April 30, 2009

Regeneron Reports First Quarter 2009 Financial and Operating Results

TARRYTOWN, N.Y.--(BUSINESS WIRE)--Apr. 30, 2009-- Regeneron Pharmaceuticals, Inc. **(Nasdaq: REGN)** today announced financial and operating results for the first quarter 2009. The Company reported a net loss of $17.5 million, or $0.22 per share (basic and diluted), for the first quarter of 2009 compared with a net loss of $11.6 million, or $0.15 per share (basic and diluted), for the first quarter of 2008.

At March 31, 2009, cash, restricted cash, and marketable securities totaled $496.0 million compared with $527.5 million at December 31, 2008.

Current Business Highlights

ARCALYST® (rilonacept) – Inflammatory Diseases

The Company shipped $4.3 million of ARCALYST® (rilonacept) Injection for Subcutaneous Use to its U.S. distributors during the first quarter of 2009, compared to $0.8 million during the first quarter of 2008. Shipments of ARCALYST began in the United States in March 2008 following marketing approval of ARCALYST from the U.S. Food and Drug Administration (FDA) 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. ARCALYST, an interleukin-1 (IL-1) blocker, is the only therapy approved in the United States for patients with CAPS. The Company currently projects shipments of ARCALYST to its distributors to total approximately $15-20 million in 2009.

During the first quarter of 2009, the Company initiated a Phase 3 clinical development program with ARCALYST for the treatment of gout. The program includes four clinical trials, three of which are currently enrolling patients: Two Phase 3 clinical trials (called PRE-SURGE 1 and PRE-SURGE 2) will evaluate 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) will evaluate treatment with ARCALYST alone versus ARCALYST in combination with a non-steroidal anti-inflammatory drug (NSAID) versus an NSAID alone. The Phase 3 program also includes a separate placebo-controlled safety study (RE-SURGE). The Company expects to report initial data from the Phase 3 program in 2010. Regeneron owns worldwide rights to ARCALYST.

Aflibercept (VEGF Trap) – Oncology

At the end of the first quarter of 2009, approximately one-half of the planned number of patients were enrolled in four Phase 3 trials that are evaluating combinations of aflibercept, an investigational anti-angiogenesis agent, 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 (VANILLA) is evaluating aflibercept as a 1st line treatment for metastatic pancreatic cancer in combination with gemcitabine. A third trial (VITAL) is evaluating aflibercept as a 2nd line treatment for metastatic non-small cell lung cancer in combination with docetaxel. The fourth trial (VENICE) is evaluating aflibercept as a 1st line treatment for metastatic androgen-independent prostate cancer in combination with docetaxel/prednisone. All four trials are studying the current standard of chemotherapy care for the cancer being studied with and without aflibercept. Initial data from the Phase 3 program are expected in 2010. In addition, a Phase 2 study (AFFIRM) of aflibercept in 1st line metastatic colorectal cancer in combination with folinic acid (leucovorin), 5-fluorouracil, and oxaliplatin began recruiting patients in January 2009.

A Phase 2 single-agent study of aflibercept in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA) is now fully enrolled, and initial data from this trial are expected by mid-2009. Aflibercept is being developed worldwide by Regeneron and its collaborator, sanofi-aventis.

VEGF Trap-Eye – Ophthalmologic Diseases

VEGF Trap-Eye is a specially purified and formulated form of VEGF Trap for use in intraocular applications that is being developed by Regeneron and its collaborator, Bayer HealthCare, for the treatment of the neovascular form of Age-related Macular Degeneration (wet AMD), Diabetic Macular Edema (DME), Central Retinal Vein Occlusion (CRVO), and other eye diseases and disorders.

In a separate news release today, Regeneron and Bayer HealthCare announced plans to initiate a Phase 3 program later this year of VEGF Trap-Eye in the treatment of CRVO. Dosing of the first patient in the Phase 3 program will entitle Regeneron to receive a $20.0 million milestone payment.

The Phase 3 program (consisting of the VIEW 1 and VIEW 2 studies) that is evaluating VEGF Trap-Eye in patients with wet AMD continued to enroll patients during the first quarter of 2009. The companies expect to complete enrollment in both trials in 2009 and report initial data in late 2010.

