

REGENERON PHARMACEUTICALS INC
Form 8-K
December 21, 2011

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 21, 2011 (December 19, 2011)

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 7.01 Regulation FD Disclosure.

Regeneron was informed by Sanofi that on December 19, 2011, Sanofi voluntarily withdrew, and plans to re-submit in early 2012, the Biologics License Application (BLA) it submitted to the U.S. Food and Drug Administration (FDA) for marketing approval of ZALTRAP® (aflibercept) in previously treated metastatic colorectal cancer. The withdrawal was based upon comments from the FDA on the Chemistry, Manufacturing and Controls section of the BLA for ZALTRAP®. ZALTRAP® is being developed in a worldwide collaboration by Regeneron and Sanofi.

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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 21, 2011

REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa

Name: Joseph J. LaRosa

Title: Senior Vice President, General Counsel and Secretary
