
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 Exchange Act of 1934

Date of Report (Date of earliest event reported) August 3, 2006 (August 3, 2006)

REGENERON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

New York

(State or other jurisdiction of
Incorporation)

000-19034

(Commission File No.)

13-3444607

(IRS Employer Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York 10591-6707

(Address of principal executive offices, including 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 the 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))
-
-

TABLE OF CONTENTS

[Item 2.02 Results of Operations and Financial Condition](#)

[Item 9.01 Financial Statements and Exhibits](#)

[SIGNATURES](#)

[Exhibit Index](#)

[EX-99.1: PRESS RELEASE](#)

[Table of Contents](#)

Item 2.02 Results of Operations and Financial Condition.

On August 3, 2006, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter and six months ended June 30, 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 as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated August 3, 2006.

[Table of Contents](#)

Exhibit Index

| <u>Number</u> | <u>Description</u> |
|---------------|-------------------------------------|
| 99.1 | Press Release dated August 3, 2006. |

FOR IMMEDIATE RELEASE**REGENERON REPORTS SECOND QUARTER
FINANCIAL AND OPERATING RESULTS****BLA Filing for Auto-Inflammatory Diseases Planned for Early 2007****Two Antibody Candidates from VelocImmune®
Program to Enter Clinical Trials Each Year Beginning in 2007**

Tarrytown, New York (August 3, 2006) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the second quarter of 2006. The Company reported a net loss of \$23.6 million, or \$0.41 per share (basic and diluted), for the second quarter of 2006 compared with a net loss of \$27.0 million, or \$0.48 per share (basic and diluted), for the second quarter of 2005. The Company reported a net loss of \$44.0 million, or \$0.77 per share (basic and diluted), for the six months ended June 30, 2006 compared with a net loss of \$31.1 million, or \$0.56 per share (basic and diluted), for the same period in 2005. Results for the first six months of 2005 included other contract income of \$30.6 million resulting from one-time, 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 sanofi-aventis and Procter & Gamble.

At June 30, 2006, cash and marketable securities totaled \$304.1 million compared with \$316.7 million at December 31, 2005. 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 second quarter of 2006, Regeneron reported clinical development progress for its lead product candidates in oncology, eye disease, 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 second quarter of 2006, Regeneron and sanofi-aventis expanded their phase 2 single-agent program for the VEGF Trap in cancer patients. Patient enrollment is now underway in studies in advanced ovarian cancer (AOC), non-small cell lung adenocarcinoma (NSCLA), and AOC patients with symptomatic malignant ascites (SMA). In addition, the companies intend to conduct three phase 3 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 late 2006 or early 2007. The companies are working to finalize plans with the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) to conduct at least ten other cancer trials, several of which are planned to initiate in 2006.

Currently, sanofi-aventis and Regeneron are conducting five safety and tolerability studies for the VEGF Trap in combination with standard chemotherapy regimens designed to support subsequent phase 3 clinical trials in a variety of cancer types. At the annual meeting of the American Society of Clinical Oncology (ASCO) in May 2006, the companies reported abstracts summarizing information from two of these studies. The first study is evaluating the VEGF Trap plus oxaliplatin, 5-fluorouracil, and leucovorin (FOLFOX4) in a phase 1 trial of patients with advanced solid tumors. The second study is evaluating the VEGF Trap plus irinotecan, 5-fluorouracil, and leucovorin (LV5FU2-CPT11) in a phase 1 trial of patients with advanced solid tumors. In both trials, patients have been treated in combination with chemotherapy in doses ranging up to 4.0 milligrams per kilogram (mg/kg) of the VEGF Trap. The abstracts, published in the 2006 ASCO Annual Meeting Proceedings, reported that the VEGF Trap could be safely combined with either FOLFOX4 or LV5FU2-

CPT11 at the dose levels studied. The maximum tolerated doses in these studies have not yet been reached, and dose escalation is continuing.

In the clinical development program for the treatment of eye diseases, the Company has initiated a 150 patient, 12 week, phase 2 trial of the VEGF Trap-Eye in the neovascular form of age-related macular degeneration (wet AMD). This trial follows positive results from the phase 1 study, which were presented at the May 2006 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO). The phase 2 trial is evaluating the safety and biological effect of repeated intravitreal (ITV) administration of the VEGF Trap-Eye using different doses and different dosing regimens. A phase 3 trial of the VEGF Trap-Eye in wet AMD is planned to begin in early 2007.

