
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):

August 4, 2005 (August 3, 2005)

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 York

(Address of principal executive offices)

10591-6707

(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:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - 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 August 4, 2005, Regeneron Pharmaceuticals, Inc. announced its financial and operating results for the quarter and six months ended June 30, 2005. A copy of the news release is attached hereto as Exhibit 99(a) and is incorporated herein by reference.

Effective January 1, 2005, Regeneron began recognizing non-cash compensation expense related to employee stock option awards (Stock Option Expense) in operating expenses in accordance with Statement of Financial Accounting Standards No. 123 (SFAS No. 123). Prior to the adoption of SFAS No. 123, compensation expense related to employee stock options was not reflected in operating expenses and prior period operating results have not been restated.

The news release includes certain financial measures that are calculated in a manner different from generally accepted accounting principles (GAAP) and are considered non-GAAP financial measures under United States Securities and Exchange Commission rules. Non-GAAP financial measures for the three and six months ended June 30, 2005 included in the news release are: (1) pro forma net income (loss) and pro forma net income (loss) per share (basic and diluted), exclusive of Stock Option Expense and (2) research and development expenses, general and administrative expenses, and contract manufacturing expenses, all exclusive of Stock Option Expense. Our management does not intend that the presentation of non-GAAP financial measures be considered in isolation or as a substitute for results prepared in accordance with GAAP.

Our management believes that the non-GAAP financial measures described above present helpful information to investors and other users of Regeneron's financial statements by providing greater transparency about the nature of and trends in our operating expenses and net income (loss) and a more useful basis for comparing our operating results for the three months and six months ended June 30, 2005 and 2004. In addition, our management uses non-GAAP financial measures which exclude Stock Option Expense internally for operating, budgeting, and financial planning purposes. The news release includes tables which provide a reconciliation of the differences between these non-GAAP financial measures and the most directly comparable financial measures calculated and presented in accordance with GAAP in the news release.

Item 8.01 Other Events

On August 3, 2005, the plaintiffs and Regeneron entered into a Stipulation and Agreement of Settlement (the “Settlement”) settling all claims against the Company in In re Regeneron Pharmaceuticals, Inc. Securities Litigation, Civ. A. No. 03 CV 3111 (RWS), a securities class action lawsuit brought in the United States District Court for the Southern District of New York on behalf of a putative class of shareholders who purchased Regeneron’s securities on the open market between March 28, 2000 and March 30, 2003. The Settlement requires no payment by Regeneron or any of the individual defendants named in the lawsuit. The Company’s primary insurance carrier agreed to make the required payment under the Settlement, which is in an immaterial amount to Regeneron. The Settlement includes no admission of wrongdoing by Regeneron or any of the individual defendants. The Settlement must be finally approved by the United States District Court for the Southern District of New York following notice and hearing.

Separately, the plaintiffs and the individual defendants named in the lawsuit entered into a Stipulation of Voluntary Dismissal, dismissing all claims against the individuals. This voluntary dismissal shall automatically become a dismissal with prejudice, without costs, upon the court entering an order and final judgment approving the Settlement.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Press Release of Regeneron Pharmaceuticals, Inc. dated August 4, 2005.

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: August 4, 2005

By: /s/ Stuart Kolinski
Stuart Kolinski
Vice President and General Counsel

Exhibit Index

<u>Number</u>	<u>Description</u>
99(a)	Press Release of Regeneron Pharmaceuticals, Inc. dated August 4, 2005.

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FOR IMMEDIATE RELEASE

REGENERON REPORTS SECOND QUARTER FINANCIAL AND OPERATING RESULTS

Tarrytown, New York (August 4, 2005) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the second quarter of 2005. Regeneron reported a net loss of \$27.0 million, or \$0.48 per share (basic and diluted), for the second quarter of 2005 and a net loss of \$31.1 million, or \$0.56 per share (basic and diluted), for the six months ended June 30, 2005. Excluding the effects of expensing stock options in 2005, Regeneron had a net loss of \$21.7 million, or \$0.38 per share (basic and diluted), in the second quarter and a net loss of \$20.4 million, or \$0.37 per share (basic and diluted), for the first six months compared with a net loss of \$14.5 million, or \$0.26 per share (basic and diluted), for the second quarter of 2004 and net income of \$50.0 million, or \$0.90 per basic share and \$0.88 per diluted share, for the first six months of 2004.

At June 30, 2005, cash and marketable securities totaled \$351.6 million compared with \$348.9 million at December 31, 2004. The Company's \$200.0 million of convertible notes, which bear interest at 5.5% per annum, mature in October 2008.

