Table of Contents

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 28, 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)

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 (*see* General Instruction A.2, below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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.
SIGNATURE
EX-99.A: PRESS RELEASE

Table of Contents

Item 2.02. Results of Operations and Financial Condition.

On October 28, 2004, Regeneron Pharmaceuticals, Inc. announced its financial results for the quarter ended September 30, 2004. A copy of the 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.

Item 9.01. Financial Statements and Exhibits.

(c) Exhibits

99(a) Press Release of Regeneron Pharmaceuticals, Inc. dated October 28, 2004.

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 hereunto duly authorized.

Regeneron Pharmaceuticals, Inc.

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

Date: October 28, 2004

Exhibit 99(a)

FOR IMMEDIATE RELEASE

REGENERON REPORTS THIRD QUARTER FINANCIAL AND OPERATING RESULTS

FDA Grants Fast Track Designation to the VEGF Trap for Specific Cancer Indication

Tarrytown, New York (October 28, 2004) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the third quarter ended September 30, 2004.

Regeneron reported a net loss of $11.1 million, or $0.20 per share (basic and diluted), for the third quarter of 2004 compared with a net loss of $27.4 million, or $0.52 per share (basic and diluted), for the third quarter of 2003. The Company reported net income of $38.9 million, or $0.70 per basic share and $0.69 per diluted share, for the nine months ended September 30, 2004 compared with a net loss of $88.1 million, or $1.80 per share (basic and diluted), for the same period in 2003. The increase in net income for the first nine months of 2004 was due in part to contract research and development revenue related to the Company's collaboration with Aventis, a member of the sanofi-aventis Group, which began in September 2003, for the joint development and commercialization of the VEGF Trap. In addition, Regeneron recognized non-recurring income in the first quarter of 2004 related to the Company's collaboration with Novartis Pharma AG following Novartis' decision to forgo its rights to jointly develop the Interleukin-1 (IL-1) Trap.

At September 30, 2004, cash, marketable securities, and restricted marketable securities totaled $361.2 million compared with $366.6 million at December 31, 2003. The Company has raised its year-end cash forecast to $325 to $350 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 $36.5 million in the third quarter of 2004 from $17.4 million in the same period of 2003. The Company's total revenue for the first nine months of 2004 increased to $126.9 million from $36.2 million for the same period of 2003. Contract research and development revenue increased to $25.6 million in the third quarter of 2004 from $10.9 million in the comparable quarter of 2003, and to $94.4 million for the first nine months of 2004 from $28.2 million for the same period of 2003, due principally to revenues earned from Aventis and Novartis.

Regeneron recognized contract research and development revenue of $22.1 million in the third quarter of 2004 and $62.0 million for the first nine months of 2004 related to the Company's collaboration with Aventis, compared with $2.6 million in both the third quarter and first nine months of 2003. The Aventis revenue for the first nine months of 2004 consisted of $53.8 million for reimbursement of VEGF Trap development expenses and $8.2 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, $68.2 million of the original $80.0 million Aventis up-front payment has been deferred as of September 30, 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 first nine months of 2004, which represented the remaining amount of a March 2003 up-front, non-refundable payment from Novartis under the collaboration that had previously been deferred. This compares to $17.1 million of contract research and development revenue under the Novartis collaboration for the same period in 2003. Regeneron does not expect to recognize any future 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 $10.9 million in the third quarter of 2004 from $6.5 million in the comparable quarter of 2003, and to $14.8 million for the first nine months of 2004 from $8.0 million for the same period of 2003. The increase in manufacturing revenue principally resulted from an increase in product shipments to Merck in 2004 compared to the same periods in 2003. The Company recognizes revenue and the related manufacturing expense as product is shipped to Merck.

Total operating expenses for the third quarter of 2004 were $46.0 million, 7% higher than the comparable quarter in 2003, and $125.3 million for the first nine months of 2004, 5% higher than the same period in 2003. Research and development (R&D) expenses decreased 5% to $32.8 million in the third quarter of 2004 and decreased 1% to $101.3 million in the first nine months of 2004 compared with the same periods in 2003. The 2004 decreases were due primarily to lower expenses related to the Company's AXOKINE® and IL-1 Trap clinical development programs, offset in part by higher VEGF Trap development expenses. Development expenses for the VEGF Trap are fully reimbursed by Aventis.

Contract manufacturing expense, which relates to the Merck agreement, increased to $9.0 million in the third quarter of 2004 from $4.8 million in the comparable quarter of 2003, and to $11.7 million for the first nine months of 2004 from $5.8 million for the same period of 2003, because more product was shipped to Merck. General and administrative expenses increased 16% to $4.2 million in the third quarter of 2004 and increased 16% to $12.2 million for the first nine months of 2004 versus the comparable periods in the prior year due primarily to increases in professional fees associated with our efforts to comply

with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and other accounting services.