Regeneron recently completed enrollment in the pivotal study of the IL-1 Trap in adult patients with *C1AS1*-Associated Periodic Syndrome (CAPS), a spectrum of rare auto-inflammatory diseases associated with mutations in the *C1AS1* gene. Interleukin-1 (IL-1) appears to play a significant role in these diseases. Participants in the trial are receiving 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 of the study 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. The Company plans to file a Biologics License Application (BLA) for CAPS in early 2007. Regeneron also 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 U.S. Food and Drug Administration has granted Orphan Drug and Fast Track designations for the IL-1 Trap in CAPS.

The Company has made significant progress in its VelocImmune® program, Regeneron's proprietary technology platform for producing fully human monoclonal antibodies. Based on the strength of the VelocImmune platform; which, in conjunction with Regeneron's other proprietary technologies

accelerates the development of fully human monoclonal antibodies, the Company plans to move two new antibody candidates into clinical trials each year going forward beginning in 2007.

Financial Results

Regeneron's total revenue increased to \$19.3 million in the second quarter of 2006 from \$16.4 million in the same quarter of 2005 and to \$37.5 million for the first six months of 2006 from \$32.6 million for the same period of 2005 due to increases in contract research and development and contract manufacturing revenue. Contract research and development revenue in 2006 principally related to the Company's VEGF Trap collaboration with sanofi-aventis in cancer indications. In 2005, contract research and development revenue related both to the Company's collaboration with sanofi-aventis and the Company's collaboration with Procter & Gamble, 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 fourth quarter of 2006.

Regeneron recognized contract research and development revenue of \$14.8 million in the second quarter of 2006 and \$28.7 million for the first six months of 2006 related to the Company's collaboration with sanofi-aventis, compared with \$9.4 million and \$19.2 million, respectively, for the same periods 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 and deferred up-front, non-refundable payments. Reimbursement of expenses increased to \$11.8 million in the second quarter of 2006 from \$7.1 million in the comparable quarter of 2005, and to \$22.6 million in the first six months of 2006 from \$14.5 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, \$3.0 million was recognized in the second quarter of 2006 compared to \$2.3 million in the same

quarter of 2005, and \$6.1 million was recognized in the first six months of 2006 compared to \$4.7 million in the same period 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 second quarter of 2006 were \$43.5 million, 10 percent lower than the comparable quarter in 2005, and \$83.4 million for the first six months of 2006, 10 percent lower than the same period in 2005, due, in part, to lower Company headcount. Average Company headcount declined to 583 in the first half of 2006 from 731 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 second quarter of 2006 and 2005 include a total of \$4.6 million and \$5.3 million, respectively, of Stock Option Expense, as follows:

For the three months ended June 30,
(in millions)

| Expenses | 2006 | | |
|----------------------------|---|----------------------|----------------------|
| | Expenses before inclusion of Stock Option Expense | Stock Option Expense | Expenses as Reported |
| Research and development | \$ 31.8 | \$ 2.6 | \$ 34.4 |
| Contract manufacturing | 2.7 | 0.1 | 2.8 |
| General and administrative | 4.4 | 1.9 | 6.3 |
| Total operating expenses | <u>\$ 38.9</u> | <u>\$ 4.6</u> | <u>\$ 43.5</u> |

For the three months ended June 30,
(in millions)

| Expenses | 2005 | | |
|----------------------------|---|----------------------|----------------------|
| | Expenses before inclusion of Stock Option Expense | Stock Option Expense | Expenses as Reported |
| Research and development | \$ 37.3 | \$ 3.3 | \$ 40.6 |
| Contract manufacturing | 1.6 | 0.1 | 1.7 |
| General and administrative | 4.3 | 1.9 | 6.2 |
| Total operating expenses | <u>\$ 43.2</u> | <u>\$ 5.3</u> | <u>\$ 48.5</u> |

Operating expenses for first half of 2006 and 2005 include a total of \$8.5 million and \$10.7 million, respectively, of Stock Option Expense, as follows:

For the six months ended June 30,
(in millions)

| Expenses | 2006 | | |
|----------------------------|---|----------------------|----------------------|
| | Expenses before inclusion of Stock Option Expense | Stock Option Expense | Expenses as Reported |
| Research and development | \$ 61.9 | \$ 4.6 | \$ 66.5 |
| Contract manufacturing | 4.5 | 0.2 | 4.7 |
| General and administrative | 8.5 | 3.7 | 12.2 |
| Total operating expenses | <u>\$ 74.9</u> | <u>\$ 8.5</u> | <u>\$ 83.4</u> |