Current Business Highlights

Regeneron is building a broad-based clinical development program with a focus on three clinical candidates in oncology, eye diseases, and inflammation. The

Company is evaluating these candidates in different stages of clinical development and in multiple therapeutic indications in each focus area.

The Vascular Endothelial Growth Factor (VEGF) Trap oncology program, which expanded during the second quarter, is being conducted in collaboration with the sanofi-aventis Group. In May 2005, Regeneron and the sanofi-aventis Group initiated a safety and tolerability study of the VEGF Trap in combination with oxaliplatin/5-fluorouracil/leucovorin (FOLFOX4) in patients with advanced solid malignancies. This study is part of a series of planned single-agent and combination studies of the VEGF Trap in a variety of cancer types.

Positive preliminary results of a phase 1 trial of the VEGF Trap, administered as a single agent in patients with solid tumors, were reported at the American Society of Oncology (ASCO) Annual Meeting in May 2005. The VEGF Trap was generally well tolerated at the dose levels evaluated. The majority of adverse events encountered were generally mild to moderate in severity. Occasional severe toxicities such as hypertension, a common side effect for the class of drugs that block VEGF, have been manageable and reversible. Preliminary efficacy analysis showed evidence of tumor size reduction and prolonged stable disease in some patients after VEGF Trap treatment. One patient achieved a partial response with disappearance of ascites, two patients had minor responses, and one patient had maintained stable disease for over 11 months.

In the VEGF Trap program for the treatment of eye diseases, Regeneron initiated a new phase 1 study in patients with the neovascular form of age-related macular degeneration (wet AMD) in June 2005. This study will evaluate the safety and tolerability of the VEGF Trap in patients with advanced AMD, using direct injections into the eye. The study is also measuring the effect of the VEGF Trap on the excess retinal thickness present in patients with wet AMD.

At the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in May 2005, researchers reported that the VEGF Trap had successfully met its pre-specified efficacy endpoint in an earlier study in patients with advanced wet AMD. This trial, which evaluated the safety and tolerability of the VEGF Trap when delivered by intravenous injections, showed a statistically significant decrease in excess retinal thickness, which increased in both magnitude and duration with higher doses. The results also indicated that the VEGF Trap caused a dose-dependent increase in blood pressure (hypertension), which appears to be a “class-effect” of systemically delivered anti-VEGF agents.

In June 2005, Regeneron announced positive preliminary results from the ongoing pilot study of once-weekly dosing of the (IL-1) Trap in patients with *CIAS1*-associated periodic syndrome (CAPS). All four patients enrolled in the study as of that date demonstrated a positive response to the IL-1 Trap, both in the initial loading dose phase and the ongoing chronic dosing phase of the study. This study is being conducted under a Cooperative Research and Development Agreement (CRADA) with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), part of the National Institutes of Health. The United States Food and Drug Administration (FDA) has granted Orphan Drug Designation to the IL-1 Trap in CAPS disorders, for which there are no approved therapies. The Company plans to initiate an advanced trial in this indication later this year.

Regeneron is evaluating the IL-1 Trap in a phase 2b study in rheumatoid arthritis (RA) and is conducting a proof-of-concept study in another indication. The RA trial is being conducted in clinical sites around the world. Participants will be given placebo, or doses of 160 milligrams (mg) or 320 mg per week, for 24 weeks. The Company plans to initiate several additional proof-of-concept studies of the IL-1 Trap in 2005 in various other diseases.

Financial Results

The Company's financial results for the quarter and the six months ended June 30, 2005 and 2004 are detailed in the table below. Effective January 1, 2005, the Company began recognizing non-cash compensation expense related to employee stock option awards (Stock Option Expense) in accordance with Statement of Financial Accounting Standards (SFAS) No. 123.

For the three months ended June 30, 2005 and 2004

(in millions, except per share data)

	<u>Net Loss</u>	<u>Net Loss per Share — Basic and Diluted</u>
2005:		
Net loss, as reported	(\$27.0)	(\$0.48)
Add: Stock Option Expense	5.3	0.10
Pro forma net loss, exclusive of Stock Option Expense	<u>(\$21.7)</u>	<u>(\$0.38)</u>
2004:		
Net loss, as reported (1)	<u>(\$14.5)</u>	<u>(\$0.26)</u>

For the six months ended June 30, 2005 and 2004

(in millions, except per share data)

	<u>Net Income (Loss)</u>	<u>Net Income (Loss) per Share</u>	
		<u>Basic</u>	<u>Diluted</u>
2005:			
Net loss, as reported	(\$31.1)	(\$0.56)	(\$0.56)
Add: Stock Option Expense	10.7	0.19	0.19
Pro forma net loss, exclusive of Stock Option Expense	<u>(\$20.4)</u>	<u>(\$0.37)</u>	<u>(\$0.37)</u>
2004:			
Net income, as reported (1)	<u>\$50.0</u>	<u>\$0.90</u>	<u>\$0.88</u>

(1) In 2004, the Company's reported net income (loss) did not include Stock Option Expense.

