REGENERON PHARMACEUTICALS INC
Form 8-K
January 08, 2018

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): **January 8, 2018 (January 7, 2018)**

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction of incorporation)

000-19034	**13-3444607**
(Commission File Number)	(I.R.S. Employer Identification No.)
777 Old Saw Mill River Road, Tarrytown, New York	**10591-6707**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(914) 847-7000**

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 (see General Instructions A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Item 1.01. **Entry into a Material Definitive Agreement.**

On January 7, 2018, Regeneron Pharmaceuticals, Inc. (Regeneron or the Company) entered into a letter agreement (the Letter Agreement) relating to (a) the Amended and Restated Investor Agreement (the Investor Agreement), dated as of January 11, 2014, by and among the Company and Sanofi (Sanofi) and certain of Sanofi s direct and indirect subsidiaries (collectively with Sanofi, the Sanofi Parties); (b) the Immuno-oncology License and Collaboration Agreement (the IO LCA), dated as of July 1, 2015, by and between the Company and Sanofi Biotechnology SAS (Sanofi SAS); and (c) the Amended and Restated License and Collaboration Agreement (as amended, the Antibody LCA), dated as of November 10, 2009, by and among the Company, Sanofi SAS (as successor-in-interest to Aventis Pharmaceuticals Inc.) and sanofi-aventis Amérique du Nord. A summary description of the Letter Agreement and certain related changes to the Investor Agreement, the IO LCA and the Antibody LCA resulting therefrom is provided below.

Increase in REGN2810 Budget Amount. Under the terms of the IO LCA, the Company and Sanofi SAS are co-developing the Company s antibody product candidate cemiplimab (REGN2810) (REGN2810) targeting the receptor known as Programmed Cell Death protein 1, or PD-1, and share equally, on an ongoing basis, development costs for REGN2810 (REGN2810 Development Costs) up to a total development budget amount set forth in the IO LCA (the REGN2810 Budget Amount). Pursuant to the Letter Agreement, the parties have agreed to increase the REGN2810 Budget Amount to $1.640 billion, an increase of $990.0 million over the REGN2810 Budget Amount set forth in the original IO LCA.

Limited Waiver of Sanofi Lock-up. The Company has agreed to grant a limited waiver of the lock-up obligations under the Investor Agreement to allow (but not require) the Sanofi Parties to sell (a) up to an aggregate of 800,000 shares (subject to adjustment to account for any stock split, stock dividend, share exchange, merger, consolidation, or similar recapitalization by the Company) (such aggregate number of shares, the REGN2810 Shares) of the Company s common stock, par value $0.001 per share (Common Stock), held by the Sanofi Parties, in order to satisfy in whole or in part Sanofi SAS s funding obligations with respect to the REGN2810 Development Costs for each quarterly period commencing on October 1, 2017 and ending on September 30, 2020 (each, a REGN2810 Covered Period and, collectively, the REGN2810 Covered Periods); and (b) up to an aggregate of 600,000 shares (subject to adjustment to account for any stock split, stock dividend, share exchange, merger, consolidation, or similar recapitalization by the Company) (such aggregate number of shares, the Dupilumab/REGN3500 Eligible Investment Shares) of Common Stock held by the Sanofi Parties, in order to satisfy in whole or in part Sanofi SAS s funding obligations with respect to the costs (the Dupilumab/REGN3500 Eligible Investment Amounts) incurred by or on behalf of the parties to the Antibody LCA with respect to certain proposed activities relating to the development of dupilumab (an antibody to the interleukin-4 receptor (IL-4R) alpha subunit) (Dupilumab) and REGN3500 (an antibody to interleukin-33) (REGN3500) and non-approval trials of Dupilumab (collectively, the Dupilumab/REGN3500 Eligible Investments) for each quarterly period commencing on January 1, 2018 and ending on September 30, 2020 (each, a Dupilumab/REGN3500 Covered Period and, collectively, the Dupilumab/REGN3500 Covered Periods).

Funding Mechanics and Related Provisions. Under the terms of the Letter Agreement, within three trading days after (a) Sanofi SAS s receipt of the applicable invoice for its share of REGN2810 Development Costs for a REGN2810 Covered Period (the REGN2810 Development Cost Invoice) and/or (b) Regeneron s deemed receipt of the applicable statement setting forth Sanofi SAS s share of the Dupilumab/REGN3500 Eligible Investment Amounts for a Dupilumab/REGN3500 Covered Period (the Eligible Investment Statement), any of the Sanofi Parties may provide