Results of the extension stage of the Phase 2 study in wet AMD (the CLEAR-IT 2 study) will be presented on May 4 at the 2009 Association for Research in Vision and Ophthalmology (ARVO) meeting in Fort Lauderdale, Florida. In late 2008, the companies reported CLEAR-IT 2 study results, which demonstrated that patients treated with VEGF Trap-Eye achieved durable improvements in visual acuity and retinal thickness for up to one year.

In the original Phase 2 study, 157 patients were initially treated for 3 months with VEGF Trap-Eye: two groups received monthly doses of 0.5 or 2.0 mg (at weeks 0, 4, 8, and 12) and three groups received quarterly doses of 0.5, 2.0, or 4.0 mg (at baseline and week 12). Following the initial 3-month fixed-dosing phase, patients continued to receive VEGF Trap-Eye at the same dose on a PRN dosing schedule through one year, based upon the physician assessment of the need for re-treatment in accordance with pre-specified criteria.

The data to be presented at ARVO will report on 117 patients who elected to enter the extension stage of the study after receiving VEGF Trap-Eye for one year. These patients were dosed on a 2.0 mg PRN basis. 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 3-month primary endpoint of the original Phase 2 study, 8.4 letters ($p<0.0001$ versus baseline) at one year, and 7.1 letters ($p<0.0001$ versus baseline) at month 6 of the extension stage. Thus, after 18 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 3.5 injections over the 15-month PRN dosing phase that extended from month 3 to month 18. Patients continue to be dosed in the extension stage of the Phase 2 study.

Among all the patients in the Phase 2 wet AMD study, VEGF Trap-Eye was generally well tolerated and there were no drug-related serious adverse events. There was one reported case of culture-negative endophthalmitis/uveitis in the study eye and two arterial thrombotic events; these were deemed not to be drug-related. Three deaths were reported—one patient with pancreatic cancer, one patient with squamous cell carcinoma of the lung, and one patient with pulmonary hypertension (a pre-existing condition), The most common adverse events were those typically associated with intravitreal injections and included conjunctival hemorrhage at the injection site and transient increased intraocular pressure following an injection.

In the Phase 2 DME study, additional clinical sites were opened during the first quarter of 2009. The study (called DA VINCI) is evaluating four different VEGF Trap-Eye regimens versus laser treatment. The study began in December 2008 and is expected to complete enrollment of approximately 200 patients in the U.S., Canada, European Union, and Australia by the end of 2009.

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

Phase 1 clinical studies have begun with the first three human monoclonal antibodies generated by Regeneron using its *VelocImmune*® technology. REGN88 is an antibody to the interleukin-6 receptor (IL-6R) that is being evaluated in rheumatoid arthritis. REGN475, an antibody to Nerve Growth Factor (NGF) that binds NGF selectively without cross-reacting with other members of the neurotrophin family, is being developed for the treatment of pain. In addition, a Phase 1 trial is in the process of being initiated to evaluate REGN421, an antibody to Delta-like ligand-4 (Dll4), in patients with advanced malignancies. These antibodies are being developed within the Company's human antibody collaboration with sanofi-aventis. Over the course of the next several years, the Company and sanofi-aventis plan to advance an average of two to three new fully human monoclonal antibodies into clinical development each year.

As part of its Academic *VelocImmune* Investigators' Program (Academic VIP), during the first quarter of 2009 Regeneron entered into an agreement with The University of Texas Southwestern Medical Center that will provide researchers at the Dallas-based medical center with access to Regeneron's *VelocImmune* technology to discover fully human monoclonal antibodies. Regeneron retains the right to develop and commercialize any antibodies discovered under the program.

Financial Results

Revenues

Total revenues increased to $75.0 million in the first quarter of 2009 from $56.4 million in the same period of 2008. The

Company's revenue was comprised of contract research and development revenue, 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 months ended March 31, 2009 and 2008 consisted of the following:

	Three months ended March 31,	
(In millions)	**2009**	**2008**
Contract research & development revenue		
Sanofi-aventis	$ 49.6	$ 35.7
Bayer HealthCare	10.0	9.0
Other	1.5	1.7
Total contract research & development revenue	$ 61.1	$ 46.4

For the three months ended March 31, 2009 and 2008, contract research and development revenue from sanofi-aventis consisted of the following:

	Three months ended March 31,	
(In millions)	**2009**	**2008**
Aflibercept:		
Regeneron expense reimbursement	$ 5.4	$ 11.7
Recognition of deferred revenue related to up-front payments	2.5	2.1
Total aflibercept	7.9	13.8
Antibody:		
Regeneron expense reimbursement	38.4	19.3
Recognition of deferred revenue related to up-front payment	2.6	2.6
Other	0.7	--
Total antibody	41.7	21.9
Total sanofi-aventis contract research & development revenue	$ 49.6	$ 35.7

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased in the first quarter of 2009, compared to the same period in 2008, primarily due to lower costs associated with manufacturing clinical drug supplies.

