

REGENERON PHARMACEUTICALS INC

Form 8-K

May 20, 2013

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 20, 2013 (May 17, 2013)

REGENERON PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Charter)

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New York
(State or other jurisdiction of

000-19034
(Commission File No.)

13-3444607
(IRS Employer Identification No.)

Incorporation)

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))

Item 1.01. Entry Into a Material Definitive Agreement.

Regeneron Pharmaceuticals, Inc. (Regeneron) has entered into agreements with Genentech, Inc. (Genentech) relating to the worldwide sales of EYLEA® (aflibercept) Injection and ZALTRAP® (ziv-aflibercept) Injection for Intravenous Infusion (also known as aflibercept outside of the United States). These agreements resolve all pending litigation with Genentech over EYLEA and ZALTRAP worldwide.

EYLEA Agreement

Regeneron and Genentech entered into an Amended and Restated Non-Exclusive License and Settlement Agreement, effective as of May 17, 2013 (the Amended Agreement), which amended their Non-Exclusive License and Partial Settlement Agreement, dated December 31, 2011 (the Original Agreement), relating to the sales of EYLEA in the United States to now include all sales of EYLEA worldwide. Under the Amended Agreement, Regeneron received a worldwide non-exclusive license to certain patents relating to VEGF receptor proteins, known as the Davis-Smyth patents, and certain other patents, for the prevention or treatment of eye diseases and eye disorders in a human through administration of EYLEA to the eye (the ocular field). The Davis-Smyth patents are the subject of patent litigation between Regeneron and Genentech relating to EYLEA, now pending in the United States District Court, Southern District of New York, which will be dismissed pursuant to the Amended Agreement. Regeneron will make payments to Genentech based on sales of EYLEA in the United States and EYLEA manufactured in the United States and sold outside the United States through May 7, 2016 using the same milestone and royalty rates as in the Original Agreement. EYLEA is sold outside the United States by affiliates of Bayer HealthCare LLC under a license and collaboration agreement (the Bayer Agreement).

Under the Original Agreement, a \$60 million milestone payment was made when cumulative U.S. sales reached \$400 million, and Regeneron is obligated to pay royalties of 4.75% on cumulative relevant sales of EYLEA between \$400 million and \$3 billion and 5.5% on any cumulative relevant sales of EYLEA over \$3 billion. All payments to Genentech under the Original Agreement and the Amended Agreement are made by Regeneron. Bayer HealthCare will share in all such payments based on the proportion of ex-U.S. EYLEA sales to worldwide EYLEA sales and determined consistent with the Bayer Agreement.

ZALTRAP Agreement

Regeneron, Genentech, Sanofi U.S. Services, Inc. and Sanofi-Aventis U.S. LLC (the latter two entities, collectively, Sanofi) entered into a Non-Exclusive License and Settlement Agreement, effective as of May 17, 2013 (the Zaltrap Agreement), under which Regeneron and Sanofi (Regeneron's global marketing partner for ZALTRAP) received a worldwide non-exclusive license to the Davis-Smyth patents, and certain other patents, in all indications for human use other than the ocular field. The Davis-Smyth patents are the subject of patent litigation between Sanofi, Regeneron and Genentech relating to ZALTRAP now pending in the United States District Court, Southern District of New York, which will be dismissed pursuant to the ZALTRAP Agreement.

Under the terms of the ZALTRAP Agreement, Sanofi and Regeneron will make payments to Genentech based on sales of ZALTRAP in the United States and of ZALTRAP that is manufactured in the United States and sold outside the United States through May 7, 2016. Sanofi and Regeneron will pay \$19 million upon cumulative relevant sales of ZALTRAP reaching \$200 million. The companies will also pay royalties of 4.5% on cumulative relevant sales of ZALTRAP between \$400 million and \$1 billion and 6.5% on any cumulative relevant sales of ZALTRAP over \$1 billion.

Other Agreement

Separately, Regeneron, Regeneron UK Ltd, Bayer Pharma AG, Bayer Australia Limited and Genentech have entered into an agreement, dated as of May 17, 2013, agreeing to dismiss proceedings involving certain other Genentech patents, and granting Regeneron and the Bayer HealthCare affiliates certain covenants not to sue as to these and other patents.

The foregoing descriptions do not purport to be complete and are qualified in their entirety by reference to the full text of the applicable documents.

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 20, 2013

REGENERON PHARMACEUTICALS, INC.

By: /s/ Joseph J. LaRosa

Name: Joseph J. LaRosa

Title: Senior Vice President, General Counsel and Secretary