

REGENERON PHARMACEUTICALS INC

Form 8-K

November 22, 2010

**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): November 22, 2010 (November 16, 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 10591-6707

(Address of principal executive offices, including 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 the 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 1.02 Termination of a Material Definitive Agreement.

On February 5, 2007, Regeneron Pharmaceuticals, Inc. entered into a six-year, non-exclusive license agreement with AstraZeneca UK Limited to allow AstraZeneca to utilize Regeneron's VelocImmune® technology in its internal research programs to discover human monoclonal antibodies. Under the terms of this agreement, AstraZeneca made \$20 million annual, non-refundable payments to Regeneron in the first quarter of 2007, 2008, 2009, and 2010. AstraZeneca had the right to terminate the agreement prior to making the final two \$20 million annual payments. On November 16, 2010, MedImmune Limited (as successor by novation from AstraZeneca UK Limited) gave written notice to voluntarily terminate the agreement, effective ninety days after such notice. Regeneron remains entitled to receive mid-single digit royalties on any future sales of antibody products discovered by MedImmune/AstraZeneca using the VelocImmune® technology.

Item 8.01 Other Events.

(a) On November 22, 2010, Regeneron Pharmaceuticals, Inc. and Bayer HealthCare issued a press release announcing that in two parallel Phase 3 studies (VIEW 1 and VIEW 2) in patients with the neovascular form of age-related macular degeneration (wet AMD), all regimens of VEGF Trap-Eye (aflibercept ophthalmic solution), including VEGF Trap-Eye dosed every two months, successfully met the primary endpoint compared to the current standard of care, ranibizumab dosed every month. The primary endpoint of the studies was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. Bayer and Regeneron plan to submit regulatory applications for marketing approval in Europe and the U.S. in the first-half of 2011 based on the positive results of the two Phase 3 studies.

In the VIEW 1 study, patients receiving VEGF Trap-Eye 2mg monthly achieved a statistically significantly greater mean improvement in visual acuity at week 52 versus baseline (secondary endpoint), compared to ranibizumab 0.5 monthly. All other dose groups of VEGF Trap-Eye in the VIEW 1 and all dose groups in the VIEW 2 studies, including the 2mg every two months group, were not statistically significantly different from ranibizumab in mean improvement in visual acuity in this secondary endpoint.

A generally favorable safety profile was observed for both VEGF Trap-Eye and ranibizumab. The incidence of ocular treatment emergent adverse events was balanced across all four treatment groups in both studies and there were no notable differences in serious non-ocular events among the study arms.

The foregoing description of the press release and the results of the VIEW 1 and VIEW 2 studies is not intended to be complete and is qualified in its entirety by the complete press release attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item.

(b) On November 19, 2010, Regeneron filed a complaint against Genentech, Inc. in the United States District Court for the Southern District of New York seeking a declaratory judgment that activities relating to its VEGF Trap do not infringe any valid claim of U.S. Patent Nos. 5,952,199, 6,100,071, 6,383,486, 6,897,294, and 7,771,721.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release Reporting Positive Top-Line Results of Two Phase 3 Studies With VEGF Trap-Eye in Wet Age-related Macular Degeneration dated November 22, 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: November 22, 2010

REGENERON PHARMACEUTICALS, INC.

By: /s/ Stuart Kolinski

Name: Stuart Kolinski

Title: Senior Vice President and General
Counsel

Exhibit Index

| Number | Description |
|--------|--|
| 99.1 | Press Release Reporting Positive Top-Line Results of Two Phase 3 Studies With VEGF Trap-Eye in Wet Age-related Macular Degeneration dated November 22, 2010. |