REGENERON PHARMACEUTICALS INC
Form 8-K
January 07, 2019

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 7, 2019 (January 2, 2019)**

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 2, 2018, Regeneron Pharmaceuticals, Inc. (Regeneron or the Company) and Sanofi Biotechnology SAS (Sanofi) entered into an Amended and Restated Immuno-oncology Discovery and Development Agreement (the Amended IO Discovery Agreement), which amended and restated that certain Immuno-oncology Discovery and Development Agreement, dated as of July 1, 2015 and executed as of July 27, 2015, by and between the Company and Sanofi, as amended (the Original IO Discovery Agreement). The Amended IO Discovery Agreement has an effective date of December 31, 2018.

Pursuant to the Amended IO Discovery Agreement, the scope of the existing discovery and development activities conducted by the Company (the IO Development Activities) has been narrowed to developing therapeutic bi-specific antibodies targeting (i) BCMA and CD3 (the BCMAxCD3 Program) and (ii) MUC16 and CD3 (the MUC16xCD3 Program) through clinical proof of concept. The Amended IO Discovery Agreement provides for Sanofi s payment of $462 million to the Company as consideration for (x) the termination of the Original IO Discovery Agreement, (y) the prepayment for certain IO Development Activities regarding the BCMAxCD3 Program and the MUC16xCD3 Program, and (z) the reimbursement of costs incurred by the Company under the Original IO Discovery Agreement during the fourth quarter of 2018. The Company is required to conduct the IO Development Activities with respect to (i) the BCMAxCD3 Program through the earlier of clinical proof of concept or the expenditure of $70 million (the BCMAxCD3 Program Costs Cap) and (ii) the MUC16xCD3 Program through the earlier of clinical proof of concept or the expenditure of $50 million (the MUC16xCD3 Program Costs Cap) (the BCMAxCD3 Program Costs Cap and MUC16xCD3 Program Costs Cap, collectively, the Program Costs Caps); provided that under certain circumstances, Sanofi will have the option to increase the MUC16xCD3 Program Costs Cap to $70 million by making a payment to the Company in the amount of $20 million. Pursuant to the Amended IO Discovery Agreement, the Company will be primarily responsible for conducting the IO Discovery Activities and, other than certain clinical trials that may be funded separately by Sanofi, will design and conduct all research activities, including antibody development, preclinical activities, toxicology studies, manufacture of preclinical and clinical supplies, filing of Investigational New Drug Applications, and clinical development through proof of concept. The Company is obligated to reimburse Sanofi for half of the development costs that are attributable to clinical development of antibody product candidates under the Amended IO Discovery Agreement from its share of future profits to the extent they are sufficient for this purpose. As the scope of the IO Development Activities has been limited, the exclusivity obligations of the parties under the Amended IO Discovery Agreement have been narrowed.

The Amended IO Discovery Agreement provides that Regeneron retains exclusive rights to all other immuno-oncology programs that were part of the Original IO Discovery Agreement; provided that Sanofi will receive a royalty on global sales of two product candidates currently in clinical development, REGN3767 (antibody to LAG-3 protein) and REGN4659 (antibody to CTLA4).

With regard to the BCMAxCD3 Program and the MUC16xCD3 Program, when clinical proof of concept is established, the applicable Program Costs Cap is reached, or in certain other limited circumstances, Sanofi will have the option to license rights to the product candidate and other antibodies targeting the same targets for immuno-oncology indications pursuant to the Immuno-oncology License and Collaboration Agreement, dated as of July 1, 2015, by and between the Company and Sanofi, as amended. If Sanofi does not exercise its option to license rights to a product candidate, the Company will retain the exclusive right to develop and commercialize such product candidate and Sanofi will receive a royalty on sales. Pursuant to the Amended IO Discovery Agreement, the parties agreed that (i) if Sanofi exercises its option with respect to a BCMAxCD3 Program antibody, Sanofi will lead the development and commercialization of such BCMAxCD3 Program antibody; and (ii) if Sanofi exercises its option with respect to a MUC16xCD3 Program antibody, (x) the Company will lead the development of such MUC16xCD3 Program antibody and commercialization of such MUC16xCD3 Program antibody within the United States and (y) Sanofi will lead the commercialization of such MUC16xCD3 Program antibody outside of the United States. The Amended IO Discovery Agreement will terminate as of the earlier of (a) Sanofi having elected to exercise or not exercise its options with respect to the BCMAxCD3 Program and the MUC16xCD3 Program in accordance with the terms of the Amended IO Discovery Agreement and (b) December 31, 2022.

The Amended IO Discovery Agreement contains other customary covenants and termination provisions, including for material breach by the other party.

The foregoing description of the Amended IO Discovery Agreement is qualified in its entirety by reference to the full text of the Amended IO Discovery Agreement, a copy of which will be filed with the United States Securities and Exchange Commission (the SEC) as an exhibit to the Quarterly Report on Form 10-Q to be filed by the Company for the quarterly period ending March 31, 2019.

Item 2.02. Results of Operations and Financial Condition.

On January 7, 2019, the Company issued a press release providing a strategic business update in connection with the Company s presentation at the 37th Annual J.P. Morgan Healthcare Conference in San Francisco, California (the 2019 J.P. Morgan Healthcare Conference). The press release includes information regarding the Company s preliminary (unaudited) U.S. net product sales of EYLEA® (aflibercept) Injection of approximately $4.07 billion for the full year 2018 (based on preliminary (unaudited) fourth quarter 2018 U.S. net product sales of EYLEA of approximately $1.07 billion). A copy of the press release is being furnished to the SEC as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference to this Item 2.02.

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 7, 2019, at the 2019 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. 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.

On January 9, 2019, at a sell-side investor meeting at the 2019 J.P. Morgan Healthcare Conference, Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron, is giving a presentation entitled 2019 Financial Overview. A copy of the presentation is furnished as Exhibit 99.3 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, 99.2, and 99.3, 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 Press Release, dated January 7, 2019.

99.2 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 37th Annual J.P. Morgan Healthcare Conference.

99.3 Presentation by Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron Pharmaceuticals, Inc., entitled 2019 Financial Overview.

EXHIBIT INDEX

Number	Description
99.1	Press Release, dated January 7, 2019.
99.2	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 37th Annual J.P. Morgan Healthcare Conference.
99.3	Presentation by Robert E. Landry, Executive Vice President, Finance and Chief Financial Officer of Regeneron Pharmaceuticals, Inc., entitled 2019 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
Executive Vice President, General Counsel and Secretary

Date: January 7, 2019