

**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):

February 23, 2005 (February 18, 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 1.01 Entry into a Material Definitive Agreement

On February 18, 2005, the Company and Merck & Co., Inc. entered into Amendment No. 5 (the "Fifth Amendment") to their Manufacturing Agreement dated as of September 18, 1995 (the "Manufacturing Agreement"). The Fifth Amendment was made effective as of January 1, 2005. Pursuant to the Manufacturing Agreement, the Company produces an intermediate for a Merck pediatric vaccine at the Company's Rensselaer, New York facility. The parties extended the Manufacturing Agreement through October 31, 2006 and provided Merck an opportunity, upon twelve-months' prior notice, to extend the Manufacturing Agreement for an additional year through October 31, 2007. The parties also agreed to other technical amendments and modifications to the Manufacturing Agreement.

Item 2.02 Results of Operations and Financial Condition

On February 22, 2005, Regeneron Pharmaceuticals, Inc. announced its financial and operating results for the quarter and year ended December 31, 2004. A copy of the press release is attached hereto as Exhibit 99(a).

The information contained in the press release shall not be deemed "filed" for purposes of, nor shall it be deemed incorporated by reference in, any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Press Release of Regeneron Pharmaceuticals, Inc. dated February 22, 2005.

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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: February 23, 2005

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

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Number	Description
99(a)	Press Release of Regeneron Pharmaceuticals, Inc. dated February 22, 2005.

FOR IMMEDIATE RELEASE

REGENERON REPORTS FOURTH QUARTER AND FULL YEAR 2004 FINANCIAL AND OPERATING RESULTS

Tarrytown, New York (February 22, 2005) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the fourth quarter and year ended December 31, 2004.

Regeneron reported net income of \$2.8 million, or \$0.05 per share (basic and diluted), for the fourth quarter of 2004 compared with a net loss of \$19.4 million, or \$0.35 per share (basic and diluted), for the fourth quarter of 2003. The Company reported net income of \$41.7 million, or \$0.75 per basic share and \$0.74 per diluted share, for the full year 2004 compared with a net loss of \$107.5 million, or \$2.13 per share (basic and diluted), in 2003. The increase in net income for 2004 was due primarily to the Company's collaboration agreements with the sanofi-aventis Group and Novartis Pharma AG. In connection with the sanofi-aventis collaboration for the joint development and commercialization of the VEGF Trap, Regeneron recognized both higher contract research and development revenue and a \$25.0 million research progress payment related to a clinical development milestone that was earned in the fourth quarter of 2004 and received in January 2005. In connection with the Novartis collaboration, in the first quarter of 2004 the Company recognized a \$17.8 million research progress payment based on Regeneron's achieving a pre-defined development milestone and \$42.75 million of non-recurring income following Novartis' decision to forego certain development rights.

At December 31, 2004, cash and marketable securities totaled \$348.9 million compared with \$366.6 million at December 31, 2003. The Company's \$200.0

million of convertible notes, which bear interest at 5.5% per annum, mature in October 2008.

Regeneron's total revenue increased to \$47.1 million in the fourth quarter of 2004 from \$21.3 million in the same period of 2003. The Company's total revenue for the full year 2004 increased to \$174.0 million from \$57.5 million in 2003. Contract research and development revenue was \$18.8 million in the fourth quarter of 2004 and \$19.1 million in the comparable quarter of 2003 as higher revenue earned from sanofi-aventis in the fourth quarter of 2004 replaced revenue earned from Novartis in the same quarter of 2003. Contract research and development revenue increased to \$113.2 million for the full year 2004 from \$47.4 million for the same period of 2003, due principally to revenues earned from sanofi-aventis.

Regeneron recognized contract research and development revenue of \$16.3 million in the fourth quarter of 2004 and \$78.3 million for the full year 2004 related to the Company's collaboration with sanofi-aventis, compared with \$11.7 million and \$14.3 million, respectively, for the same periods of 2003. Contract research and development revenue from the sanofi-aventis collaboration for the full year 2004 consisted of \$67.8 million for reimbursement of VEGF Trap development expenses and \$10.5 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, \$65.8 million of the original \$80.0 million sanofi-aventis up-front payment has been deferred as of December 31, 2004 and will be recognized as revenue in future periods.

Contract research and development revenue related to the Novartis collaboration was \$22.1 million for the full year 2004, representing the remaining deferred amount of the March 2003 up-front, non-refundable payment of \$27.0 million from Novartis. This compares with \$21.4 million of contract research and

development revenue under the Novartis collaboration for the full year 2003. Regeneron does not expect to recognize any future contract research and development revenue from Novartis. In the first quarter of 2004, 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.

Contract manufacturing revenue relates to Regeneron's long-term manufacturing agreement with Merck & Co., Inc. Contract manufacturing revenue increased to \$3.3 million in the fourth quarter of 2004 from \$2.2 million for the same period of 2003 and to \$18.1 million for the full year 2004 from \$10.1 million in 2003. The increase in contract manufacturing revenue principally resulted from an increase in product shipments to Merck in 2004 compared with the same periods of 2003. The Company recognizes revenue and the related manufacturing expense as product is shipped to Merck.

Total operating expenses for the fourth quarter of 2004 were \$43.1 million, 12% higher than the same quarter in 2003 and \$168.4 million for the full year 2004, 7% higher than in 2003. Research and development (R&D) expenses increased 5% to \$34.8 million in the fourth quarter of 2004 and less than 1% to \$136.1 million for the full year of 2004 compared with the same periods of 2003. In 2004, the Company incurred higher development expenses for the VEGF Trap (which are fully reimbursed by sanofi-aventis) and the IL-4/13 Trap. These were partially offset by a decline in expenses for the Company's AXOKINE® and IL-1 Trap clinical development programs, compared with 2003.

