# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

# FORM 8-K

# **CURRENT REPORT**

## Pursuant to Section 13 or 15(d) of the Securities and Exchange Act of 1934

Date of Report (Date of earliest event reported):

May 4, 2006 (May 3, 2006)

# **REGENERON PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**New York** 

(State or other jurisdiction of incorporation)

**000-19034** (Commission File Number)

133444607 (I.R.S. Employer Identification Number)

777 Old Saw Mill River Road, Tarrytown, New York10591-6707(Address of principal executive offices)(Zip Code)

(914) 347-7000

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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## Item 2.02 Results of Operations and Financial Condition

On May 3, 2006, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter and three months ended March 31, 2006. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached hereto as Exhibit 99(a).

#### Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Press Release of Regeneron Pharmaceuticals, Inc. dated May 3, 2006.

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

## REGENERON PHARMACEUTICALS, INC.

Dated: May 4, 2006

By: /s/ Stuart Kolinski

Stuart Kolinski Vice President and General Counsel

## Exhibit Index

<u>Number</u>	Description
99(a)	Press Release of Regeneron Pharmaceuticals, Inc. dated May 3, 2006.

#### **Regeneron Reports First Quarter Financial and Operating Results**

TARRYTOWN, N.Y.—(BUSINESS WIRE)—Regeneron Pharmaceuticals, Inc. (Nasdaq: REGN) today announced financial and operating results for the first quarter of 2006. The Company reported a net loss of \$20.4 million, or \$0.36 per share (basic and diluted) for the first quarter of 2006 compared with a net loss of \$4.1 million, or \$0.07 per share (basic and diluted) for the first quarter of 2005. Results for the first quarter of 2005 included a \$25.0 million one-time, non-recurring payment from the sanofi-aventis Group in connection with an amendment to the Company's collaboration agreement with sanofi-aventis, which was recognized as other contract income.

At March 31, 2006, cash and marketable securities totaled \$324.2 million compared with \$316.7 million at December 31, 2005. In January 2006, Regeneron received an up-front payment of \$25.0 million from sanofi-aventis related to the expansion of the companies' VEGF Trap collaboration program to include Japan. The Company's \$200.0 million of convertible notes, which bear interest at 5.5% per annum, mature in October 2008.

#### **Current Business Highlights**

In the first quarter of 2006, Regeneron continued to expand its broad-based clinical development program that is centered on product candidates in oncology, eye diseases, and inflammatory indications. In oncology, Regeneron's Vascular Endothelial Growth Factor (VEGF) Trap is being developed in collaboration with sanofi-aventis. The Company is independently developing the VEGF Trap-Eye, a specially purified and formulated form of the VEGF Trap for use in intraocular applications, and the Interleukin-1 (IL-1) Trap for certain inflammatory indications.

In the first quarter of 2006, Regeneron and sanofi-aventis initiated their phase 2 single-agent program for the VEGF Trap in cancer. Patient enrollment is underway in non-small cell lung adenocarcinoma (NSCLA), and two additional safety/efficacy studies in advanced ovarian cancer and symptomatic malignant ascites (SMA) are planned to begin shortly. In addition, the companies intend to conduct three trials evaluating the safety and efficacy of the VEGF Trap in combination with standard chemotherapy regimens, the first of which is planned to begin in the second half of 2006. Currently, there are five safety and tolerability studies underway for the VEGF Trap in combination with standard chemotherapy regimens in a variety of cancer types. The companies are also finalizing plans with the National Cancer Institute (NCI) Cancer Therapeutics Evaluation Program to commence at least ten other cancer trials in 2006.

In the clinical development program for the treatment of eye diseases, at the May 2006 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO),

the Company reported positive preliminary results from its phase 1 trial of the VEGF Trap-Eye in patients with the neovascular form of age-related macular degeneration (wet AMD). A total of 21 patients received a single dose of VEGF Trap-Eye at doses ranging from .05 milligrams (mg) to 4 mg intravitreally (direct injection into the eye) and were evaluated for six weeks to measure the durability of effects and provide guidance for dosing regimens to be used in future trials. All dose levels were generally well tolerated, and a maximum tolerated dose was not reached in the study. Patients receiving the VEGF Trap-Eye demonstrated large, rapid, and sustained (at least six weeks) reductions in retinal thickness, a clinical measure of disease activity in wet AMD as measured by ocular coherence tomography (OCT). As measured by the OCT reading center (posterior pole OCT scans), the median excess retinal thickness was 194 microns at baseline and 60 microns at 6 weeks. As measured by the computerized Fast Macular Scan protocol, the median excess retinal thickness was 119 microns at baseline and 27 microns at 6 weeks.

