

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) **April 27, 2004 (April 26, 2004)**

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

NEW YORK

0-19034

No. 13-3444607

(State or other jurisdiction
of incorporation)

(Commission
File Number)

(IRS Employer
Identification No.)

777 OLD SAW MILL RIVER ROAD, TARRYTOWN, NY

10591-6707

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code _____ (914) 347-7000

NOT APPLICABLE

(Former name or former address, if changed since last report)

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INFORMATION TO BE INCLUDED IN REPORT

Item 7. Financial Statements and Exhibits.

Item 12. Results of Operations and Financial Condition.

SIGNATURE

PRESS RELEASE

INFORMATION TO BE INCLUDED IN REPORT

Item 7. Financial Statements and Exhibits.

(c) Exhibits

99(a) Press Release dated April 26, 2004.

Item 12. Results of Operations and Financial Condition.

On April 26, 2004, we reported our first quarter 2004 results. Our first quarter 2004 results are discussed in detail in the press release attached hereto as Exhibit 99(a), which is incorporated by reference in its entirety. The information furnished under Item 12 of this Current Report on Form 8-K, including Exhibit 99(a), shall be deemed "filed" for purposes of the Securities Exchange Act of 1934, as amended and incorporated by reference in any of our filings under the Securities Act of 1933, as amended, as may be specified in such filing.

SIGNATURE

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

Regeneron Pharmaceuticals, Inc.

By: /s/ Murray A. Goldberg _____

Murray A. Goldberg
Senior Vice President, Finance and
Administration, Chief Financial Officer,
Treasurer & Assistant Secretary

Date: April 27, 2004

FOR IMMEDIATE RELEASE

REGENERON REPORTS FIRST QUARTER FINANCIAL AND OPERATING RESULTS

Tarrytown, New York (April 26, 2004) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the first quarter of 2004.

Regeneron reported net income of \$64.5 million, or \$1.17 per basic share and \$1.06 per diluted share, for the first quarter of 2004 compared with a net loss of \$30.3 million, or \$0.68 per share (basic and diluted), for the first quarter of 2003. The increase in net income was due principally to non-recurring income related to the Company's collaboration with Novartis Pharma AG. In the first quarter of 2004, Novartis notified Regeneron of its decision to forgo its right under the collaboration to jointly develop the Interleuken-1 (IL-1) Trap and agreed to pay \$42.75 million to satisfy its obligation to fund development costs for the IL-1 Trap for the nine month period following its notification and for the two months prior to that notice. Regeneron included this \$42.75 million in other contract income in the first quarter. In addition, the Company recognized contract research and development revenue of \$22.1 million which represents the remaining amount of the March 2003 up-front, non-refundable payment from Novartis that had previously been deferred. Novartis also forgave all of its outstanding loans to Regeneron totaling \$17.8 million, based on Regeneron's achieving a pre-defined development milestone, which was recognized as a research progress payment.

At March 31, 2004, cash, marketable securities, and restricted marketable securities totaled \$351.4 million compared with \$366.6 million at December 31, 2003. In April 2004, the Company received the \$42.75 million payments from

Novartis described above. The Company expects to end the year with a cash balance of \$300 to \$325 million. The Company's \$200.0 million of convertible notes, which bear interest at 5.5% per annum, mature in 2008.

Regeneron's total revenue increased to \$62.0 million in the first quarter of 2004 from \$9.9 million in the same period of 2003 due principally to the Company's collaborations with Novartis and Aventis. Contract research and development revenue increased to \$41.6 million in the first quarter of 2004 from \$9.2 million in the same period of 2003. Contract research and development revenue related to the Novartis collaboration was \$22.1 million in the first quarter of 2004 (as described above) compared to \$6.5 million in the first quarter of 2003. Regeneron does not expect future contract research and development revenue from Novartis. Contract research and development revenue also increased in the first quarter of 2004 compared with 2003 due to the recognition of \$16.4 million of revenue related to the Company's collaboration with Aventis for the joint development and commercialization of the VEGF Trap. The Aventis revenue consists of \$13.7 million for reimbursement of VEGF Trap development expenses and \$2.7 million related to a September 2003 up-front, non-refundable payment. The Company recognizes revenue in connection with collaborations in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition*. As a result, \$73.6 million of the Aventis up-front payment has been deferred as of March 31, 2004 and will be recognized as revenue in future periods.

Contract manufacturing revenue relates to Regeneron's long-term manufacturing agreement with Merck & Co., Inc. Contract manufacturing revenue increased to \$2.6 million in the first quarter of 2004 from \$0.7 million in the same period of 2003 because the Company shipped more product to Merck during the quarter. The Company recognizes revenue and the related manufacturing expense as product is shipped to Merck.

Total operating expenses for the first quarter of 2004 were \$38.2 million, one percent lower than the same period in 2003. Research and development (R&D)

expenses decreased 6.4% to \$32.2 million in the first quarter of 2004 from \$34.4 million in the comparable quarter of 2003 primarily due to a decline in development expenses for the Company's AXOKINE® and IL-1 Trap programs. This decline in expenses for the AXOKINE and IL-1 Trap programs was partially offset by increased VEGF Trap development expenses, which are being fully funded by Aventis.

