

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): December 20, 2010 (December 20, 2010)

REGENERON PHARMACEUTICALS, INC.  
(Exact Name of Registrant as Specified in Charter)

New York

(State or other jurisdiction of  
Incorporation)

000-19034

(Commission File No.)

13-3444607

(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 8.01 Other Events.**

On December 20, 2010, Regeneron Pharmaceuticals, Inc. (“Regeneron”) and Bayer HealthCare issued a press release announcing results for VEGF Trap-Eye (aflibercept ophthalmic solution) in a Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in a Phase 2 Study in Diabetic Macular Edema (DME).

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and incorporated by reference into this Item. As noted during our investor teleconference on December 20, 2010, the attached press release inadvertently omitted certain information, which Regeneron does not consider to be material. To reflect inclusion of such omitted information, the sentence that reads “VEGF Trap-Eye was generally well-tolerated, and there were no ocular or non-ocular drug-related serious adverse events reported in the study” would be replaced with the following “In this study, VEGF Trap-Eye was generally well-tolerated and no patients experienced ocular drug-related serious adverse events. With respect to the number of patients with non-ocular serious adverse events judged by investigators to be drug-related, there were none during the first six months of the study and one in the second six months.”

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

99.1 Press Release Reporting Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME) dated December 20, 2010.

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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: December 20, 2010

REGENERON PHARMACEUTICALS, INC.

By: /s/ Murray A. Goldberg

Name: Murray A. Goldberg

Title: Senior Vice President, Finance and  
Administration, Chief Financial Officer, Treasurer,  
and Assistant Secretary

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Exhibit Index

Number	Description
99.1	Press Release Reporting Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME) dated December 20, 2010.

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## For Immediate Release

### Press Release

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## **Regeneron and Bayer Report Positive Results for VEGF Trap-Eye in Phase 3 Study in Central Retinal Vein Occlusion (CRVO) and in Phase 2 Study in Diabetic Macular Edema (DME)**

*In Phase 3 study in CRVO, 56 percent of VEGF Trap-Eye patients gained at least 15 letters of vision compared to 12 percent in control group; VEGF Trap-Eye patients on average gained 17 letters of vision compared to mean loss of 4 letters in control group*

*In Phase 2 study in DME, patients in all VEGF Trap-Eye dose groups, including VEGF Trap-Eye dosed every two months, maintained or increased vision gains through 52-weeks*

*Regeneron to receive \$20 million in milestone payments in connection with VEGF Trap-Eye program*

**Tarrytown, NY, USA, and Berlin, Germany, December 20, 2010** -- Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) and Bayer HealthCare today announced positive top-line results for VEGF Trap-Eye (aflibercept ophthalmic solution) in the COPERNICUS study, which is led by Regeneron, the first of two Phase 3 studies in patients with macular edema due to central retinal vein occlusion (CRVO). In this trial, 56.1 percent of patients receiving VEGF Trap-Eye 2 milligrams (mg) monthly gained at least 15 letters of vision from baseline, compared to 12.3 percent of patients receiving sham injections ( $p < 0.0001$ ), the primary endpoint of the study. Patients receiving VEGF Trap-Eye 2mg monthly gained, on average, 17.3 letters of vision compared to a mean loss of 4.0 letters with sham injections ( $p < 0.001$ ), a secondary endpoint. The second Phase 3 study, GALILEO, is currently ongoing and is led by Bayer HealthCare.

VEGF Trap-Eye was generally well tolerated and the most common adverse events were those typically associated with intravitreal injections or the underlying disease. A total of 114 patients were randomized to receive VEGF Trap-Eye and 73 patients to the control arm. Serious ocular adverse events in the VEGF Trap-Eye group were uncommon (3.5%) and were more frequent in the control group (13.5%). The incidence of non-ocular serious adverse events was generally well-balanced between the treatment arms. There were no deaths among the 114 patients treated with VEGF Trap-Eye and two in the 73 (2.7%) patients treated with sham injections.

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“In the COPERNICUS trial, patients treated with VEGF Trap-Eye experienced a marked improvement in vision,” said George D. Yancopoulos, M.D., Ph.D., President of Regeneron Research Laboratories. “If these results are confirmed by data from the GALILEO study, expected in the second quarter of 2011, VEGF Trap-Eye could provide patients and physicians with a new treatment option for central retinal vein occlusion.”