In the first quarter of 2004, Novartis agreed to pay Regeneron $42.75 million to satisfy certain funding obligations under the collaboration, which was recognized as other contract income. Investment income increased 10% in the third quarter of 2004 and increased 1% for the first nine months of 2004 compared with the same periods in 2003. Interest expense increased 1% in the third quarter of 2004 and increased 4% for the first nine months 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 nine months ended September 30, 2004, the weighted average number of shares outstanding increased to 55.4 million shares (basic) and 56.3 million shares (diluted) compared with 48.9 million shares (basic and diluted) 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 and preclinical development programs. These include several oncology indications, eye diseases, rheumatoid arthritis and other inflammatory diseases, and asthma and allergies. Regeneron's lead product candidate, the VEGF Trap, is partnered with Aventis and is being evaluated in patients with a diverse set of cancer indications and in selected eye diseases.

During the last quarter, the U.S. Food and Drug Administration (FDA) granted Fast Track designation to the VEGF Trap for a specific niche cancer indication. As a result of the FDA's decision, Regeneron and Aventis plan to initiate a clinical trial in that indication in 2005.

In addition, Regeneron and Aventis are currently conducting a phase 1 trial designed to test the safety and tolerability of intravenous delivery of the VEGF Trap in advanced cancer patients. This trial is designed to evaluate higher doses of the VEGF Trap than were administered with subcutaneous injections in the initial phase 1 trial. The companies updated the preliminary results from the initial phase 1 trial of the subcutaneous VEGF Trap in a poster session at the 16th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in September 2004.

The VEGF Trap clinical development program has been expanded by initiating two separate phase 1 clinical trials of the VEGF Trap in eye diseases. The first trial includes 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 years old. This study is evaluating the VEGF Trap delivered systemically by intravenous injections in patients with wet AMD. Regeneron and Aventis have started a phase 1 trial of intravenous VEGF Trap, also delivered systemically, in patients with diabetic macular edema (DME). DME is a complication of diabetic retinopathy, a disease affecting the blood vessels of the retina. Diabetic retinopathy, in its late stages, can cause multiple problems involving blood vessels, including excess blood vessel growth. A major cause of vision loss in patients with diabetes, DME affects nearly 500,000 people in the United States. In addition to other programs, we will also explore the possibility of studying the VEGF Trap through intravitreal administration.

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 and its Form 10-Q for the quarter ended June 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. ###

Contacts:
Investors
Charles Poole
VP, Investor Relations
914.345.7641
charles.poole@regeneron.com

Media:
Lauren Tortorete
Biosecto2
212.845.5609
ltortorete@biosector2.com

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2004	**2003**	**2004**	**2003**
Revenues				
Contract research and development	$ 25,621	$ 10,882	$ 94,377	$ 28,245
Research progress payment			17,770	
Contract manufacturing	10,898	6,510	14,780	7,980
	36,519	17,392	126,927	36,225
Expenses				
Research and development	32,828	34,650	101,306	102,757
Contract manufacturing	8,986	4,844	11,740	5,769
General and administrative	4,184	3,601	12,209	10,548
	45,998	43,095	125,255	119,074
Income (loss) from operations	(9,479)	(25,703)	1,672	(82,849)
Other income (expense)				
Other contract income			42,750	
Investment income	1,417	1,285	3,646	3,594
Interest expense	(3,014)	(2,982)	(9,161)	(8,826)
	(1,597)	(1,697)	37,235	(5,232)
Net income (loss)	($11,076)	($27,400)	$ 38,907	($88,081)
Net income (loss) per share:				
Basic	($0.20)	($0.52)	$ 0.70	($1.80)
Diluted	($0.20)	($0.52)	$ 0.69	($1.80)
Weighted average shares outstanding:				
Basic	55,468	52,902	55,378	48,926
Diluted	55,468	52,902	56,295	48,926

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

	September 30, 2004	December 31 2003
ASSETS		
Cash, marketable securities, and restricted marketable securities	$361,184	$366,566
Receivables	24,866	15,529
Inventory	4,266	9,006
Property, plant, and equipment, net	73,942	80,723
Other assets	8,427	7,731
Total assets	$472,685	$479,555
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	$ 20,284	$ 18,933
Deferred revenue	73,492	109,003
Notes payable	200,000	200,000
Other liabilities	36	13,976
Stockholders' equity	178,873	137,643
Total liabilities and stockholders' equity	$472,685	$479,555