Contract manufacturing expense, which relates to the Merck agreement, increased to \$2.2 million in the first quarter of 2004 from \$0.7 million in the comparable quarter of 2003 primarily because more product was shipped to Merck. General and administrative expenses increased 9.6% to \$3.8 million in the first quarter of 2004 from \$3.5 million in the comparable quarter of 2003 primarily due to an increase in professional fees and patent-related expenses.

Investment income declined 7.0% in the first quarter of 2004 compared with the same period of 2003 due to lower effective interest rates on investment securities. Interest expense increased 6.7% in the first quarter of 2004 compared with the same period in 2003. 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. For the quarter ended March 31, 2004, the weighted average number of shares outstanding (basic) increased to 55.3 million shares compared with 44.3 million shares in the same period last year, due primarily to the sale of 7.5 million and 2.8 million shares of the Company's Common Stock to Novartis and Aventis, respectively, in 2003.

Current Business Highlights

Regeneron has a diversified pipeline of clinical programs. In the first quarter of 2004, Aventis and Regeneron expanded the VEGF Trap clinical development

program to include the potential treatment of eye diseases. The initial phase 1 trial is a randomized, placebo-controlled, dose-escalating study in patients with the neovascular or “wet” form of age-related macular degeneration (wet AMD), a major cause of severe vision impairment and blindness in adults over 55. This trial is designed to assess the safety and tolerability of the VEGF Trap and to obtain a preliminary assessment of the potential effect of the VEGF Trap on visual acuity. Patients will receive treatment via intravenous infusions. The companies expect to expand the ocular program to include additional indications, such as diabetic retinopathy (DR), where the excess growth of blood vessels can cause blindness in diabetic patients. They also plan to study use of the VEGF Trap utilizing direct eye injections, the route of delivery used with other treatments.

Aventis and Regeneron also initiated a phase 1 clinical trial of the VEGF Trap in cancer by intravenous infusions. The initial phase 1 trial in cancer of the VEGF Trap delivered by subcutaneous injection is nearing completion. The maximum dose in the initial trial was limited to 1.6 mg/kg (milligram per kilogram of weight) per week, and there is no indication to date that a maximum tolerated dose has been reached. Intravenous infusions will allow the companies to assess even higher doses to obtain higher plasma levels of VEGF Trap than could be achieved in the earlier trial.

Regeneron also announced in the first quarter that it plans to initiate a phase 2b trial of the IL-1 Trap in rheumatoid arthritis later in 2004. The decision was made based on the recommendation of a panel of experts in rheumatoid arthritis who had examined the results of the phase 2 trial, which was completed in the second half of 2003. The phase 2b trial will be conducted in a larger patient population, testing higher doses over a longer period of time than in the phase 2 trial. The Company also plans to begin evaluating the IL-1 Trap in a number of other inflammatory conditions where interleukin-1 is believed to play an important detrimental role.

The phase 1 trial for the IL-4/13 Trap in patients with mild to moderate asthma completed. The IL-4/13 Trap was generally safe and well tolerated at the doses tested in this trial, and there were no indications that a maximum tolerated dose had been reached. The results of the trial will be reported at the American Thoracic Society meeting in May 2004.

The Company's proprietary Trap program has been the principal source of the therapeutic candidates being examined in clinical trials. These molecules have been designed to block specific cytokines and growth factors in the blood stream that, in excess, have been shown to cause harmful biological activity. In addition to the Traps in clinical studies, Regeneron has other Traps in preclinical development.

About Regeneron

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, rheumatoid arthritis, asthma, and obesity 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, including its Form 10-K/A for the year ended December 31, 2003. 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.

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Contact Information:

Investors:

Charles Poole
Vice President, Investor Relations
(914) 345-7640
charles.poole@regeneron.com

Media:

Lauren Tortorete
Media Relations
(212) 845-5609
ltortorete@biosector2.com

Additional Information about Regeneron and recent news releases are available on Regeneron's Worldwide Web Home Page at www.regeneron.com.

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

	<u>March 31, 2004</u>	<u>December 31, 2003</u>
ASSETS		
Cash, marketable securities, and restricted marketable securities	\$351,378	\$366,566
Receivables	59,882	15,529
Inventory	9,098	9,006
Property, plant, and equipment, net	77,616	80,723
Other assets	8,204	7,731
Total assets	<u>\$506,178</u>	<u>\$479,555</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	\$ 18,947	\$ 18,933
Deferred revenue	83,009	109,003
Notes payable	200,000	200,000
Other liabilities	116	13,976
Stockholders' equity	204,106	137,643
Total liabilities and stockholders' equity	<u>\$506,178</u>	<u>\$479,555</u>

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

	For the three months ended March 31,	
	2004	2003
Revenues		
Contract research and development	\$41,610	\$9,213
Research progress payment	17,770	
Contract manufacturing	2,610	712
	61,990	9,925
Expenses		
Research and development	32,181	34,390
Contract manufacturing	2,225	666
General and administrative	3,790	3,459
	38,196	38,515
Income (loss) from operations	23,794	(28,590)
Other income (expense)		
Other contract income	42,750	
Investment income	1,124	1,208
Interest expense	(3,136)	(2,939)
	40,738	(1,731)
Net income (loss)	\$64,532	(\$30,321)
Net income (loss) per share:		
Basic	\$1.17	(\$0.68)
Diluted	\$1.06	(\$0.68)
Weighted average shares outstanding:		
Basic	55,283	44,309
Diluted	63,620	44,309