#### 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) October 31, 2003 (October 30, 2003)

## 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, TARRYTO	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)				
Page 1 of 10				

## **TABLE OF CONTENTS**

## <u>INFORMATION TO BE INCLUDED IN REPORT</u>

<u>Item 7. Financial Statements and Exhibits</u>

Item 9. Regulation FD Disclosure and Item 12. Disclosure of Operations and Financial Condition

**SIGNATURE** 

PRESS RELEASE

#### **Table of Contents**

#### INFORMATION TO BE INCLUDED IN REPORT

#### Item 7. Financial Statements and Exhibits.

- (c) Exhibits
  - 99(a) Press Release dated October 30, 2003.

#### Item 9. Regulation FD Disclosure and Item 12. Disclosure of Operations and Financial Condition.

The following information is furnished pursuant to "Item 9. Regulation FD Disclosure" and "Item 12. Disclosure of Operations and Financial Condition." On Thursday, October 30, 2003, Regeneron Pharmaceuticals, Inc. issued a press release to report the company's financial results for the fiscal quarter ended September 30, 2003. This press release corrected a minor error in a previous press release issued by the Company on September 29, 2003. A copy of the October 30, 2003 press release is attached hereto as Exhibit 99(a).

The information included in this Current Report on Form 8-K 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.

#### **Table of Contents**

#### 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/ Stuart Kolinski

Stuart Kolinski Vice President & General Counsel

Date: October 31, 2003

## **Table of Contents**

## EXHIBIT INDEX

Exhibit No.	Description
-------------	-------------

99(a) Press Release of Regeneron Pharmaceuticals, Inc. dated October 30, 2003.

#### FOR IMMEDIATE RELEASE

## REGENERON REPORTS THIRD QUARTER FINANCIAL AND OPERATING RESULTS

CORRECTION: Issued by Regeneron Pharmaceuticals, Inc. October 30, 2003: The following corrected version replaces the release reporting financial and operating results dated October 29, 2003.

Tarrytown, New York (October 30, 2003) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the third quarter of 2003.

Regeneron reported a net loss of \$27.4 million, or \$0.52 per share, for the third quarter of 2003 compared with a net loss of \$32.8 million, or \$0.75 per share, for the third quarter of 2002. The Company reported a net loss of \$88.1 million, or \$1.80 per share, for the nine months ended September 30, 2003 compared with a net loss of \$88.7 million, or \$2.02 per share, for the same period in 2002.

At September 30, 2003, cash, marketable securities, and restricted marketable securities totaled \$391.1 million compared with \$295.2 million at December 31, 2002. On September 5, 2003, the Company entered into a collaboration agreement with Aventis under which the two companies will jointly develop and commercialize Vascular Endothelial Growth Factor (VEGF) Trap, Regeneron's lead anti-angiogenesis compound. Aventis made an up-front payment of \$80.0 million and purchased 2.8 million newly issued shares of the Company's common stock for \$45.0 million.

Regeneron's total revenue increased to \$17.4 million in the third quarter of 2003 from \$6.6 million in the same period of 2002. The Company's total revenue for

the first nine months of 2003 increased to \$36.2 million from \$17.1 million for the comparable period of 2002. The increase in revenue is attributable primarily to higher contract research and development revenue. The increase in contract research and development revenue compared with 2002 resulted from the recognition of \$7.8 million of revenue for the third quarter of 2003 and \$19.7 million for the first nine months of 2003 related to our collaboration with Novartis Pharma AG on the IL-1 Trap, which began in the first quarter of 2003, and our collaboration with Aventis on the VEGF Trap, which began in the third quarter of 2003. The Company recognizes revenue in connection with these collaborations in accordance with Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*. As a result, \$102.0 million of non-refundable payments that have been received or are receivable as of September 30, 2003 in connection with our Novartis and Aventis collaborations have been deferred 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 \$6.5 million in the third quarter of 2003 from \$3.8 million in the same period of 2002 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. Contract manufacturing revenue decreased to \$8.0 million in the first nine months of 2003 from \$8.9 million in the prior year period, due primarily to the receipt of a non-recurring \$1.0 million payment in the third quarter of 2002 related to the Merck agreement.

Total operating expenses for the third quarter of 2003 were \$43.1 million, 11 percent higher than the same period in 2002. For the first nine months of 2003, total operating expenses rose 14 percent from the prior year to \$119.1 million. Research and development (R&D) expenses increased 1 percent to \$34.7 million in the third quarter of 2003 compared with the same period of 2002. Increased development expenses for the IL-1 Trap and VEGF Trap in the third quarter of 2003, compared with the same quarter last year, were offset in part by

a decline in development expenses related to the AXOKINE® program. For the first nine months of 2003, R&D expenses increased 14 percent to \$102.8 million compared with the same period in 2002. The increase for the first nine months of 2003 was primarily due to expenses associated with the Company's development programs for the IL-1 Trap for the treatment of rheumatoid arthritis and VEGF Trap for the treatment of cancer.

