

REGENERON PHARMACEUTICALS INC
Form 8-K
July 31, 2015

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): **July 31, 2015 (July 27, 2015)**

REGENERON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

New York

(State or other jurisdiction of incorporation)

000-19034
(Commission
File Number)

13-3444607
(I.R.S. Employer
Identification No.)

777 Old Saw Mill River Road, Tarrytown, New York
(Address of principal executive offices)

10591-6707
(Zip Code)

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

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

On July 27, 2015, Regeneron Pharmaceuticals, Inc. (Regeneron or the Company) and Sanofi Biotechnology SAS (Sanofi) entered into an exclusive, global strategic collaboration to discover, develop, and commercialize antibody-based cancer treatments in the field of immuno-oncology (the IO Collaboration). The IO Collaboration is governed by an Immuno-oncology Discovery and Development Agreement (the IO Discovery Agreement) and an Immuno-oncology License and Collaboration Agreement (the IO License and Collaboration Agreement).

IO Discovery Agreement

The IO Discovery Agreement provides for a \$265 million upfront payment to the Company. Pursuant to the IO Discovery Agreement, the Company will spend up to \$1,090 million to identify and validate potential immuno-oncology targets and develop therapeutic antibodies against such targets through clinical proof of concept (the IO Discovery Program). Sanofi will reimburse the Company for up to \$825 million of these costs of conducting the IO Discovery Program, subject to certain annual limits. The \$825 million represents (i) \$750 million in new funding and (ii) \$75 million of funding that would have otherwise been available to Regeneron under the existing Amended and Restated Discovery and Preclinical Development Agreement (the Existing Discovery Agreement), dated as of November 10, 2009, between Regeneron and Sanofi, which will reduce the funding available in the aggregate under the Existing Discovery Agreement by such amount. The Existing Discovery Agreement was amended to effect this funding reduction and to exclude immuno-oncology antibodies and targets. It is anticipated that the IO Discovery Program will last five years, subject to Sanofi's option to extend it for up to an additional three years for the continued development of selected ongoing programs at its expense. Pursuant to the IO Discovery Agreement, the Company will be primarily responsible for conducting the IO Discovery Program and, other than certain clinical trials that may be funded separately by Sanofi, will design and conduct all research activities, including target identification and validation, 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 will reimburse Sanofi for half of the development costs that are attributable to clinical development of antibody product candidates under the IO Discovery Agreement from its share of future profits to the extent they are sufficient for this purpose.

With regard to product candidates for which proof of concept is established, and in certain other limited circumstances, Sanofi will have the option to license rights to the candidate pursuant to the IO License and Collaboration Agreement. 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.

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

The foregoing description of the IO Discovery Agreement is qualified in its entirety by reference to the full text of the IO Discovery Agreement, a copy of which will be filed with the Securities and Exchange Commission (the SEC) as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ending September 30, 2015 (the 3Q15 Quarterly Report).

IO License and Collaboration Agreement

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The IO License and Collaboration Agreement provides for a \$375 million upfront payment to the Company. If Sanofi exercises its option to license rights to a product candidate under the IO Discovery Agreement, it will co-develop the drug candidate with the Company through product approval under the IO License and Collaboration Agreement. Principal control of development of each product candidate that enters development under the IO License and Collaboration Agreement will alternate between the Company and Sanofi on a candidate-by-candidate basis. Development costs will be shared between the Company and Sanofi, with Sanofi funding drug candidate development costs up front for the candidates for which it is the principal controlling party (and the Company reimbursing half of the total development costs for all such candidates from its share of future profits to the extent they are sufficient for this purpose), and Sanofi and the Company sharing equally, on an ongoing basis,

the development costs for the drug candidates for which the Company is the principal controlling party. The party having principal control over the development of a product candidate will also lead the commercialization activities for such product candidate in the United States. For all products commercialized under the IO License and Collaboration Agreement, Sanofi will lead commercialization activities outside of the United States. Each party will have the right to co-promote licensed products in countries where it is not the lead commercialization party. The parties will share equally in any profits from worldwide sales of collaboration products (subject to the above-mentioned reimbursement arrangement, if applicable).

Under the terms of the IO License and Collaboration Agreement, the parties will also co-develop the Company's antibody product candidate targeting the receptor known as Programmed Cell Death protein 1, or PD-1 (REGN2810). The parties will share equally, on an ongoing basis, development expenses for REGN2810 up to a total development budget of \$650 million. The Company will have principal control over the development of REGN2810 and will lead commercialization activities in the United States, subject to Sanofi's right to co-promote, while Sanofi will lead commercialization activities outside of the United States and the parties will equally share profits from worldwide sales. The Company will be entitled to a milestone payment of \$375 million in the event that sales of all licensed products targeting PD-1 (including REGN2810), together with sales of any other products licensed under the IO License and Collaboration Agreement and sold for use in combination with a licensed product targeting PD-1, equal or exceed \$2 billion in any consecutive twelve-month period.

With respect to each product candidate that enters development under the IO License and Collaboration Agreement, Sanofi or the Company may, by giving twelve months' notice, opt-out of further development and/or commercialization of the product, in which event the other party will retain exclusive rights to continue the development and/or commercialization of such product.

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

The foregoing description of the IO License and Collaboration Agreement is qualified in its entirety by reference to the full text of the IO License and Collaboration Agreement, a copy of which will be filed with the SEC as an exhibit to the 3Q15 Quarterly Report.

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.

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

Date: July 31, 2015