# 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):

November 3, 2005

## REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

	New York	000-19034	133444607
	(State or other jurisdiction of	(Commission File Number)	(I.R.S. Employer Identification Number)
	incorporation)		idendification Number)
	777 Old Saw Mill Divay Dood Tayyutayu	n Naw York	10591-6707
	777 Old Saw Mill River Road, Tarrytown (Address of principal executive of		(Zip Code)
	(	,	(
		<u>(914) 347-7000</u>	
		(Registrant's telephone number, including area code	2)
	Check the appropriate box below if the Form following provisions:	8-K filing is intended to simultaneously satisfy the	filing obligation of registrant under any of the
£	Written communications pursuant to Rule 42	5 under the Securities Act (17 CFR 230.425)	
£	Soliciting material pursuant to Rule 14a-12 u	under the Exchange Act (17 CFR 240.14a-12)	
£	Pre-commencement communications pursual	nt to Rule 14d-2(b) under the Exchange Act (17 CF	R 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

<u>Item 2.02 Results of Operations and Financial Condition</u> <u>Item 9.01 Financial Statements and Exhibits</u> Exhibit Index EX-99.A: PRESS RELEASE

#### **Table of Contents**

#### Item 2.02 Results of Operations and Financial Condition

On November 3, 2005, Regeneron Pharmaceuticals, Inc. announced its financial and operating results for the quarter and nine months ended September 30, 2005. A copy of the news release is attached hereto as Exhibit 99(a) and is incorporated herein by reference.

Effective January 1, 2005, Regeneron began recognizing non-cash compensation expense related to employee stock option awards (Stock Option Expense) in operating expenses in accordance with Statement of Financial Accounting Standards No. 123 (SFAS No. 123). Prior to the adoption of SFAS No. 123, compensation expense related to employee stock options was not reflected in operating expenses and prior period operating results have not been restated.

The news release includes certain financial measures that are calculated in a manner different from generally accepted accounting principles (GAAP) and are considered non-GAAP financial measures under United States Securities and Exchange Commission rules. Non-GAAP financial measures for the three and nine months ended September 30, 2005 included in the news release are: (1) pro forma net loss and pro forma net loss per share (basic and diluted), exclusive of Stock Option Expense and (2) research and development expenses, general and administrative expenses, and contract manufacturing expenses, all exclusive of Stock Option Expense. Our management does not intend that the presentation of non-GAAP financial measures be considered in isolation or as a substitute for results prepared in accordance with GAAP.

Our management believes that the non-GAAP financial measures described above present helpful information to investors and other users of Regeneron's financial statements by providing greater transparency about the nature of and trends in our operating expenses and net income (loss) and a more useful basis for comparing our operating results for the three months and nine months ended September 30, 2005 and 2004. In addition, our management uses non-GAAP financial measures which exclude Stock Option Expense internally for operating, budgeting, and financial planning purposes. The news release includes tables which provide a reconciliation of the differences between these non-GAAP financial measures and the most directly comparable financial measures calculated and presented in accordance with GAAP in the news release.

#### Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99(a) Press Release of Regeneron Pharmaceuticals, Inc. dated November 3, 2005.

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: November 3, 2005

By: /s/ Stuart Kolinski

Stuart Kolinski

Vice President and General Counsel

#### **Table of Contents**

#### **Exhibit Index**

<u>Number</u>	<u>Description</u>
99(a)	Press Release of Regeneron Pharmaceuticals, Inc. dated November 3, 2005.

REGENERON REGENERON PHARMACEUTICALS, INC.

777 OLD SAW MILL RIVER ROAD TARRYTOWN, NY 10591 TELEPHONE: 914-345-7400

FAX: 914-345-7797

#### FOR IMMEDIATE RELEASE

## REGENERON REPORTS THIRD QUARTER FINANCIAL AND OPERATING RESULTS

Tarrytown, New York (November 3, 2005) — Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today announced financial and operating results for the third quarter of 2005. Regeneron reported a net loss of \$34.7 million, or \$0.62 per share (basic and diluted), for the third quarter of 2005 and a net loss of \$65.8 million, or \$1.18 per share (basic and diluted), for the nine months ended September 30, 2005. Excluding the effects of expensing stock options in 2005, Regeneron had a net loss of \$29.2 million, or \$0.52 per share (basic and diluted), in the third quarter and a net loss of \$49.6 million, or \$0.89 per share (basic and diluted), for the first nine months compared with a net loss of \$11.1 million, or \$0.20 per share (basic and diluted), for the third quarter of 2004 and net income of \$38.9 million, or \$0.70 per basic share and \$0.69 per diluted share, for the first nine months of 2004.

