# 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 Exchange Act of 1934

Date of Report (Date of earliest event reported): May 13, 2010 (May 12, 2010)

# REGENERON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

	New York	000-19034	13-3444607
	(State or other jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)
	777	Old Saw Mill River Road, Tarrytown, New York 10591-6	707
		(Address of principal executive offices, including zip code)	
		(914) 347-7000	
		(Registrant's telephone number, including area code)	
	neck the appropriate box below if the Form 8-K ovisions:	filing is intended to simultaneously satisfy the filing oblig	ation of the registrant under any of the following
C	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)		
С	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)		
C	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))		

c Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

# **Item 8.01** Other Events.

On May 12, 2010, Regeneron Pharmaceuticals, Inc. issued a press release reporting preliminary clinical trial results for two antibody product candidates in development, REGN727, a fully human antibody that targets Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9), and REGN475, a fully human antibody that targets nerve growth factor (NGF). A copy of this press release is filed as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

# **Item 9.01** Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated May 12, 2010.

# SIGNATURES

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.

Date: May 13, 2010 REGENERON PHARMACEUTICALS, INC.

By: <u>/s/ Stuart Kolinski</u> Name: Stuart Kolinski

Title: Senior Vice President and General Counsel

Exhibit No. Description

99.1 Press Release dated May 12, 2010.



### **FOR IMMEDIATE RELEASE**

**Press Release** 

# **Regeneron Provides Initial Data on Two Antibody Product Candidates**

More corporate and clinical updates to be provided during company's first Investor Day on July 15, 2010

**Tarrytown, New York (May 12, 2010)** -- Regeneron Pharmaceuticals, Inc. (Nasdaq: **REGN**) today provided an update on two antibody product candidates in its pipeline and scheduled its first Investor Day to be held in New York City on July 15, 2010. Both product candidates, REGN727 (SAR236553) and, REGN475 (SAR164877) are being developed with sanofi-aventis under a global, strategic collaboration to discover, develop, and commercialize fully human antibodies.

### REGN727 (Anti-PCSK9)

REGN727 is a fully human antibody that targets Proprotein Convertase Subtilisin/Kexin type 9 (PCSK9), a naturally-occurring molecule involved in regulating cholesterol levels by modulating low-density lipoprotein (LDL) cholesterol receptors. In an interim efficacy analysis of a dose-escalating, randomized, double-blind, placebo-controlled, Phase 1 trial in healthy volunteers, REGN727 achieved substantial, dose dependent decreases of LDL (bad) cholesterol. The trial is ongoing with both intravenous and subcutaneous routes of administration being studied. At the highest dose tested to date, there was a highly significant lowering of mean LDL cholesterol that lasted for more than one month following a single dose, with a maximum mean reduction of more than 60%. There have been no serious adverse events and no dose limiting toxicities observed. Dose escalation is ongoing. Additional data will be presented at an upcoming Investor Day event.

### REGN475 (Anti-NGF)

REGN475 is a fully human antibody that selectively targets nerve growth factor (NGF), a naturally-occurring molecule demonstrated to modulate pain. In an interim efficacy analysis of a randomized, double-blind, four-arm, placebo-controlled Phase 2 trial, in 217 patients with osteoarthritis of the knee, REGN475 demonstrated significant improvements at the two highest doses tested as compared to placebo in average walking pain scores over 8 weeks following a single intravenous infusion (p<0.01). Pain was measured by the Numeric Rating Scale (NRS), as well as the Western Ontario and McMaster Osteoarthritis Index (WOMAC) pain and function subscales.

The primary endpoint of this study is safety, and REGN475 was generally well tolerated. Serious treatment emergent adverse events were rare and balanced between placebo and drug arms with three events (5.5%) in the placebo group and four events (2.5%) in the combined REGN475 groups. The most frequent adverse events reported among patients receiving REGN475 included sensory abnormalities, arthralgias, hyper/hypo-reflexia, peripheral edema, and injection site reactions. The types and frequencies of adverse events reported were similar to those previously reported from other investigational studies involving an anti-NGF antibody. Additional data, which will include results following a second infusion at week 8, will be presented at an upcoming Investor Day event.