Of the 20 patients evaluable for efficacy, 95 percent had stabilization or improvement in visual acuity, defined as less than or equal to 15 letter loss on the Early Treatment of Diabetic Retinopathy Study (ETDRS) eye chart. Patients were also evaluated for best-corrected visual acuity (BCVA), the best acuity a person can achieve with glasses. BCVA for all patients in the study increased by a mean of 4.8 letters at 6 weeks. In the two highest dose groups (2 mg and 4 mg), the mean improvement in BCVA was 13.5 letters, with three of six patients gaining 15 or more letters.

Based on the preliminary phase 1 results in wet AMD, the Company has initiated a 150 patient, 12 week, phase 2 trial of the VEGF Trap in wet AMD. The trial is designed to evaluate treatment with multiple doses of the VEGF Trap-Eye using different doses and different dosing regimens, as well as safety and efficacy. The Company plans to conduct an initial evaluation of study results after all patients have completed 12 weeks of treatment, which is expected to be prior to the end of 2006. Subject to a review of the initial phase 2 study results, Regeneron plans to initiate a phase 3 trial of the VEGF Trap in wet AMD in early 2007.

Regeneron recently completed enrollment in the pivotal study of the IL-1 Trap in patients with CIAS1-Associated Periodic Syndrome (CAPS), a spectrum of rare diseases associated with mutations in the CIAS1 gene. Interleukin-1 (IL-1) appears to play a significant role in these diseases. Participants in the trial will receive a 160 milligram dose of the IL-1 Trap once a week through subcutaneous self-administration. The six-month placebo-controlled, double-blind, efficacy phase is expected to be completed and preliminary data available by the end of 2006. The efficacy phase will be followed by a six-month open-label extension phase. In addition, Regeneron has ongoing proof-of-concept studies in other indications in which IL-1 may play a significant role, such as systemic juvenile idiopathic arthritis (SJIA). The Company has received Orphan Drug designation for the IL-1 Trap in CAPS and SJIA.

#### **Financial Results**

Regeneron's total revenue increased to \$18.2 million in the first quarter of 2006 from \$16.2 million in the same period of 2005 due to increases of \$1.1 million in contract

research and development revenue and \$0.9 million in contract manufacturing revenue in the first quarter of 2006 from the same period of 2005. Contract research and development revenue in the first quarter of 2006 principally related to the Company's VEGF Trap collaboration with sanofi-aventis in cancer indications. In the first quarter of 2005, contract research and development revenue related both to the Company's collaboration with sanofi-aventis and the Company's collaboration with The Procter & Gamble Company, which ended in June 2005. Contract manufacturing revenue relates to Regeneron's long-term manufacturing agreement with Merck & Co., Inc., which will expire in the second half of 2006.

Regeneron recognized contract research and development revenue of \$13.9 million in the first quarter of 2006 related to the Company's collaboration with sanofi-aventis, compared with \$9.8 million in the same period of 2005. Contract research and development revenue from the sanofi-aventis collaboration consists of reimbursement of VEGF Trap development expenses plus recognition of amounts related to \$105.0 million of previously received up-front, non-refundable payments. Reimbursement of expenses increased to \$10.8 million in the first quarter of 2006 from \$7.4 million in the same period of 2005, primarily due to higher costs in 2006 related to the Company's manufacture of VEGF Trap clinical supplies. With respect to the up-front payments from sanofi-aventis, \$3.1 million was recognized as revenue in the first quarter of 2006 compared to \$2.4 million in the same quarter of 2005.

Sanofi-aventis also incurs VEGF Trap development expenses which are increasing because of the growing number of clinical trials sanofi-aventis is overseeing in the VEGF Trap oncology program. During the term of the collaboration, sanofi-aventis pays 100% of agreed-upon VEGF Trap development expenses incurred by both companies. Following commercialization of a VEGF Trap product by the collaboration, the Company will repay out of VEGF Trap profits 50% of these VEGF Trap development expenses previously paid by sanofi-aventis.

Total operating expenses for the first quarter of 2006 were \$39.9 million, 10 percent lower than the same period in 2005, due, in part, to lower Company headcount. Average Company headcount declined to 587 in the first quarter of 2006 from 734 in the same period of 2005 primarily as a result of workforce reductions made in the fourth quarter of 2005.