Contract manufacturing expense, which relates to the Merck agreement, increased to \$3.5 million in the fourth quarter of 2004 from \$0.9 million in the same quarter of 2003, and to \$15.2 million for the full year 2004 from \$6.7 million in 2003, primarily because more product was shipped to Merck and the Company incurred unfavorable manufacturing costs in the fourth quarter and for

the full year 2004 compared with the same periods of 2003. General and administrative expenses increased 15% to \$4.9 million in the fourth quarter of 2004 and 15% to \$17.1 million for the full year 2004 compared with the same periods in 2003. In 2004, the Company incurred higher accounting and other professional fees, primarily related to its efforts to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and incurred costs associated with higher administrative headcount needed to support the Company's operations.

In the first quarter of 2004, in connection with its decision to forego its rights 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 fourth quarter and for the full year 2004 compared with prior year periods due primarily to higher effective interest rates on investment securities. Interest expense was essentially unchanged for the fourth quarter and full year of 2004 compared with the same periods 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 full year 2004, the weighted average number of shares outstanding increased to 55.4 million shares (basic) and 56.2 million shares (diluted) compared with 50.5 million shares (basic and diluted) 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 sanofi-aventis, respectively, in 2003.

Current Business Highlights

Regeneron has built a broad-based clinical development program that is evaluating several product candidates in different stages of clinical development. The Company's two lead candidates are the VEGF Trap and the IL-1 Trap.

In January 2005, sanofi-aventis reaffirmed their commitment to develop the VEGF Trap in oncology in collaboration with Regeneron. In addition, the companies agreed that the exclusive right to develop and commercialize the VEGF Trap for eye diseases through local delivery systems would revert to Regeneron. In connection with this agreement, sanofi-aventis made a \$25.0 million payment to Regeneron in January 2005, 50% of which is repayable to sanofi-aventis following commercialization of the VEGF Trap. The collaboration will not currently pursue systemic delivery of the VEGF Trap for eye disease.

Regeneron and sanofi-aventis plan to evaluate the VEGF Trap in a variety of cancer types, both in single-agent studies and in combination with chemotherapy. The VEGF Trap has been granted Fast Track designation by the US Food and Drug Administration (FDA) for a specific niche cancer indication.

Regeneron recently announced plans to move the IL-1 Trap development program forward in 2005 with the initiation of pivotal studies in rheumatoid arthritis and in rare genetic auto-inflammatory diseases and exploratory proof-of-concept studies in a wide variety of other diseases. These other diseases may include other rheumatological disorders and diseases associated with inflammation in blood vessels.

During the last quarter of 2004, Regeneron initiated an exploratory trial 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. In January 2005, the Company received Orphan Drug designation for the IL-1 Trap in these diseases. The Company expects the preliminary results from this study to be reported at a scientific meeting later this year.

The Company plans to initiate, in the second quarter of 2005, a phase 1 trial of the VEGF Trap in the neovascular form of age-related macular degeneration (wet AMD) utilizing local delivery to the eye.

In February 2005, the Company and Merck amended their long-term manufacturing agreement for production of an intermediate for a Merck pediatric vaccine at the Company's Rensselaer, New York facility. The amendment extends the manufacturing agreement for one full year through October 2006 and provides Merck an opportunity, upon twelve-months' prior notice, to extend the agreement for an additional year through October 2007.

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, 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 and the Form 10-Q for the quarter ended September 30, 2004. 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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REGENERON PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS (Unaudited)
(In thousands)

	December 31,	
	2004	2003
ASSETS		
Cash and marketable securities (including restricted marketable securities in 2003)	\$ 348,912	\$ 366,566
Receivables	43,102	15,529
Inventory	3,229	9,006
Property, plant and equipment, net	71,239	80,723
Other assets	6,626	7,731
Total assets	\$473,108	\$479,555
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	\$ 18,872	\$ 18,933
Deferred revenue	71,693	109,003
Notes payable	200,000	200,000
Other liabilities		13,976
Stockholders' equity	182,543	137,643
Total liabilities and stockholders' equity	\$473,108	\$479,555

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

	For the three months ended December 31,		For the year ended December 31,	
	2004	2003	2004	2003
Revenues				
Contract research and development	\$ 18,780	\$ 19,121	\$ 113,157	\$ 47,366
Research progress payments	25,000		42,770	
Contract manufacturing	3,310	2,151	18,090	10,131
	<u>47,090</u>	<u>21,272</u>	<u>174,017</u>	<u>57,497</u>
Expenses				
Research and development	34,789	33,267	136,095	136,024
Contract manufacturing	3,474	907	15,214	6,676
General and administrative	4,853	4,237	17,062	14,785
	<u>43,116</u>	<u>38,411</u>	<u>168,371</u>	<u>157,485</u>
Income (loss) from operations	<u>3,974</u>	<u>(17,139)</u>	<u>5,646</u>	<u>(99,988)</u>
Other income (expense)				
Other contract income			42,750	
Investment income	1,832	868	5,478	4,462
Interest expense	(3,014)	(3,106)	(12,175)	(11,932)
	<u>(1,182)</u>	<u>(2,238)</u>	<u>36,053</u>	<u>(7,470)</u>
Net income (loss)	<u>\$ 2,792</u>	<u>(\$19,377)</u>	<u>\$ 41,699</u>	<u>(\$107,458)</u>
Net income (loss) per share:				
Basic	\$ 0.05	(\$0.35)	\$ 0.75	(\$2.13)
Diluted	\$ 0.05	(\$0.35)	\$ 0.74	(\$2.13)
Weighted average shares outstanding:				
Basic	55,541	55,183	55,419	50,490
Diluted	55,719	55,183	56,172	50,490