

REGENERON PHARMACEUTICALS INC
Form 8-K
February 13, 2012

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): February 13, 2012 (February 13, 2012)

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) 847-7000
(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 2.02 Results of Operations and Financial Condition.

On February 13, 2012, Regeneron Pharmaceuticals, Inc. issued a press release announcing its financial and operating results for the quarter and year ended December 31, 2011. The press release is being furnished to the Securities and Exchange Commission pursuant to Item 2.02 of Form 8-K and is attached as Exhibit 99.1 to this Form 8-K.

Item 7.01 Regulation FD Disclosure.

On February 13, 2012, Regeneron Pharmaceuticals Inc. (Company) provided the U.S. Food and Drug Administration (FDA) with information relating to adverse events reported to the Company for EYLEA® (aflibercept) Injection since the drug became commercially available in November, 2011. Among other things, the Company reported that since launch approximately 30,000 injections have been administered in the United States, and the Company has received reports of sterile intraocular inflammation following the administration of EYLEA at a rate of approximately 0.05% per injection. This rate was driven primarily by a cluster of events occurring at a single practice with the overall rate, excluding this practice, being approximately 0.01% per injection. The incidence of adverse events of intraocular inflammation reported thus far during commercial use of EYLEA is within the reported incidence in the literature with the intravitreal injection of anti-VEGF agents and other drugs as well as the rate observed during the clinical development program, even accounting for the possibility of underreporting. In addition, the lack of association of these adverse events with a single lot of drug product further led the Company to conclude that factors other than the drug are likely to be responsible for the occurrence of these events. The full letter to the FDA is furnished with this Current Report as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release dated February 13, 2012.

99.2 Letter to the FDA dated February 13, 2012.

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: February 13, 2012

REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa
Name: Joseph J. LaRosa
Title: Senior Vice President, General Counsel and
Secretary

Exhibit Index

| Number | Description |
|--------|--|
| 99.1 | Press Release dated February 13, 2012. |
| 99.2 | Letter to the FDA dated February 13, 2012. |