notice (a REGN2810 Sale Notice or Dupilumab/REGN3500 Sale Notice, as applicable) to the Company indicating the dollar amount (the REGN2810 Sale Value or Dupilumab/REGN3500 Sale Value, as applicable) of such REGN2810 Development Cost Invoice or Eligible Investment Statement in respect of which such Sanofi Party (on behalf of itself and the other Sanofi Parties) may be willing (but is not obligated) to sell REGN2810 Shares or Dupilumab/REGN3500 Eligible Investment Shares, as applicable, to the Company or in the open market. Subject to the Sanofi Parties agreement to sell, Regeneron may elect to purchase such REGN2810 Shares or Dupilumab/REGN3500 Eligible Investment Shares (as applicable) at the applicable Measurement Price (as defined below) in an amount not to exceed the quotient (rounded down to the nearest whole number) of (x) the applicable REGN2810 Sale Value or Dupilumab/REGN3500 Sale Value and (y) the volume-weighted average price of a share of Common Stock on the NASDAQ on the second trading day after the Sanofi Parties send the applicable REGN2810 Sale Notice or Dupilumab/REGN3500 Sale Notice to Regeneron (the Measurement Price). If

Regeneron purchases REGN2810 Shares or Dupilumab/REGN3500 Eligible Investment Shares in an amount less than such quotient, the Sanofi Parties may sell, in one or more open-market transactions, the applicable number of REGN2810 Shares (if any) or Dupilumab/REGN3500 Eligible Investment Shares (if any) equal to such quotient less the applicable number of REGN2810 Shares or Dupilumab/REGN3500 Eligible Investment Shares purchased by Regeneron within six months of the due date of the applicable REGN2810 Development Cost Invoice or the date of the applicable Eligible Investment Statement, as applicable (subject to extension in certain circumstances) (the REGN2810 Sale Period or Dupilumab/REGN3500 Sale Period, as applicable). The Sanofi Parties may also sell the applicable number of REGN2810 Shares or Dupilumab/REGN3500 Eligible Investment Shares if Regeneron fails to respond to outreach by the Sanofi Parties to discuss the purchase of such REGN2810 Shares or Dupilumab/REGN3500 Eligible Investment Shares or none of the parties initiates an attempt to discuss such purchase in the time frame contemplated by the Letter Agreement. Sales by the Sanofi Parties may not exceed, in the aggregate, (i) on any trading day, 10% of the average daily trading volume of Common Stock on the NASDAQ over the immediately preceding 20 trading days or (ii) in any calendar quarter, 300,000 shares of Common Stock (subject to adjustment to account for any stock split, stock dividend, share exchange, merger, consolidation, or similar recapitalization by the Company).

Director Designation Right; Limited Waiver of Sanofi Parties Obligation to Maintain Highest Percentage Threshold. Under the terms of the Investor Agreement, the Sanofi Parties have a right to designate a director to serve on Regeneron s Board of Directors (the Director Designation Right) for so long as the Sanofi Parties maintain a specified minimum ownership percentage of the Company s then outstanding shares of Common Stock and Class A Stock, par value $0.001 per share (collectively, Capital Stock). Pursuant to the Letter Agreement, the Company and the Sanofi Parties have agreed that (a) effective August 26, 2017 and until the Termination Date (as defined below), the Sanofi Parties will not be required to maintain such ownership percentage in order to maintain the Director Designation Right and (b) effective as of the Termination Date, such minimum ownership percentage of Capital Stock will equal the lower of (i) 25% of the Capital Stock then outstanding and (ii) the higher of (x) the Sanofi Parties percentage ownership of Capital Stock on the Termination Date and (y) the highest percentage ownership of Capital Stock the Sanofi Parties attain following the Termination Date. The parties have also agreed to an extension of the first cure period afforded to the Sanofi Parties to maintain the applicable minimum ownership percentage following the Termination Date.

Term. The Letter Agreement will be in effect until the date that is the later of the last day of the REGN2810 Amendment Term and the last day of the Dupilumab/REGN3500 Amendment Term (each as defined below) (the Termination Date). Pursuant to the Letter Agreement, the REGN2810 Amendment Term means the period between the date of the Letter Agreement and the date when the earliest of the following occurs: (i) the date when the Sanofi Parties have disposed of all of the REGN2810 Shares; (ii) if a Sanofi Party does not submit a REGN2810 Sale Notice in respect of the REGN2810 Development Cost Invoice for the last REGN2810 Covered Period, the later of (x) the due date of such REGN2810 Development Cost Invoice and (y) the last day of any then-existing REGN2810 Sale Period; (iii) the end of the REGN2810 Sale Period relating to the last REGN2810 Covered Period in respect of which a Sanofi Party submits a REGN2810 Sale Notice; and (iv) the effective date of termination of the IO LCA pursuant to its terms. Pursuant to the Letter Agreement, the Dupilumab/REGN3500 Amendment Term means the period between the date of the Letter Agreement and the date when the earliest of the following occurs: (i) the date when the Sanofi Parties have disposed of all of the Dupilumab/REGN3500 Eligible Investment Shares; (ii) if a Sanofi Party does not submit a Dupilumab/REGN3500 Sale Notice in respect of the Eligible Investment Statement for the last Dupilumab/REGN3500 Covered Period, the last day of any then-existing Dupilumab/REGN3500 Sale Period; (iii) the end of the Dupilumab/REGN3500 Sale Period relating to the last Dupilumab/REGN3500 Covered Period in respect of which a Sanofi Party submits a Dupilumab/REGN3500 Sale Notice; and (iv) the effective date of termination of the Antibody LCA pursuant to its terms.