The Company recognized non-cash compensation expense related to employee stock option awards (Stock Option Expense) in accordance with Statement of Financial Accounting Standards No. (SFAS) 123 in 2005, and in accordance with SFAS 123R (which is a revision of SFAS 123), effective January 1, 2006. Operating expenses in the first quarter of 2006 and 2005 include a total of \$3.9 million and \$5.4 million, respectively of Stock Option Expense, as follows:

#### For the three months ended March 31,

(in millions)	2006						
	Expenses before		St	ock			
	inclusio	inclusion of Stock		Option		Expenses as	
Expenses	Optior	Option Expense		oense	Reported		
Research and development	\$	30.1	\$	2.0	\$	32.1	
Contract manufacturing		1.8		0.1		1.9	
General and administrative		4.1		1.8		5.9	
Total operating expenses	\$	36.0	\$	3.9	\$	39.9	

#### For the three months ended March 31,

(in millions)		2005					
		Expenses before		nses before Stock			
		inclusion of Stock					
Expenses	Option	Option Expense		Dense	Reported		
Research and development	\$	32.5	\$	3.4	\$ 35.9		
Contract manufacturing		2.5			2.5		
General and administrative		4.1		2.0	6.1		
Total operating expenses	\$	39.1	\$	5.4	\$ 44.5		

Research and development (R&D) expenses decreased to \$32.1 million in the first quarter of 2006 from \$35.9 million in the comparable quarter of 2005. In addition to the impact of lower Company headcount, as described above, in the first quarter of 2006, the Company incurred lower development expenses for the IL-1 Trap and other clinical development programs, which were partly offset by higher development expenses for the VEGF Trap.

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS 123, Accounting for Stock-Based Compensation, using the modified prospective method described in SFAS 148, Accounting for Stock-Based Compensation — Transition and Disclosure. As a result, in 2005, the Company recognized compensation expense in an amount equal to the fair market value of share-based payments (including stock option awards) on their date of grant over the vesting period of the awards using the multiple-option approach. Under the modified prospective method, compensation expense for the Company is recognized for (a) all share-based payments granted on or after January 1, 2005 and (b) all awards granted to employees prior to January 1, 2005 that were unvested on that date.

Effective January 1, 2006, the Company adopted the provisions of SFAS 123R, Share-Based Payment, which is a revision of SFAS 123. SFAS 123R requires companies to estimate the number of awards that are expected to be forfeited at the time of grant and to revise this estimate, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to the adoption of SFAS 123R, the Company recognized the effect of forfeitures in stock-based compensation cost in the period when they occurred, in accordance with SFAS 123. Upon adoption of SFAS 123R effective January 1, 2006, the Company was required to record a cumulative effect adjustment to reflect the effect of estimated forfeitures related to outstanding awards that are not expected to vest as of the

SFAS 123R adoption date. This adjustment reduced the Company's loss by \$0.8 million and is included in the Company's operating results for the first quarter of 2006 as a cumulative-effect adjustment of a change in accounting principle.

About Regeneron Pharmaceuticals

Regeneron is a biopharmaceutical company that discovers, develops, and intends to commercialize therapeutic medicines for the treatment of serious medical conditions. Regeneron has therapeutic candidates in clinical trials for the potential treatment of cancer, eye diseases, and inflammatory diseases, and has preclinical programs in other diseases and disorders.

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, programs, finances, and business, all of which involve a number of risks and uncertainties, such as risks associated with preclinical and clinical development of our drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict our ability to continue to develop or commercialize our drug candidates, competing drugs that are superior to our product candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including our agreement with the sanofi-aventis Group, 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, 2005. 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, 2006	December 31, 2005
ASSETS		
Cash and marketable securities	\$ 324,229	\$ 316,654
Receivables	11,010	36,521
Inventory	3,254	2,904
Property, plant, and equipment, net	57,421	60,535
Other assets	6,175	6,887
Total assets	\$402,089	\$ 423,501
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	\$ 18,383	\$ 23,337
Deferred revenue	81,383	86,162
Notes payable	200,000	200,000
Stockholders' equity	102,323	114,002
Total liabilities and stockholders' equity	\$402,089	\$ 423,501

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

		For the three months ended March 31,	
	2006	2005	
Revenues			
Contract research and development	\$ 14,587	\$ 13,502	
Contract manufacturing	3,632	2,707	
	18,219	16,209	
Expenses			
Research and development	32,084	35,912	
Contract manufacturing	1,852	2,491	
General and administrative	5,946	6,146	
	39,882	44,549	
Loss from operations	(21,663)	(28,340)	
Other income (expense)			
Other contract income		25,000	
Investment income	3,481	2,230	
Interest expense	(3,011)	(3,013)	
	470	24,217	
Net loss before cumulative effect of a change in accounting principle	(21,193)	(4,123)	
Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R")	813		
Net loss	(\$ 20,380)	(\$ 4,123)	
Net loss per share amounts, basic and diluted:			
Net loss before cumulative effect of a change in accounting principle	(\$ 0.37)	(\$ 0.07)	
Cumulative effect of adopting SFAS 123R	0.01		
Net loss	<u>(\$ 0.36</u> )	<u>(\$ 0.07</u> )	
Weighted average shares outstanding, basic and diluted	56,727	55,815	
Q			



# CONTACT :

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