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): June 2, 2022 (June 1, 2022)

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 Instruction A.2):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock – par value $0.001 per share	REGN	Nasdaq Global Select Market

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 ☐

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. ☐

Item 1.01. Entry into a Material Definitive Agreement.

A&R IO License and Collaboration Agreement. On June 1, 2022, Regeneron Pharmaceuticals, Inc., a New York corporation ("Regeneron" or the "Company"), and Sanofi Biotechnology SAS, a société par actions simplifée organized under the laws of France ("Sanofi Biotechnology"), entered into the Amended and Restated Immuno-Oncology License and Collaboration Agreement (the "A&R IO LCA"), which amends the Immuno-Oncology License and Collaboration Agreement, dated as of July 1, 2015 and executed as of July 27, 2015 (as amended), by and between the Company and Sanofi Biotechnology (the "Original IO LCA"). The A&R IO LCA is subject to and will become effective on the first day of the first month following receipt of all necessary authorizations and expiration of all necessary waiting periods applicable to the consummation of the A&R IO LCA (such date, the "A&R Effective Date").

The Original IO LCA provides for Regeneron and Sanofi Biotechnology to collaborate on the development and commercialization of certain immuno-oncology products, including Libtayo® (cemiplimab). From and after the A&R Effective Date, Regeneron will have the sole right to develop and commercialize Libtayo worldwide and no other products will be subject to the A&R IO LCA; and Regeneron will also obtain a license under certain intellectual property rights of Sanofi Biotechnology to develop and commercialize Libtayo worldwide and Sanofi Biotechnology will transfer to Regeneron certain regulatory, promotional, and other rights relating to the commercialization of Libtayo outside the United States. The parties have also entered into a transition services agreement, a transitional distribution agreement, and a manufacturing services agreement, pursuant to which, during certain transitional periods, Sanofi Biotechnology will perform for Regeneron certain transition, distribution, and manufacturing services, respectively.

Under the A&R IO LCA, the quarterly period ended March 31, 2022 is the last quarter for which Sanofi Biotechnology and Regeneron share net profits and losses for Libtayo under the Original IO LCA. From and after April 1, 2022 (after giving effect to certain true-up payments as set forth in the A&R IO LCA), Regeneron will be entitled to all profits from Libtayo and will pay Sanofi Biotechnology an 11% royalty on net product sales of Libtayo through March 31, 2034. In addition, the A&R IO LCA provides for the following payments by Regeneron to Sanofi Biotechnology: (i) a $900 million upfront payment, payable within 10 business days after the A&R Effective Date; (ii) a $100 million development milestone payment upon the first marketing approval from the U.S. Food and Drug Administration or the European Commission of Libtayo in non-small cell lung cancer in combination with chemotherapy; and (iii) sales milestone payments of up to $100 million in the aggregate upon achieving certain amounts of worldwide net product sales of Libtayo in 2022 or 2023.

Under the A&R IO LCA, the amount of development costs incurred under the Original IO LCA for which Regeneron is obligated to reimburse Sanofi Biotechnology is $35 million. Regeneron will reimburse Sanofi Biotechnology for such development costs by paying Sanofi a 0.5% royalty on Regeneron's net product sales of Libtayo until Regeneron has reimbursed Sanofi Biotechnology for all such development costs.

Fifth Amendment to Antibody LCA. On June 1, 2022, Regeneron, Sanofi Biotechnology, and Sanofi, a société anonyme organized under the laws of France ("Sanofi Parent"), entered into the Fifth Amendment to Amended and Restated License and Collaboration Agreement (the "Fifth Amendment"), which amends the Amended and Restated License and Collaboration Agreement, dated as of November 10, 2009 (as amended), by and between the Company, Sanofi Biotechnology (as successor in interest to Aventis Pharmaceuticals Inc.) and Sanofi Parent (the "Antibody LCA") and will become effective on the A&R Effective Date. Pursuant to the Fifth Amendment, the parties amended the Antibody LCA, among other matters, to, from and after April 1, 2022, increase from 10% to 20% the percentage of Regeneron's share of profits used to reimburse Sanofi Biotechnology for the remaining development costs incurred under the Antibody LCA subject to reimbursement by Regeneron.

The foregoing description of the A&R IO LCA and the Fifth Amendment is qualified in its entirety by reference to the full text of the A&R IO LCA and the Fifth Amendment, a copy of each of which will be filed with the U.S. Securities and Exchange Commission as an exhibit to the Quarterly Report on Form 10-Q to be filed by the Company for the quarterly period ending June 30, 2022.

Note Regarding Forward-Looking Statements

This Current Report on Form 8-K (this "Report") includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. Risks that may cause these forward-looking statements to be inaccurate include, among others: risks related to the satisfaction or waiver of the conditions to closing the proposed restructuring (the "Proposed Restructuring") of the Company's Immuno-oncology Collaboration with Sanofi related to Libtayo® (cemiplimab) (including the failure to obtain necessary regulatory approvals) in the anticipated timeframe or at all; risks related to the Company's ability to realize the anticipated benefits of the Proposed Restructuring, including the possibility that the expected benefits from the Proposed Restructuring will not be realized or will not be realized within the expected time period; and the impact of the Proposed Restructuring on Regeneron's business, operating results, and financial condition, as well as effects of this announcement or the consummation of the Proposed Restructuring on the market price of the Company's common stock. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

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: June 2, 2022