



Regeneron Reports Second Quarter 2009 Financial and Operating Results

August 4, 2009

Regeneron Reports Second Quarter 2009 Financial and Operating Results TARRYTOWN, N.Y.--(BUSINESS WIRE)--Aug. 4, 2009-- Regeneron Pharmaceuticals, Inc. (**Nasdaq: REGN**) today announced financial and operating results for the second quarter of 2009. The Company reported a net loss of \$14.9 million, or \$0.19 per share (basic and diluted), for the second quarter of 2009 compared with a net loss of \$18.7 million, or \$0.24 per share (basic and diluted), for the second quarter of 2008. The Company reported a net loss of \$30.3 million, or \$0.38 per share (basic and diluted), for the six months ended June 30, 2009 compared with a net loss of \$30.5 million, or \$0.39 per share (basic and diluted), for the same period in 2008.

At June 30, 2009, cash, restricted cash, and marketable securities totaled \$466.4 million compared with \$527.5 million at December 31, 2008.

Current Business Highlights

ARCALYST® (rilonacept) – Inflammatory Diseases

The Company shipped \$5.4 million of ARCALYST® (rilonacept) Injection for Subcutaneous Use to its U.S. distributors during the second quarter of 2009, compared to \$1.6 million during the same period of 2008. Shipments during the first six months of 2009 were \$9.8 million

compared to \$2.4 million in the prior year period. ARCALYST, an interleukin-1 (IL-1) blocker, was approved 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 \$15-20 million in 2009. In July 2009, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion for the marketing authorization in the European Union of rilonacept 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, three 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 Phase 3 clinical development 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.

Additional data from the previously reported Phase 2 study of ARCALYST for the prevention of gout flares induced by the initiation of urate-lowering drug therapy were presented at the annual meeting of the European League Against Rheumatism (EULAR) in June 2009. Through 16 weeks of treatment, patients treated with ARCALYST® (rilonacept) on average experienced significantly fewer gout flares per patient than did patients treated with placebo. The mean number of flares per patient was 0.93 with placebo and 0.22 with ARCALYST ($p=0.0036$). These data are consistent with the previously reported results through 12 weeks of treatment, in which the mean number of flares per patient was 0.79 with placebo and 0.15 with ARCALYST ($p=0.0011$). Adverse events after 16 weeks of treatment were similar to those reported after 12 weeks. Reported adverse events were similar between treatment groups, with the most common categories being infections and musculoskeletal system disorders.

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 second quarter of 2009, more than 60 percent of the planned number of patients were enrolled in four 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 (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.

Results of a Phase 2 single-agent study of aflibercept in advanced ovarian cancer (AOC) patients with symptomatic malignant ascites (SMA) were reported in a press release issued on June 11, 2009. Symptomatic malignant ascites is an abnormal build-up of fluid in the abdominal cavity in patients with advanced cancer. Patients treated with aflibercept experienced a statistically significant improvement in the primary study endpoint, mean time to first repeat paracentesis (removal of fluid from the abdominal cavity), versus placebo control. The types and frequencies of adverse events reported with aflibercept in this study were generally consistent with those reported in clinical studies with other anti-VEGF therapies in advanced ovarian cancer patients. Regeneron and sanofi-aventis decided that because it is difficult, based on this study, to definitively assess the overall clinical benefit that might be derived from treatment in a clinical practice setting, they will not submit these Phase 2 data to regulatory authorities for accelerated approval in symptomatic malignant ascites.

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. Full enrollment in the Phase 3 program (consisting of the VIEW 1 and VIEW 2 studies) evaluating VEGF Trap-Eye in patients with the neovascular form of Age-related Macular Degeneration (wet AMD) is expected later in 2009, and initial data from this program are expected 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) completed enrollment in July 2009, and initial data are expected during the first half of 2010. Regeneron and Bayer HealthCare also initiated a Phase 3 program in Central Retinal Vein Occlusion (CRVO) in July 2009. In connection with dosing the first patient in a Phase 3 study in CRVO, Regeneron received a \$20.0 million

milestone payment.