At September 30, 2005, cash and marketable securities totaled \$333.6 million compared with \$348.9 million at December 31, 2004. The Company's \$200.0 million of convertible notes, which bear interest at 5.5% per annum, mature in October 2008.

#### **Current Business Highlights**

Regeneron is building a broad-based clinical development program with a focus on three clinical candidates in oncology, eye diseases, and inflammation.

The Vascular Endothelial Growth Factor (VEGF) Trap oncology program, which is being conducted in collaboration with the sanofi-aventis Group, continued to expand during the third quarter. A second safety and tolerability trial of the VEGF Trap in combination with a standard chemotherapy regimen was started. Regeneron recently announced plans with sanofi-aventis to initiate up to 19 additional trials for the VEGF Trap in various cancer indications, some of which would begin in the fourth quarter of 2005.

The companies plan to initiate up to six new efficacy/safety trials with the VEGF Trap, and up to ten additional trials may be conducted through the National Cancer Institute (NCI) under a Clinical Trials Agreement between the Cancer

Therapeutics Evaluation Program (CTEP), NCI, and sanofi-aventis. Three of the efficacy/safety studies are planned to be single-agent trials that will be conducted in a variety of indications. These studies are planned to begin in the fourth quarter of 2005 and the first quarter of 2006. Three other efficacy/safety studies will evaluate the VEGF Trap in combination with standard chemotherapy regimens in patients with different cancer types. Two of these studies could begin as early as the second half of 2006, following successful completion of initial combination safety and tolerability studies. Two safety and tolerability combination studies were ongoing at the end of the third quarter of 2005 and a third study was initiated in October 2005. Two more are scheduled to begin as early as the fourth quarter of 2005. In addition, CTEP plans to sponsor up to ten exploratory efficacy/safety studies evaluating the VEGF Trap in a variety of cancer types. These trials are planned to start in 2006.

In the VEGF Trap program for the treatment of eye diseases, Regeneron initiated a Phase 1 study in patients with the neovascular form of agerelated macular degeneration (wet AMD) in June 2005 that is evaluating the safety and tolerability of the VEGF Trap using direct injections into
the eye. The Phase 1 study is also measuring the effect of the VEGF Trap on the excess retinal thickness present in patients with wet AMD.
The Phase 1 study includes a "Part A", in which safety and tolerability are being evaluated in a dose-escalating paradigm and a "Part B", in
which the safety and tolerability of a single intravitreal injection of the VEGF Trap will be further evaluated compared with an approved
treatment for wet AMD.

In September 2005, the Company announced that it could initiate a Phase 2 trial of the VEGF Trap in wet AMD as early as late 2005 or early 2006.

At the Retinal Society Meeting in September 2005, researchers reported that the VEGF Trap had successfully met its pre-specified efficacy endpoint in an earlier Phase 1 study in patients with advanced wet AMD. This trial evaluated the safety and tolerability of the VEGF Trap when delivered by intravenous injections, and showed a statistically significant decrease in excess retinal thickness, which increased in both magnitude and duration with higher doses. The results also indicated that the VEGF Trap caused a dose-dependent increase in blood pressure (hypertension), which appears to be a "class-effect" of systemically delivered anti-VEGF agents.

In September 2005, the Company announced that it was in discussions with the FDA to finalize the design of a pivotal registration study of the Interleukin-1 (IL-1) Trap in patients with *CIAS1*-associated periodic syndrome (CAPS). This study is planned to begin in the fourth quarter of 2005. In June 2005, Regeneron announced positive preliminary results from the ongoing pilot study of once-weekly dosing of the IL-1 Trap in four CAPS patients. As of that date, each of these patients had demonstrated a positive response to the IL-1 Trap, both in the initial loading dose phase and the ongoing chronic dosing phase of the study.

This study is being conducted under a Cooperative Research and Development Agreement (CRADA) with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), part of the National Institutes of Health. The FDA has granted Orphan Drug Designation to the IL-1 Trap in CAPS disorders, for which there are no approved therapies.

