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): September 26, 2005 (September 20, 2005)

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

<u>New York</u> (State or other jurisdiction of incorporation) <u>000-19034</u> (Commission File Number) <u>133444607</u> (I.R.S. Employer Identification Number)

777 Old Saw Mill River Road, Tarrytown, New York (Address of principal executive offices) <u>10591-6707</u> (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 2.05 Costs Associated with Exit or Disposal Activities

On September 20, 2005, the Company's Board of Directors approved a reduction in Company headcount from 730 to approximately 565. The workforce reduction results from plans to narrow the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, the recent expiration of the Company's collaboration with The Procter & Gamble Company, and the expected completion of contract manufacturing for Merck & Co, Inc. in late 2006. The majority of the headcount reduction will occur by the end of 2005, with the remainder planned for 2006 following the completion of the Company's contract manufacturing activities for Merck. In connection with the workforce reduction, the Company estimates that it will incur between \$2.5 million and \$3.5 million of severance and related costs, the substantial majority of which will be cash expenditures. The Company expects to incur the majority of these costs in the fourth quarter of 2005 and the remainder in 2006.

Item 7.01 Regulation FD Disclosure

On September 26, 2005, the Company issued a press release announcing plans to expand the VEGF Trap oncology program and updating its development pipeline and financial guidance. The press release is included as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits

99.1 Press Release of Regeneron Pharmaceuticals, Inc. dated September 26, 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: September 26, 2005

By: /s/ Stuart Kolinski Stuart Kolinski

Vice President and General Counsel

Exhibit Index

Description Press Release of Regeneron Pharmaceuticals, Inc. dated September 26, 2005. <u>Number</u> 99.1

REGENERON

REGENERON PHARMACEUTICALS, INC. 777 OLD SAW MILL RIVER ROAD TARRYTOWN, NY 10591 TELEPHONE: 914-345-7400 FAX: 914-345-7797

VEGF TRAP ONCOLOGY PROGRAM WITH SANOFI-AVENTIS PLANNED TO EXPAND RAPIDLY

Regeneron Updates Clinical Programs and Financial Guidance

September 26, 2005 (Tarrytown, NY) – Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today described plans with the sanofi-aventis Group to expand the VEGF Trap oncology program and provided an update of its development pipeline and financial guidance. Leonard S. Schleifer, M.D., Ph.D., chief executive officer and president of Regeneron, will discuss the Company's plans at the UBS Global Life Sciences Conference on Tuesday, September 27 at 12:00 PM (EDT). The presentation will be webcast live in the investor relations section of the Company's website (www.regeneron.com) and be available at that link through October 26, 2005.

VEGF Trap Program in Oncology

Regeneron and sanofi-aventis, who are collaborating in the development and commercialization of the Vascular Endothelial Growth Factor (VEGF) Trap in oncology, are expanding the VEGF Trap development program. The companies plan to initiate up to six new efficacy/safety trials, 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 designed as single-agent trials that will

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be conducted in a variety of indications, including one that has already received fast track designation from the U.S. Food and Drug Administration (FDA). 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 are ongoing, and three 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.

VEGF Trap Program in Eye Disease

Regeneron is developing the VEGF Trap for the treatment of the neovascular form of age-related macular degeneration (wet AMD) utilizing intravitreal (or direct) injection into the eye. A Phase 1 dose-escalating study to assess the safety and tolerability of the VEGF Trap commenced in June 2005. Regeneron could initiate a Phase 2 trial in this indication as early as late 2005 or early 2006. Preclinical data, clinical trial results from the Company's intravenous (systemic delivery) VEGF Trap Phase 1 trial in wet AMD, and clinical results from other molecules that target VEGF provide a strong rationale for this program. There are approximately 1.6 million people in the United States who are affected by wet AMD.

IL-1 Trap Development Program

Regeneron's Interleukin (IL-1) Trap program is directed towards diseases where IL-1 may play an important role. In the fourth quarter of 2004, the Company

initiated a pilot study of the IL-1 Trap in patients with *CIAS1*-associated periodic syndrome (CAPS), a spectrum of rare genetic diseases. Preliminary clinical data from this study have been encouraging. Regeneron is currently in discussions with the FDA to finalize the design of a pivotal registration study, which is planned to begin in the fourth quarter of 2005.

In the fourth quarter of 2005, Regeneron plans to initiate a pilot study in systemic onset juvenile idiopathic arthritis (SoJIA), a disease in which IL-1 is believed to play an important role. It is estimated that between 5,000-10,000 children in the United States suffer from SoJIA, which continues to be a disease with a major unmet medical need.

The Company has also initiated pilot studies in osteoarthritis (OA) and polymyalgia rheumatica (PMR). In addition, at the American Heart Association Scientific Sessions meeting in November 2005, the Company will report positive preliminary data from a pilot study indicating that the IL-1 Trap provided prolonged suppression of C-reactive Protein (CRP), a marker of inflammation, in otherwise healthy adults.

Regeneron has discontinued development of the IL-1 Trap in adult rheumatoid arthritis. The increasing number of treatments approved or in development for adult rheumatoid arthritis makes development and commercialization of new treatments for this disease extremely challenging.

Updated Financial Guidance

Regeneron expects to end 2005 with \$285 — \$295 million of cash and marketable securities and believes that, based on current plans, it has sufficient funds to operate through mid-2008. Sanofi-aventis funds 100 percent of VEGF Trap oncology development costs, of which 50 percent are repayable to sanofi-aventis following commercialization of the VEGF Trap. Regeneron currently funds the VEGF Trap eye program, and will seek to partner this program prior to initiating

Phase 3 development.

Regeneron plans to reduce its workforce from the current level of 730 to approximately 565. The reductions result principally from narrowing the focus of the Company's research and development efforts, substantial improvements in manufacturing productivity, and the expected completion of contract manufacturing for Merck & Co., Inc. in late 2006. The majority of this reduction will occur by the end of 2005 with the remainder in 2006 following the completion of contract manufacturing.

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 drugs and biologics, determinations by regulatory and administrative governmental authorities, competitive factors, technological developments, unanticipated expenses, 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 (SEC), including its Form 10-K for the year ended December 31, 2004 and the Form 10-Q dated 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.

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Contact Information:	
Investors:	Media:
Charles Poole	Lauren Tortorete
Vice President, Investor Relations	Media Relations
(914) 345-7640	(212) 845-5609
charles.poole@regeneron.com	ltortorete@biosector2.com
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Additional information about Regeneron and recent news releases are available on Regeneron's worldwide web site at <u>www.regeneron.com</u>

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