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 are underway with 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. REGN421, an antibody to Delta-like ligand-4 (DII4), is being studied 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.

Other

In June 2009, the Company announced that it had entered into two royalty agreements with Novartis Pharma AG that replaced a previous collaboration and license agreement. Under the first royalty agreement, Regeneron is entitled to receive royalties on worldwide sales of Novartis' canakinumab (ACZ885), a fully human anti-interleukin-IL1 β antibody approved to treat CAPS and in development for a number of other inflammatory diseases. On the basis of the same agreement, Regeneron waived its rights to opt-in to the development and commercialization of canakinumab. Under the second royalty agreement, Novartis is entitled to receive royalties on worldwide sales of a second-generation interleukin-1 Trap, should Regeneron decide to proceed in the development of this Trap. The financial terms of both agreements are identical in relation to stepped royalties to be paid on the basis of future sales, which start at 4 percent and reach 15 percent when annual sales exceed \$1.5 billion. The agreements do not include any upfront or milestone payments or any sharing of development expenses.

Financial Results

Revenues

Total revenues increased to \$90.0 million in the second quarter of 2009 from \$60.7 million in the same quarter of 2008 and increased to \$165.0 million for the first half of 2009 from \$117.0 million for 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 and six months ended June 30, 2009 and 2008 consisted of the following:

<i>(In millions)</i>	Three months ended		Six months ended	
	June 30,		June 30,	
	2009	2008	2009	2008
Contract research & development revenue				
Sanofi-aventis	\$ 60.7	\$ 38.6	\$ 110.4	\$ 74.3
Bayer HealthCare	12.8	10.2	22.8	19.2
Other	2.0	1.9	3.4	3.5
Total contract research & development revenue	\$ 75.5	\$ 50.7	\$ 136.6	\$ 97.0

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

	Three months ended		Six months ended	
	June 30,		June 30,	
<i>(In millions)</i>	2009	2008	2009	2008
Aflibercept:				
Regeneron expense reimbursement	\$ 9.2	\$ 10.3	\$ 14.6	\$ 22.0
Recognition of deferred revenue related to up-front payments	2.5	2.1	5.0	4.2
Total aflibercept	11.7	12.4	19.6	26.2
Antibody:				
Regeneron expense reimbursement	45.7	23.6	84.1	42.9
Recognition of deferred revenue related to up-front payment	2.6	2.6	5.3	5.2

Recognition of revenue related to <i>VelociGene</i> [®] agreement	0.7	1.4		
Total antibody	49.0	26.2	90.8	48.1
Total sanofi-aventis contract research & development revenue \$	\$ 60.7	\$ 38.6	\$ 110.4	\$ 74.3

Sanofi-aventis' reimbursement of Regeneron's aflibercept expenses decreased for the three and six months ended June 30, 2009, compared to the same periods in 2008, primarily due to lower Company costs associated with internal research activities and 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 six months ended June 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 REGN88, REGN421, and REGN475 under the collaboration's license agreement.

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

	June 30,		June 30,	
	2009	2008	2009	2008
<i>(In millions)</i>				
Cost-sharing of Regeneron VEGF Trap-Eye development expenses	\$ 10.4	\$ 6.9	\$ 17.9	\$ 12.6
Recognition of deferred revenue related to up-front and milestone payments	2.4	3.3	4.9	6.6
Total Bayer HealthCare contract research & development revenue	\$ 12.8	\$ 10.2	\$ 22.8	\$ 19.2

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 six months ended June 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.

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 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 six months ended June 30, 2009, the Company recognized as revenue \$4.5 million and \$8.4 million of ARCALYST[®]

(riloncept) net product sales, respectively, for which the right of return no longer exists and rebates can be reasonably estimated. At June 30, 2009 and 2008, deferred revenue related to ARCALYST net product sales totaled \$4.9 million and \$2.3 million, respectively.