In addition to the CAPS development program, Regeneron is pursuing other indications where IL-1 may play an important role. Earlier this year, the Company initiated a pilot study of the IL-1 Trap in polymyalgia rheumatica (PMR). In the fourth quarter, Regeneron plans to initiate a pilot study in systemic-onset juvenile idiopathic arthritis (SoJIA). The Company does not currently plan to conduct any further studies of the IL-1 Trap in adult rheumatoid arthritis or osteoarthritis.

#### **Financial Results**

The Company's financial results for the quarter and the nine months ended September 30, 2005 and 2004 are detailed in the table below. Effective January 1, 2005, the Company began recognizing non-cash compensation expense related to employee stock option awards (Stock Option Expense) in accordance with Statement of Financial Accounting Standards (SFAS) No. 123.

For the three months ended September 30, 2005 and 2004

(in millions, except per share data)

		Net Loss per Share -
2005:	Net Loss	Basic and Diluted
Net loss, as reported	(\$34.7)	(\$0.62)
Add: Stock Option Expense	5.5	0.10
Pro forma net loss, exclusive of Stock Option Expense	<u>(\$29.2)</u>	(\$0.52)
2004:		
Net loss, as reported (1)	(\$11.1)	<u>(\$0.20</u> )

For the nine months ended September 30, 2005 and 2004

(in millions, except per share data)

		Net Income (Loss) per Share	
2005:	Net Income (Loss)	Basic	Diluted
Net loss, as reported	(\$65.8)	(\$1.18)	(\$1.18)
Add: Stock Option Expense	16.2	0.29	0.29
Pro forma net loss, exclusive of Stock Option Expense	(\$49.6)	(\$0.89)	(\$0.89)
2004:			
Net income, as reported (1)	\$ 38.9	\$ 0.70	\$ 0.69
	<del></del>		

<sup>(1)</sup> In 2004, the Company's reported net income (loss) did not include Stock Option Expense.

Net loss in the first nine months of 2005 included non-recurring payments of \$25.0 million from sanofi-aventis 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. Net income in the first nine months of 2004 included \$82.6 million of income related to the Company's collaboration with Novartis Pharma AG, consisting of a \$17.8 million research progress payment and \$64.8 million of non-recurring income following Novartis' decision to forego certain development rights.

Regeneron's total revenue decreased to \$16.2 million in the third quarter of 2005 from \$36.5 million in the comparable quarter of 2004, and to \$48.8 million for the first nine months of 2005 from \$126.9 million for the same period of 2004, due primarily to a decline in contract research and development revenue. Contract research and development revenue decreased to \$11.5 million in the third quarter of 2005 from \$25.6 million in the comparable quarter of 2004, and to \$38.6 million for the first nine months of 2005 from \$94.4 million for the same period of 2004.

Regeneron recognized contract research and development revenue of \$11.2 million in the third quarter of 2005 and \$30.4 million for the first nine months of 2005 related to the Company's collaboration with sanofi-aventis, compared with \$22.1 million and \$62.0 million, respectively, for the same periods of 2004. Contract research and development revenue from the sanofi-aventis collaboration consists of reimbursement of the Company's VEGF Trap development expenses plus recognition of amounts related to an \$80.0 million up-front, non-refundable payment received from sanofi-aventis in September 2003. Sanofi-aventis also incurs VEGF Trap development expenses which are increasing because of the greater role of sanofi-aventis in overseeing the VEGF Trap oncology program. During the term of the collaboration, agreed-upon development expenses incurred by both companies are funded by sanofi-aventis. If the collaboration becomes profitable, the Company will reimburse sanofi-aventis for 50% of total VEGF Trap development expenses.

Reimbursement of the Company's VEGF Trap development expenses by sanofi-aventis decreased to \$8.9 million in the third quarter of 2005 from \$19.4 million in the comparable quarter of 2004, and to \$23.4 million in the first nine months of 2005 from \$53.8 million in the same period of 2004, primarily due to lower clinical supply manufacturing costs. The Company manufactured VEGF Trap clinical supplies during the first nine months of 2004, but not during the first nine months of 2005. \$2.3 million of the \$80.0 million up-front payment received from sanofiaventis in 2003 was recognized as revenue in the third quarter of 2005 compared to \$2.7 million in the same quarter of 2004, and \$7.0 million of this up-front payment was recognized as revenue in the first nine months of 2005 compared to \$8.2 million in the same period of 2004. The Company recognizes revenue in connection with collaborations in accordance with Staff Accounting Bulletin No. 104, *Revenue Recognition*. As a result, \$58.8 million of the original \$80.0 million

up-front payment has been deferred as of September 30, 2005 and will be recognized as revenue in future periods.