Preliminary analysis of interim efficacy data from a Phase 2 trial of REGN 475 in the acute setting of nerve root compression induced pain (acute sciatica) suggests that REGN475 therapy will not be effective in this setting.

"We are extremely pleased by the productivity of our antibody collaboration with sanofi-aventis, and the progress of the NGF and PCSK9 antibodies, in particular," said Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer. "The collaboration is not yet three years old, and we have been able to advance five antibodies into the clinic, highlighting the power of our *VelocImmune*® technology. Both REGN727 and REGN475 are being developed to address areas of high unmet medical need and represent important new additions to our clinical pipeline."

Regeneron will provide additional corporate and clinical updates at its first Investor Day in New York City on July 15.

### **About REGN727 (Anti-PCSK9)**

Coronary artery disease (CAD) remains the leading cause of death in the U.S. for both men and women and is a leading cause of death across the developed world. LDL cholesterol levels in the blood have been shown to correlate with coronary artery disease risk, and lowering LDL has been proven to reduce the risk of cardiac events, such as death and heart attacks, in patients with CAD. However, despite the relatively wide use of LDL cholesterol-lowering therapies, including the statin class of agents, coronary artery disease remains a leading cause of morbidity and mortality. REGN727 is a fully human monoclonal antibody intended to robustly lower LDL cholesterol through a novel mechanism of action. REGN727 is targeted at inhibiting PCSK9, which results in prevention of the degradation of LDL receptors in the liver and facilitates LDL clearance from the systemic circulation, thereby lowering LDL levels in the blood.

### About REGN475 (Anti-NGF)

Despite the availability of several classes of pain relievers, millions of Americans continue to suffer from moderate to severe pain due to a variety of medical disorders (e.g., osteoarthritis, cancer, inflammation, neuropathic diseases, etc.). In addition to inadequate pain relief, patients may be exposed to the adverse effects of various pain medications, including gastrointestinal distress and bleeding, renal effects, interference with control of high blood pressure by antihypertensive agents, change in cognition, and constipation. REGN475 is a fully human monoclonal antibody against NGF (nerve growth factor), which is designed to block pain sensitization in neurons. The efficacy and safety of REGN475 are being evaluated in several Phase 2 studies in short-term pain settings, as well in the treatment of moderate to severe pain caused by osteoarthritis.

#### **About Regeneron Pharmaceuticals**

Regeneron is a fully integrated biopharmaceutical company that discovers, develops, and commercializes medicines for the treatment of serious medical conditions. In addition to ARCALYST® (rilonacept) Injection for Subcutaneous Use, its first commercialized product, Regeneron has therapeutic candidates in Phase 3 clinical trials for the potential treatment of gout, diseases of the eye (wet age-related macular degeneration and central retinal vein occlusion), and certain cancers. Additional therapeutic candidates are in earlier stage development programs in rheumatoid arthritis and other inflammatory conditions, pain, cholesterol reduction, allergic and immune conditions, and cancer. Additional information about Regeneron and recent news releases are available on Regeneron's web site at www.regeneron.com.

### Forward Looking Statement

This news release discusses historical information and includes forward-looking statements about Regeneron and its products, development programs, finances, and business, all of which involve a number of risks and uncertainties. These include, among others, risks and timing associated with preclinical and clinical development of Regeneron's drug candidates, determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize its product and drug candidates, competing drugs that are superior to Regeneron's product and drug candidates (a number of other companies are developing product candidates targeting PCSK9 and NGF and we expect these areas to be highly competitive), uncertainty of market acceptance of Regeneron's product and drug candidates, unanticipated expenses, the availability and cost of capital, the costs of developing, producing, and selling products, the potential for any collaboration agreement, including Regeneron's agreements with the sanofi-aventis Group and Bayer HealthCare, to be canceled or terminated without any product success, and risks associated with third party intellectual property. 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, 2009 and Form 10-Q for the quarter ended March 31, 2010. 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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