For the six months ended June 30,
(in millions)

| Expenses | 2005 | | |
|----------------------------|---|----------------------|----------------------|
| | Expenses before inclusion of Stock Option Expense | Stock Option Expense | Expenses as Reported |
| Research and development | \$ 69.8 | \$ 6.7 | \$ 76.5 |
| Contract manufacturing | 4.1 | 0.1 | 4.2 |
| General and administrative | 8.5 | 3.9 | 12.4 |
| Total operating expenses | <u>\$ 82.4</u> | <u>\$ 10.7</u> | <u>\$ 93.1</u> |

Research and development (R&D) expenses decreased to \$34.4 million in the second quarter of 2006 from \$40.6 million in the comparable quarter of 2005, and to \$66.5 million in the first six months of 2006 from \$76.5 million in the same period of 2005. In addition to the impact of lower Company headcount, as described above, in the first half 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 six months 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 and

Form 10-Q for the quarter ended March 31, 2006. 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.

###

Contacts:

Investors:
Charles Poole
914.345.7640
Investor.relations@regeneron.com

Media:
Lauren Tortorete
212.845.5609
ltortorete@biosector2.com

REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

| | June 30, 2006 | December 31, 2005 |
|---|--------------------------|--------------------------|
| ASSETS | | |
| Cash and marketable securities | \$ 304,083 | \$ 316,654 |
| Receivables | 12,141 | 36,521 |
| Inventory | 2,128 | 2,904 |
| Property, plant, and equipment, net | 53,854 | 60,535 |
| Other assets | <u>6,126</u> | <u>6,887</u> |
| Total assets | <u>\$ 378,332</u> | <u>\$ 423,501</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Accounts payable and accrued expenses | \$ 16,466 | \$ 23,337 |
| Deferred revenue | 78,099 | 86,162 |
| Notes payable | 200,000 | 200,000 |
| Stockholders' equity | <u>83,767</u> | <u>114,002</u> |
| Total liabilities and stockholders' equity | <u>\$ 378,332</u> | <u>\$ 423,501</u> |

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, | |
|--|--|--------------------|--------------------------------------|--------------------|
| | 2006 | 2005 | 2006 | 2005 |
| Revenues | | | | |
| Contract research and development | \$ 14,991 | \$ 13,545 | \$ 29,578 | \$ 27,047 |
| Contract manufacturing | 4,267 | 2,821 | 7,899 | 5,528 |
| | <u>19,258</u> | <u>16,366</u> | <u>37,477</u> | <u>32,575</u> |
| Expenses | | | | |
| Research and development | 34,398 | 40,642 | 66,482 | 76,554 |
| Contract manufacturing | 2,810 | 1,675 | 4,662 | 4,166 |
| General and administrative | 6,299 | 6,216 | 12,245 | 12,362 |
| | <u>43,507</u> | <u>48,533</u> | <u>83,389</u> | <u>93,082</u> |
| Loss from operations | <u>(24,249)</u> | <u>(32,167)</u> | <u>(45,912)</u> | <u>(60,507)</u> |
| Other income (expense) | | | | |
| Other contract income | | 5,640 | | 30,640 |
| Investment income | 3,684 | 2,539 | 7,165 | 4,769 |
| Interest expense | (3,011) | (3,011) | (6,022) | (6,024) |
| | <u>673</u> | <u>5,168</u> | <u>1,143</u> | <u>29,385</u> |
| Net loss before cumulative effect of a change in accounting principle | (23,576) | (26,999) | (44,769) | (31,122) |
| Cumulative effect of adopting Statement of Financial Accounting Standards No. 123R ("SFAS 123R") | | | 813 | |
| Net loss | <u>(\$ 23,576)</u> | <u>(\$ 26,999)</u> | <u>(\$ 43,956)</u> | <u>(\$ 31,122)</u> |
| Net loss per share amounts, basic and diluted: | | | | |
| Net loss before cumulative effect of a change in accounting principle | (\$ 0.41) | (\$ 0.48) | (\$ 0.79) | (\$ 0.56) |
| Cumulative effect of adopting SFAS 123R | | | 0.02 | |
| Net loss | <u>(\$ 0.41)</u> | <u>(\$ 0.48)</u> | <u>(\$ 0.77)</u> | <u>(\$ 0.56)</u> |
| Weighted average shares outstanding, basic and diluted | 56,915 | 55,917 | 56,821 | 55,866 |