“After reporting positive results from our global Phase 3 program (VIEW 1 and VIEW 2 studies) for the treatment of the neovascular form of age related macular degeneration (wet AMD), we are pleased to also have a positive Phase 3 trial with VEGF Trap-Eye in central retinal vein occlusion, a potential second indication,” said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. “We are working diligently with Regeneron to prepare regulatory filings for VEGF Trap-Eye in wet AMD to submit in the first half of 2011.”

Detailed results for COPERNICUS will be presented at the Angiogenesis Conference in Miami, Florida in February 2011.

Regeneron will receive a \$10 million milestone payment from Bayer HealthCare in connection with the COPERNICUS trial meeting its primary endpoint and received a \$10 million milestone payment in December 2010 for the positive VIEW 1 and VIEW 2 trial results in wet AMD.

#### **Phase 2 DME Results**

Regeneron and Bayer HealthCare also reported 52 week follow-up results from the Phase 2 DA VINCI study in patients with diabetic macular edema (DME). In this study, the previously reported visual acuity gains achieved with VEGF Trap-Eye treatment over 24 weeks (the primary endpoint of the study) were maintained or numerically improved up to completion of the study at week 52 in all VEGF Trap-Eye study groups, including 2mg dosed every other month. Based on these positive results, Regeneron and Bayer HealthCare are discussing plans to initiate Phase 3 studies.

In this double-masked, prospective, randomized, multi-center Phase 2 trial, entitled **DA VINCI (DME And VEGF Trap-Eye: INvestigation of Clinical Impact)**, 221 patients with clinically significant DME with central macular involvement were randomized and 219 patients were treated with balanced distribution over five groups. The control group received macular laser therapy at baseline, and patients were eligible for repeat laser treatments, but no more frequently than at 16 week intervals. Two groups received monthly doses of 0.5 or 2mg of VEGF Trap-Eye throughout the 12-month dosing period. Two groups received three initial monthly doses of 2mg of VEGF Trap-Eye (at baseline and weeks 4 and 8), followed through week 52 by either every two months dosing or PRN (as-needed) dosing with very strict repeat dosing criteria. Mean gains in visual acuity versus baseline were as follows:

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	Laser	0.5mg monthly	2mg monthly	2mg every two months*	2mg PRN*
n	44	44	44	42	45
Mean change in visual acuity at week 24 versus baseline <sup>1</sup> (letters)	2.5	8.6**	11.4**	8.5**	10.3**
Mean change in visual acuity at week 52 versus baseline (letters)	-1.3	11.0**	13.1**	9.7**	12.0**

\*Following 3 initial monthly doses

\*\*p<0.01 versus laser

<sup>1</sup> Primary endpoint

No significant differences among the VEGF Trap-Eye arms were observed. Approximately 80 percent of the VEGF Trap-Eye patients and 75 percent of the laser patients remained in the study through 52 weeks.

VEGF Trap-Eye was generally well-tolerated, and there were no ocular or non-ocular drug-related serious adverse events reported in the study. The most common adverse events reported were those typically associated with intravitreal injections or the underlying disease. The most frequent ocular adverse events reported among patients receiving VEGF Trap-Eye included conjunctival hemorrhage, eye pain, ocular redness (hyperemia), and increased intraocular pressure. The incidence of non-ocular serious adverse events was generally well balanced between all treatment arms. There were six deaths (3.4%) among the 175 patients treated with VEGF Trap-Eye and one (2.3%) in the 44 patients treated with laser over 12 months.

Detailed results for DA VINCI will be presented at the Angiogenesis Conference in Miami, Florida in February 2011.