Net loss in the first six months of 2005 included non-recurring payments of \$25.0 million from the sanofi-aventis Group and \$5.6 million from The Procter & Gamble Company in connection with amendments to the Company's collaboration agreements with the sanofi-aventis Group and Procter & Gamble. Net income in the first six months of 2004 included \$82.6 million of income related to the Company's collaboration with Novartis Pharma AG, consisting of a \$17.8 million research progress payment and \$64.8 million of non-recurring income following Novartis' decision to forego certain development rights.

Regeneron's total revenue decreased to \$16.4 million in the second quarter of 2005 from \$28.4 million in the comparable quarter of 2004, and to \$32.6 million for the first six months of 2005 from \$90.4 million for the same period of 2004, due primarily to a decline in contract research and development revenue. Contract research and development revenue decreased to \$13.5 million in the second quarter of 2005 from \$27.1 million in the comparable quarter of 2004, and to \$27.0 million for the first six months of 2005 from \$68.8 million for the same period of 2004.

Regeneron recognized contract research and development revenue of \$9.4 million in the second quarter of 2005 and \$19.2 million for the first six months of 2005 related to the Company's collaboration with the sanofi-aventis Group, compared with \$23.4 million and \$39.8 million, respectively, for the same periods of 2004. Contract research and development revenue from the sanofi-aventis Group collaboration consists of reimbursement of the Company's VEGF Trap development expenses plus recognition of amounts related to an \$80.0 million up-front, non-refundable payment received from the sanofi-aventis Group in September 2003. The sanofi-aventis Group is incurring additional VEGF Trap development expenses and, during the term of the collaboration, agreed-upon development expenses incurred by both companies will be funded by the sanofi-aventis Group. If the collaboration becomes profitable, the Company will reimburse the sanofi-aventis Group for 50% of the VEGF Trap development expenses.

Reimbursement of the Company's VEGF Trap development expenses by the sanofi-aventis Group decreased to \$7.1 million in the second quarter of 2005 from \$20.7 million in the comparable quarter of 2004, and to \$14.5 million in the first six months of 2005 from \$34.4 million in the same period of 2004, primarily due to lower clinical supply manufacturing costs. The Company manufactured VEGF Trap clinical supplies during the first six months of 2004, but not during the first six months of 2005. \$2.4 million of the up-front payment was recognized in the

second quarter of 2005 compared to \$2.7 million in the same quarter of 2004, and \$4.7 million of the up-front payment was recognized in the first six months of 2005 compared to \$5.5 million in the same period of 2004. The Company recognizes revenue in connection with collaborations in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition*. As a result, \$61.1 million of the original \$80.0 million up-front payment has been deferred as of June 30, 2005 and will be recognized as revenue in future periods.

In the first quarter of 2004, the Company recognized \$22.1 million of contract research and development revenue related to the Novartis collaboration which represented the remaining amount of a \$27.0 million March 2003 up-front payment that had previously been deferred. Subsequent to the first quarter of 2004, Regeneron has not received, and does not expect to receive, any further contract research and development revenue from Novartis. Novartis also forgave all of its outstanding loans to Regeneron in the first quarter of 2004, totaling \$17.8 million, based on Regeneron's achieving a pre-defined development milestone, which was recognized as a research progress payment.

Contract manufacturing revenue relates to Regeneron's long-term manufacturing agreement with Merck & Co., Inc. Contract manufacturing revenue increased to \$2.8 million in the second quarter of 2005 from \$1.3 million in the comparable quarter of 2004, and to \$5.5 million for the first six months of 2005 from \$3.9 million for the same period in 2004, as the Company shipped more product to Merck. The Company recognizes revenue and the related manufacturing expense as product is shipped to Merck.