Contract manufacturing expense increased in both the third quarter and first nine months of 2003 compared with the same periods in 2002 because more product was shipped to Merck. General and administrative expenses increased in the third quarter and for the first nine months of 2003 versus comparable periods in 2002 primarily due to increased administrative costs required to support the Company's expanding development pipeline, higher insurance costs, and expenses for external service providers.

Investment income declined in the third quarter and for the first nine months of 2003 compared with prior year periods due to lower effective interest rates on investment securities and lower levels of interest-bearing investments. Interest expense declined slightly compared with last year's third quarter. Interest expense is attributable primarily to \$200.0 million of convertible notes issued in October 2001, which mature in 2008 and bear interest at 5.5% per annum.

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 September 30, 2003, the weighted average number of shares outstanding increased to 52.9 million shares compared with 44.0 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 currently has four product candidates in clinical development. AXOKINE is in Phase III trials for the treatment of obesity. The other three

therapeutic candidates emerged from the Company's proprietary Trap program. These molecules have been designed to attach to (or "trap") specific cytokines and growth factors in the blood stream that, in excess, may cause harmful biological activity. The IL-1 Trap recently completed a Phase II trial for rheumatoid arthritis. The VEGF Trap is in a Phase I trial for cancer, and the IL-4/13 Trap is in a Phase I trial for asthma.

In the AXOKINE program, Regeneron announced during the third quarter that it was moving forward with its Phase III program for the treatment of obesity. The decision was made following a meeting with the United States Food and Drug Administration (FDA) during which the Company reviewed results from the initial pivotal trial and its plans for future development.

Regeneron and Novartis, who entered into a collaboration agreement earlier this year to develop and commercialize the IL-1 Trap, reported in October 2003 that they would be working together to evaluate the data from the recently completed Phase II trial and determine the best path forward for the next clinical study. In a dose-ranging Phase II study, which involved approximately 200 subjects, the IL-1 Trap demonstrated evidence of clinical activity in patients with rheumatoid arthritis and a favorable safety and tolerability profile.

During the third quarter, the Company entered into a collaboration agreement with Aventis to jointly develop and commercialize the VEGF Trap in cancer and other indications. Aventis has one of the pharmaceutical industry's leading oncology portfolios. A Phase I dose-escalation study, in which subjects receive a weekly subcutaneous injection of the VEGF Trap, is currently in progress and an intravenous phase of this study is planned. This trial is designed to assess the preliminary safety and tolerability of the VEGF Trap in people with solid tumor malignancies or with non-Hodgkin's lymphoma. Under the agreement, Aventis has agreed to a broad development program for the VEGF Trap in various cancer indications. They also noted that they would move rapidly to study the VEGF Trap in eye diseases, where the abnormal formation of new

blood vessels – a process termed "angiogenesis" – is deemed pathologic and can cause serious problems. Possible other indications are also under consideration.

Regeneron is also conducting a Phase I study of the IL-4/13 Trap in subjects with mild to moderate asthma. This trial is a placebo-controlled, double-blind, dose-escalation study to assess the preliminary safety and tolerability of the IL-4/13 Trap.

#### About Regeneror

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 obesity, rheumatoid arthritis, cancer, 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, including its Form 10-K for the year ended December 31, 2002 and the Form 10-Q for the quarter ended June 30, 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.

###

#### **Investor Contact:**

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

Lauren Tortorete Biosector2 ltortorete@biosector2.com (212) 414-5647

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)

	September 30, 2003	December 31, 2002
ASSETS		
Cash, marketable securities and restricted marketable securities	\$391,123	\$295,246
Receivables	9,197	4,017
Inventory	7,698	6,831
Property, plant and equipment, net	83,715	76,825
Other assets	8,768	8,655
Total assets	\$500,501	\$391,574
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	\$ 20,967	\$ 30,309
Deferred revenue	114,036	15,134
Notes payable	200,000	200,000
Other liabilities	9,296	150
Stockholders' equity	156,202	145,981
Total liabilities and stockholders' equity	\$500,501	\$391,574

# REGENERON PHARMACEUTICALS, INC. CONDENSED STATEMENTS OF OPERATIONS (Unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2003	2002	2003	2002
Revenues				
Contract research and development	\$ 10,882	\$ 2,780	\$ 28,245	\$ 8,215
Contract manufacturing	6,510	3,786	7,980	8,861
	17,392	6,566	36,225	17,076
Expenses				
Research and development	34,650	34,295	102,757	90,473
Contract manufacturing	4,844	1,637	5,769	4,757
General and administrative	3,601	2,811	10,548	9,167
	43,095	38,743	119,074	104,397
Loss from operations	(25,703)	(32,177)	(82,849)	(87,321)
Other income (expense)				
Investment income	1,285	2,378	3,594	7,703
Interest expense	(2,982)	(3,017)	(8,826)	(9,066)
	(1,697)	(639)	(5,232)	(1,363)
Net loss	\$(27,400)	\$(32,816)	\$ (88,081)	\$ (88,684)
Net loss per share amounts, basic and diluted	\$ (0.52)	\$ (0.75)	\$ (1.80)	\$ (2.02)
Weighted average number of Common and Class A shares outstanding: basic and diluted	52,902	43,950	48,926	43,895

(In thousands, except per share data)