In the first quarter of 2004, the Company recognized \$22.1 million of contract research and development revenue related to the Novartis collaboration which represented the remaining amount of a \$27.0 million March 2003 up-front payment that had previously been deferred. Subsequent to the first quarter of 2004, Regeneron has not received, and does not expect to receive, any further 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., which will expire in October 2006. Contract manufacturing revenue decreased to \$4.7 million in the third quarter of 2005 from \$10.9 million in the comparable quarter of 2004, and to \$10.2 million for the first nine months of 2005 from \$14.8 million for the same period in 2004, as the Company shipped less product to Merck. The Company recognizes revenue and the related manufacturing expense as product is shipped to Merck.

Total operating expenses for the third quarter of 2005 were \$50.6 million, 10 percent higher than the comparable quarter in 2004, and \$143.7 million for the first nine months of 2005, 15 percent higher than the same period in 2004. Operating expenses in the third quarter and the first nine months of 2005 include a total of \$5.5 million and \$16.2 million of Stock Option Expense, respectively, as follows:

For the three months ended September 30, (in millions)	2005			2004
(III IIIIIIOIIS)	Stock Expenses exclusive of		2004	
	Expenses	Option	Stock Option	Expenses as
Expenses	as Reported	Expense	Expense	Reported (1)
Research and development	\$41.1	\$ 3.3	\$37.8	\$32.8
Contract manufacturing	3.3	0.3	3.0	9.0
General and administrative	6.2	1.9	4.3	4.2
Total operating expenses	\$50.6	\$ 5.5	\$45.1	\$46.0
For the nine months ended September 30,				
(in millions)		2005		2004
,		Stock	Expenses exclusive	
	Expenses	Option	of Stock Option	Expenses as
Expenses	as Reported	Expense	Expense	Reported (1)
Research and development	\$117.7	\$10.1	\$107.6	\$101.3
Contract manufacturing	7.4	0.3	7.1	11.7
General and administrative	18.6	5.8	12.8	12.2
Total operating expenses	\$143.7	\$ <u>16.2</u>	\$127.5	\$125.2

<sup>(1)</sup> In 2004, expenses as reported in the Company's Statement of Operations did not include Stock Option Expense.

Effective January 1, 2005, the Company adopted the fair value based method of accounting for stock-based employee compensation under the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, using the modified prospective method described in SFAS No. 148, *Accounting for Stock-Based Compensation* — *Transition and Disclosure*. As a result, the Company has begun recognizing 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. 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. Prior to the adoption of the fair value method, the Company accounted for stock-based compensation to employees under the intrinsic value method of accounting set forth in Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related interpretations. Therefore, compensation expense related to employee stock options was not reflected in operating expenses in any period prior to the first quarter of 2005 and prior period operating results have not been restated.

Research and development (R&D) expenses, exclusive of Stock Option Expense, increased to \$37.8 million in the third quarter of 2005 from \$32.8 million in the comparable quarter of 2004, and to \$107.6 million in the first nine months of 2005 from \$101.3 million in the same period of 2004. In the third quarter and first nine months of 2005, the Company incurred higher development expenses for the IL-1 Trap, due primarily to higher costs related to clinical studies, including costs incurred in 2005 to manufacture IL-1 Trap clinical supplies. These higher IL-1 Trap costs were partially offset by lower expenses for other clinical development programs, compared with the same periods in 2004.

Contract manufacturing expense relates to the Merck agreement. Exclusive of Stock Option Expense, contract manufacturing expense decreased to \$3.0 million in the third quarter of 2005 from \$9.0 million in the comparable quarter of 2004, and to \$7.1 million for the first nine months of 2005 from \$11.7 million for the same period of 2004 as the Company shipped less product to Merck. General and administrative expenses, exclusive of Stock Option Expense, increased slightly to \$4.3 million in the third quarter of 2005 from \$4.2 million for the comparable quarter of 2004, and to \$12.8 million for the first nine months of 2005 from \$12.2 million for the same period of 2004 due primarily to higher administrative personnel and facility costs.