Total operating expenses for the second quarter of 2005 were \$48.5 million, 18 percent higher than the comparable quarter in 2004, and \$93.1 million for the first six months of 2005, 17 percent higher than the same period in 2004. Operating expenses in the second quarter and the first half of 2005 include a

total of \$5.3 million and \$10.7 million of Stock Option Expense, respectively, as follows:

For the three months ended June 30,

(in millions)

Expenses	2005			2004
	Expenses as Reported	Stock Option Expense	Expenses exclusive of Stock Option Expense	Expenses as Reported (1)
Research and development	\$40.6	\$3.3	\$37.3	\$36.3
Contract manufacturing	1.7	0.1	1.6	0.5
General and administrative	6.2	1.9	4.3	4.2
Total operating expenses	<u>\$48.5</u>	<u>\$5.3</u>	<u>\$43.2</u>	<u>\$41.0</u>

For the six months ended June 30,

(in millions)

Expenses	2005			2004
	Expenses as Reported	Stock Option Expense	Expenses exclusive of Stock Option Expense	Expenses as Reported (1)
Research and development	\$76.5	\$6.7	\$69.8	\$68.5
Contract manufacturing	4.2	0.1	4.1	2.8
General and administrative	12.4	3.9	8.5	8.0
Total operating expenses	<u>\$93.1</u>	<u>\$10.7</u>	<u>\$82.4</u>	<u>\$79.3</u>

(1) In 2004, expenses as reported in the Company's Statement of Operations did not include Stock Option Expense.

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, using the modified prospective method described in SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*. As a result, the Company has begun recognizing 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. 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. Prior to the adoption of the fair value method, the Company accounted for stock-based compensation to employees under the intrinsic value method of accounting set

forth in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period operating results have not been restated.

Research and development (R&D) expenses, exclusive of Stock Option Expense, increased slightly to \$37.3 million in the second quarter of 2005 from \$36.3 million in the comparable quarter of 2004, and to \$69.8 million in the first six months of 2005 from \$68.5 million in the same period of 2004. In the second quarter and first six months of 2005, the Company incurred higher development expenses for the IL-1 Trap, due primarily to costs incurred to manufacture IL-1 Trap clinical supplies for use in planned studies. These higher IL-1 Trap costs were offset primarily by lower expenses for other clinical development programs, compared with the same periods in 2004.

Contract manufacturing expense relates to the Merck agreement. Exclusive of Stock Option Expense, contract manufacturing expense increased to \$1.6 million in the second quarter of 2005 from \$0.5 million in the comparable quarter of 2004, and to \$4.1 million for the first six months of 2005 from \$2.8 million for the same period of 2004 as the Company shipped more product to Merck. General and administrative expenses, exclusive of Stock Option Expense, increased to \$4.3 million in the second quarter of 2005 from \$4.2 million for the comparable quarter of 2004, and to \$8.5 million for the first six months of 2005 from \$8.0 million for the same period of 2004 due primarily to higher administrative personnel and facility costs.

In January 2005, the Company and the sanofi-aventis Group amended their collaboration agreement to exclude from the scope of the collaboration the development of the VEGF Trap for eye diseases through local delivery systems. In connection with the amendment, the sanofi-aventis Group made a one-time \$25.0 million payment to the

Company, which was recognized as other contract income. In June 2005, the Company and Procter & Gamble amended their collaboration agreement and agreed that the research activities of the parties under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble agreed to make a one-time \$5.6 million payment to the Company, which has been recognized as other contract income. In the first quarter of 2004, in connection with its decision to forego its right to jointly develop the IL-1 Trap, Novartis agreed to pay Regeneron \$42.75 million to satisfy certain funding obligations under their collaboration agreement, which was recognized as other contract income.

Investment income increased in the second quarter and first six months of 2005 compared with the same periods of 2004 due primarily to higher effective interest rates on investment securities. Interest expense was unchanged in the second quarters of 2005 and 2004, and decreased slightly for the first six months of 2005 compared with the same period in 2004. Interest expense is attributable primarily to the Company's convertible notes.

Per share amounts are based on the weighted average number of shares of the Company's Common Stock and Class A Stock outstanding. The weighted average number of shares outstanding was 55.9 million shares (basic and diluted) for the first six months of 2005 and 55.3 million shares (basic) and 63.2 million shares (diluted) for the first six months of 2004.

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, inflammatory diseases, and asthma, 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 drugs and biologics, determinations by regulatory and administrative governmental authorities, competitive factors, technological developments, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement to be canceled or to terminate without any product success, and other material risks. A more complete description of these 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, 2004 and Form 10-Q for the quarter ended March 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.

This news release includes certain financial measures that are calculated in a manner different from generally accepted accounting principles (GAAP) and are considered non-GAAP financial measures under SEC rules. Non-GAAP financial measures for the six months ended June 30, 2005 included in this news release are: (1) pro forma net loss and pro forma net loss per share (basic and diluted), exclusive of Stock Option Expense and (2) research and development expenses, general and administrative expenses, and contract manufacturing expenses, all exclusive of Stock Option Expense. As required, we have provided reconciliations of non-GAAP amounts to GAAP amounts in tables shown above. Additional required information is located in the Form 8-K filed with the SEC in connection with this news release.

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