Other Amendments to the IO LCA. Pursuant to the Letter Agreement, the parties have also agreed to (a) revise the REGN2810 Global Development Plan and REGN2810 Global Development Budget (each as defined in the IO LCA) to reflect the increased REGN2810 Budget Amount and (b) provide for additional governance procedures, including (i) regularly scheduled meetings between representatives of the Company and Sanofi SAS to discuss any material proposed change to the REGN2810 Global Development Plan or the REGN2810 Global Development Budget prior to implementation and (ii) Regeneron s good faith consideration of Sanofi SAS s input and comments addressed during such meetings prior to any final implementation, with Regeneron retaining final decision-making authority with respect to the REGN2810 Global Development Plan, consistent with the purpose of the collaboration as set forth in the IO LCA and the REGN2810 Global Development Budget.

Other Amendments to the Antibody LCA. Pursuant to the Letter Agreement, the parties have also agreed to allocate additional funds (the Dupilumab/REGN3500 Eligible Investment Budget) to the Dupilumab/REGN3500 Eligible Investments and to spend a specified portion of the Dupilumab/REGN3500 Eligible Investment Budget on the Dupilumab/REGN3500 Eligible Investments, or such other activities as the parties may mutually agree, prior to the end of 2023. The amounts allocated to, and spent on, the development and commercialization of Dupilumab and REGN3500 pursuant to the Letter Agreement are in addition to, and not in lieu of, other amounts the parties may spend on development and commercialization activities for Dupilumab and REGN3500 pursuant to the terms of the Antibody LCA.

The foregoing description of the Letter Agreement is qualified in its entirety by reference to the full text of the Letter Agreement, a copy of which will be filed with the United States Securities and Exchange Commission as an exhibit to the Quarterly Report on Form 10-Q to be filed by Regeneron for the quarterly period ending March 31, 2018.

Item 2.02. Results of Operations and Financial Condition.

On January 8, 2018, at the 36th Annual J.P. Morgan Healthcare Conference in San Francisco, California (the 2018 J.P. Morgan Healthcare Conference), Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron, and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron, are providing a corporate update. Their presentation includes information regarding the Company s preliminary (unaudited) U.S. net product sales of EYLEA® (aflibercept) Injection of approximately $3.7 billion for the full year 2017 and the preliminary (unaudited) net product sales of EYLEA outside of the United States of more than $2.0 billion for the full year 2017. Regeneron records net product sales of EYLEA in the United States. Outside the United States, EYLEA net product sales comprise sales by Bayer in countries other than Japan and sales by Santen Pharmaceutical Co., Ltd. in Japan under a co-promotion agreement with an affiliate of Bayer. The Company recognizes its share of the profits (including a percentage on sales in Japan) from EYLEA sales outside the United States within Bayer collaboration revenue in its Statements of Operations.

Item 7.01. Regulation FD Disclosure.

The information set forth under Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 to this Current Report on Form 8-K is incorporated by reference herein.

On January 10, 2018, at a sell-side investor meeting at the 2018 J.P. Morgan Healthcare Conference, Robert E. Landry, Senior Vice President, Finance and Chief Financial Officer of Regeneron, is giving a presentation entitled 2018 Financial Overview. A copy of the presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

The information included or incorporated in Item 2.02 and Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information and exhibit be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific

reference in such a filing.

Item 9.01. **Financial Statements and Exhibits.**

(d) Exhibits.

99.1	Presentation by Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron Pharmaceuticals, Inc., at the 36th Annual J.P. Morgan Healthcare Conference.
99.2	Presentation by Robert E. Landry, Senior Vice President, Finance and Chief Financial Officer of Regeneron Pharmaceuticals, Inc., entitled 2018 Financial Overview.

EXHIBIT INDEX

Number	Description
99.1	Presentation by Leonard S. Schleifer, M.D., Ph.D., President and Chief Executive Officer of Regeneron Pharmaceuticals, Inc., and George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron Pharmaceuticals, Inc., at the 36th Annual J.P. Morgan Healthcare Conference.
99.2	Presentation by Robert E. Landry, Senior Vice President, Finance and Chief Financial Officer of Regeneron Pharmaceuticals, Inc., entitled 2018 Financial Overview.

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 thereunto duly authorized.

REGENERON PHARMACEUTICALS, INC.

/s/ Joseph J. LaRosa
Joseph J. LaRosa
Senior Vice President, General Counsel and Secretary

Date: January 8, 2018