Other contract income includes the payments to the Company in 2005 and 2004 described below. In January 2005, the Company and sanofiaventis amended their collaboration agreement to exclude from the scope of the collaboration the development of the VEGF Trap for eye diseases through local delivery systems. In connection with the amendment, sanofi-aventis made a one-time \$25.0 million

payment to the Company. In June 2005, the Company and Procter & Gamble amended their collaboration agreement and agreed that the research activities of the parties under the collaboration agreement were completed. In connection with the amendment, Procter & Gamble made a one-time \$5.6 million payment to the Company. In the first quarter of 2004, in connection with its decision to forego its right to jointly develop the IL-1 Trap, Novartis made a one-time \$42.75 million payment to Regeneron to satisfy certain funding obligations under their collaboration agreement.

Investment income increased in the third quarter and first nine months of 2005 compared with the same periods of 2004 due primarily to higher effective interest rates on investment securities. Interest expense was unchanged in the third quarters of 2005 and 2004, and decreased slightly for the first nine months of 2005 compared with the same period in 2004. 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. The weighted average number of shares outstanding was 55.9 million shares (basic and diluted) for the first nine months of 2005 and 55.4 million shares (basic) and 56.3 million shares (diluted) for the first nine months of 2004.

#### **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 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, 2004 and Form 10-Q for the quarter ended June 30, 2005. 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.

This news release includes certain financial measures that are calculated in a manner different from generally accepted accounting principles (GAAP) and are considered non-GAAP financial measures under SEC rules. Non-GAAP financial measures for the nine months ended September 30, 2005 included in this news release are: (1) pro forma net loss and pro forma net loss per share (basic and diluted), exclusive of Stock Option Expense and (2) research and development expenses, general and administrative expenses, and contract manufacturing expenses, all exclusive of Stock Option Expense. As required, we have provided reconciliations of non-GAAP amounts to GAAP amounts in tables shown above. Additional required information is located in the Form 8-K filed with the SEC in connection with this news release.

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

	September 30, 2005	December 31, 2004
ASSETS		
Cash and marketable securities	\$ 333,562	\$ 348,912
Receivables	10,536	43,102
Inventory	2,837	3,229
Property, plant and equipment, net	64,044	71,239
Other assets	8,296	6,626
Total assets	<u>\$ 419,275</u>	\$ 473,108
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable and accrued expenses	\$ 20,599	\$ 18,872
Deferred revenue	62,295	71,693
Notes payable	200,000	200,000
Stockholders' equity	136,381	182,543
Total liabilities and stockholders' equity	<u>\$ 419,275</u>	\$ 473,108
12		

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

		For the three months ended September 30,		For the nine months ended September 30,	
	2005	2004	2005	2004	
Revenues					
Contract research and development	\$ 11,533	\$ 25,621	\$ 38,580	\$ 94,377	
Research progress payments				17,770	
Contract manufacturing	<u>4,661</u>	10,898	10,189	14,780	
	16,194	36,519	48,769	126,927	
Expenses					
Research and development	41,116	32,828	117,670	101,306	
Contract manufacturing	3,246	8,986	7,412	11,740	
General and administrative	6,219	4,184	18,581	12,209	
	50,581	45,998	143,663	125,255	
Income (loss) from operations	(34,387)	(9,479)	(94,894)	1,672	
Other income (expense)					
Other contract income			30.640	42,750	
Investment income	2,746	1,417	7,515	3,646	
Interest expense	(3,011)	(3,014)	(9,035)	(9,161)	
	(265)	(1,597)	29,120	37,235	
Net income (loss)	(\$34,652)	(\$11,076)	(\$65,774)	\$ 38,907	
Net income (loss) per share:					
Basic	(\$0.62)	(\$0.20)	(\$1.18)	\$ 0.70	
Diluted	(\$0.62)	(\$0.20)	(\$1.18)	\$ 0.69	
Weighted average shares outstanding:					
Basic	55,978	55,468	55,903	55,378	
Diluted	55,978	55,468	55,903	56,295	