Sanofi-aventis' reimbursement of Regeneron's expenses under the antibody collaboration increased in the first quarter of 2009, compared to the same period in 2008, due to an increase in research activities conducted under the collaboration's discovery agreement and increases in development activities for REGN88, REGN421, and REGN475 under the collaboration's license agreement.

For the three months ended March 31, 2009 and 2008, contract research and development revenue from Bayer HealthCare consisted of the following:

	Three months ended March 31,	
(In millions)	**2009**	**2008**
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	$ 7.5	$ 5.7
Recognition of deferred revenue related to up-front and milestone payments	2.5	3.3
Total Bayer HealthCare contract research & development revenue	$ 10.0	$ 9.0

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. The Company incurred higher VEGF Trap-Eye development expenses under the collaboration for the three months ended March 31, 2009, compared to the same period in 2008, primarily in connection with the collaboration's clinical development programs in wet AMD and DME.

Technology Licensing Revenue

Regeneron has entered into non-exclusive license agreements with AstraZeneca and Astellas that allow those companies to utilize *VelocImmune*® 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 AstraZeneca and $40.0 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 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 ended March 31, 2009, the Company recognized as revenue $3.9 million of ARCALYST® (rilonacept) net product sales for which the right of return no longer exists and rebates can be reasonably estimated. At March 31, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled $4.2 million and $0.8 million, respectively.

Expenses

Total operating expenses for the first quarter of 2009 were $94.2 million, 30 percent higher than the same period in 2008. Average headcount increased to 938 for the first quarter of 2009 compared to 714 for the same period in 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 $7.7 million and $8.3 million, in the first quarters of 2009 and 2008, respectively.

Research and development (R&D) expenses increased to $82.1 million in the first quarter of 2009 from $61.3 million in the comparable quarter of 2008. In the first quarter 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 REGN88, 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 $11.7 million in the first quarter of 2009 from $11.0 million in the comparable quarter of 2008. In the first quarter of 2009, the Company incurred higher selling expenses related to ARCALYST® (rilonacept), higher compensation expense associated with expanding the Company's SG&A headcount, and higher SG&A facility-related costs.

Other Income and Expense

Investment income decreased to $1.8 million in the first quarter of 2009 from $7.3 million in the comparable quarter of 2008. The decrease in investment income was due to lower yields on, and lower balances of, cash and marketable securities in the first quarter of 2009 compared to the same quarter in 2008. Interest expense in the first quarter of 2008 was attributable to the Company's 5.5% Convertible Senior Subordinated Notes; no Notes were outstanding in 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 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. 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)

	March 31, 2009	December 31, 2008
ASSETS		
Cash, restricted cash, and marketable securities	$ 495,992	$ 527,461
Receivables	48,209	35,212
Property, plant, and equipment, net	109,840	87,853
Other assets	27,380	19,512
Total assets	$ 681,421	$ 670,038
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 44,832	$ 36,168
Deferred revenue	213,119	209,925
Other liabilities	13,150	5,093
Stockholders' equity	410,320	418,852
Total liabilities and stockholders' equity	$ 681,421	$ 670,038

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

	For the three months ended March 31,	
	2009	2008
Revenues		
Contract research and development	$ 61,090	$ 46,383
Technology licensing	10,000	10,000
Net product sales	3,891	
	74,981	56,383
Expenses		
Research and development	82,146	61,270
Selling, general, and administrative	11,674	11,024
Cost of goods sold	392	
	94,212	72,294
Loss from operations	(19,231)	(15,911)
Other income (expense)		
Investment income	1,750	7,304
Interest expense		(3,011)
	1,750	4,293
Net loss	$ (17,481)	$ (11,618)
Net loss per share amounts, basic and diluted	$ (0.22)	$ (0.15)
Weighted average shares outstanding, basic and diluted	79,498	78,493

Source: Regeneron Pharmaceuticals, Inc.

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