### About the Phase 3 CRVO Program

Patients in the COPERNICUS (Controlled Phase 3 Evaluation of Repeated intravitreal administration of VEGF Trap-Eye In Central retinal vein occlusion: Utility and Safety) and the identical GALILEO (General Assessment Limiting Infiltration of Exudates in central retinal vein Occlusion with VEGF Trap-Eye) studies receive six monthly injections of either VEGF Trap-Eye at a dose of 2mg or sham injections. Patients in the COPERNICUS trial were randomized in a 3:2 ratio with 114 patients randomized to receive VEGF Trap-Eye and 73 randomized to the control arm. At the end of the initial six months, all patients randomized to VEGF Trap-Eye are dosed on a PRN (as needed) basis for another six months. In the COPERNICUS trial, patients randomized to sham injections in the first six months are eligible to cross over to VEGF Trap-Eye PRN dosing in the second six months. During the second six months of the studies, all patients are eligible for rescue laser treatment. Visual acuity was measured as a score based on the total number of letters read correctly on the Early Treatment Diabetic Retinopathy Study (ETDRS) eye chart, a standard chart used in research to measure visual acuity.

**About Central Retinal Vein Occlusion (CRVO)**

Over 100,000 people in the United States and more than 66,000 people in key European countries are estimated to suffer from CRVO. CRVO is caused by obstruction of the central retinal vein that leads to a back up of blood and fluid in the retina. This causes retinal injury and loss of vision. The retina can also become "ischemic" (starved for oxygen), resulting in the growth of new, inappropriate blood vessels that can cause further vision loss and more serious complications. Release of vascular endothelial growth factor (VEGF) contributes to increased vascular permeability in the eye and inappropriate new vessel growth. It is believed that anti-VEGF treatment may help decrease vascular permeability and edema and prevent the inappropriate growth of new blood vessels in the retina in patients with CRVO.

**About Diabetic Macular Edema (DME)**

DME is the most prevalent cause of moderate vision loss in patients with diabetes. DME is a common complication of Diabetic Retinopathy (DR), a disease affecting the blood vessels of the retina. Clinically significant DME is a leading cause of blindness in younger adults (under 50). Clinically significant DME occurs when fluid leaks into the center of the macula, the light-sensitive part of the retina responsible for sharp, direct vision. Fluid in the macula can cause severe vision loss or blindness.

Approximately 370,000 Americans currently suffer from clinically significant DME, with 95,000 new cases arising each year. According to the American Diabetes Association, more than 18 million Americans currently suffer from diabetes, and many other people are at risk for developing diabetes. With the incidence of diabetes steadily climbing, it is projected that up to 10 percent of all patients with diabetes will develop DME during their lifetime.

**About VEGF Trap-Eye**

VEGF Trap-Eye is a fully human fusion protein, consisting of soluble VEGF receptors 1 and 2, that binds all forms of VEGF-A along with the related Placental Growth Factor (PlGF). VEGF Trap-Eye is a specific and highly potent blocker of these growth factors. VEGF Trap-Eye is specially purified and contains iso-osmotic buffer concentrations, allowing for injection into the eye.

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Regeneron and Bayer HealthCare are collaborating on the global development of VEGF Trap-Eye for the treatment of the neovascular form of age related macular degeneration (wet AMD), diabetic macular edema (DME), central retinal vein occlusion (CRVO), and other eye diseases and disorders. In November 2010, Regeneron and Bayer HealthCare announced positive top-line results from two parallel Phase 3 studies in patients with wet AMD, VIEW 1 and VIEW 2. In these trials, all regimens of VEGF Trap-Eye, 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 was statistical non-inferiority in the proportion of patients who maintained (or improved) vision over 52 weeks compared to ranibizumab. 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. There were no notable differences in non-ocular adverse events among the study arms. Bayer HealthCare and Regeneron are planning to submit regulatory applications for marketing approval for the treatment of wet AMD in Europe and the U.S. in the first-half of 2011.

Bayer HealthCare will market VEGF Trap-Eye outside the United States, where the companies will share equally in profits from any future sales of VEGF Trap-Eye. Regeneron maintains exclusive rights to VEGF Trap-Eye in the United States.

#### **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 developed from proprietary Regeneron technologies for creating fully human monoclonal antibodies 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](http://www.regeneron.com).

#### **About Bayer HealthCare**

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of more than EUR 15.9 billion (2009), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 53,400 employees and is represented in more than 100 countries. Find more information at [www.bayerhealthcare.com](http://www.bayerhealthcare.com).

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### **Regeneron Forward Looking Statement**

This news release 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, 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 license or collaboration agreement, including Regeneron's agreements with Astellas, 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 September 30, 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.

### **Bayer Forward-Looking Statements**

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at [www.bayer.com](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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