,431
Stockholders' equity	422,443	421,514
Total liabilities and stockholders' equity	$742,192	$724,220

* 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 September 30,		For the nine months ended September 30,	
	2009	2008	2009	2008
		(Revised)*		(Revised)*
Revenues				
Contract research and development	$82,482	$52,878	$219,104	$149,914
Research progress payments	20,000		20,000	
Technology licensing	10,000	10,000	30,000	30,000
Net product sales	4,973	2,706	13,364	2,706
	117,455	65,584	282,468	182,620
Expenses				
Research and development	105,434	72,089	279,972	200,335
Selling, general, and administrative	12,840	11,103	35,892	35,652

Cost of goods sold	472	292	1,299	292
	118,746	83,484	317,163	236,279
Loss from operations	(1,291)	(17,900)	(34,695)	(53,659)
Other income (expense)				
Investment income	857	3,674	3,935	15,513
Interest expense	(581)	(1,772)	(581)	(7,457)
Loss on early extinguishment of debt	(7)		(938)	
	276	1,895	3,354	7,118
Net loss before income tax expense	(1,015)	(16,005)	(31,341)	(46,541)
Income tax expense		3,079		3,079
Net loss	$(1,015)	$(19,084)	$(31,341)	$(49,620)
Net loss per share amounts, basic and diluted	$(0.01)	$(0.24)	$(0.39)	$(0.63)
Weighted average shares outstanding, basic and diluted	79,866	78,937	79,663	78,706

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

SOURCE Regeneron Pharmaceuticals, Inc.

http://www.regeneron.com