Expenses

Total operating expenses for the second quarter of 2009 were \$106.3 million, 32 percent higher than the same period in 2008, and \$198.4 million for the first six months of 2009, 30 percent higher than the same period in 2008. Average headcount increased to 966 in the second quarter of 2009 from 771 in the same period of 2008 and increased to 952 for the first half of 2009 from 742 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 \$7.4 million in the second quarter of 2009 and \$15.1 million for the first six months of 2009, compared with \$8.2 million and \$16.5 million, respectively, for the same periods of 2008.

Research and development (R&D) expenses increased to \$94.2 million in the second quarter of 2009 from \$66.8 million in the comparable quarter of 2008, and to \$174.5 million in the first six months of 2009 from \$128.2 million in the same period of 2008. In the second quarter and first half 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 decreased to \$11.6 million in the second quarter of 2009 from \$13.5 million in the comparable quarter of 2008, and to \$23.1 million in the first six months of 2009 from \$24.5 million in the same period of 2008. In the second quarter and first half of 2009, the Company incurred lower selling expenses related to ARCALYST, lower SG&A recruitment costs, lower market research costs related to various development programs, and lower legal and professional fees related to various corporate matters, which were partly offset by higher compensation expense associated with additional SG&A headcount.

Other Income and Expense

Investment income decreased to \$1.3 million in the second quarter of 2009 from \$4.5 million in the comparable quarter of 2008 and to \$3.1 million in the first half of 2009 compared to \$11.8 million in the first half 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 in the second quarter and first half of 2008 was attributable to the Company's 5.5 percent Convertible Senior Subordinated Notes; no Notes were outstanding in 2009. In the second quarter of 2008, the Company repurchased \$81.3 million in principal amount of these convertible notes, which were due in October 2008, and recognized a \$0.9 million loss on early extinguishment of debt.

Revision of Previously Issued Financial Statements

The Company has revised its financial statements at December 31, 2008 and for the three and six months ended June 30, 2008, in connection with the application of Emerging Issues Task Force Statement No. 97-10, *The Effect of Lessee Involvement in Asset Construction* (EITF 97-10), 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 June 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[®] (riloncept) 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 June 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.

REGENERON PHARMACEUTICALS, INC.

CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

June 30,	December 31,
2009	2008
	<i>(Revised)*</i>

ASSETS

Cash, restricted cash, and marketable securities	\$ 466,363	\$ 527,461
Receivables	60,046	35,212
Property, plant, and equipment, net	195,408	142,035
Other assets	20,528	19,512
Total assets	\$ 742,345	\$ 724,220

LIABILITIES AND STOCKHOLDERS' EQUITY

Accounts payable and accrued expenses	\$ 51,881	\$ 36,168
		\$
Deferred revenue	215,798	209,925
Facility lease obligation	62,925	56,019
Other long term liabilities	1,235	594
Stockholders' equity	410,506	421,514
Total liabilities and stockholders' equity	\$ 742,345	\$ 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 June 30,		For the six months ended June 30,	
2009	2008	2009	2008
			<i>(Revised)*</i>
	<i>(Revised)*</i>		

Revenues

Contract research and development	75,532	50,653	136,622	97,036
	\$	\$	\$	\$
	10,000	10,000	20,000	20,000
Technology licensing				
Net product sales	4,500		8,391	
	90,032	60,653	165,013	117,036

Expenses

Research and development	94,231	66,777	174,538	128,246
Selling, general, and administrative	11,632	13,495	23,052	24,549
Cost of goods sold	435		827	
	106,298	80,272	198,417	152,795

Loss from operations (16,266) (19,619) (33,404) (35,759)

Other income (expense)

Investment income	1,328	4,535	3,078	11,839
Interest expense		(2,674)		(5,685)
Loss on early extinguishment of debt		(931)		(931)
	1,328	930	3,078	5,223

Net loss \$ (14,938) \$ (18,689) \$ (30,326) \$ (30,536)

Net loss per share amounts, basic and diluted \$ (0.19) \$ (0.24) \$ (0.38) \$ (0.39)

Weighted average shares outstanding, basic and diluted 79,626 78,689 79,562 78,591

* Revised as described in the paragraph of this press release titled "Revision of Previously

Issued Financial Statements."

Source: Regeneron Pharmaceuticals, Inc.

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