REGENERON PHARMACEUTICALS INC
Form 8-K
April 10, 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): April 10, 2019 (April 8, 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	**(I.R.S. Employer**
File Number)	**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.

Collaboration with Alnylam Pharmaceuticals, Inc.

On April 8, 2019, Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company") and Alnylam Pharmaceuticals, Inc. ("Alnylam") entered into a global, strategic collaboration to discover, develop, and commercialize RNA interference (RNAi) therapeutics for a broad range of diseases by addressing therapeutic disease targets expressed in the eye and central nervous system ("CNS"), in addition to a select number of targets expressed in the liver (collectively, the "Collaboration"). The Collaboration is governed by a Master Collaboration Agreement (the "Master Agreement"), dated April 8, 2019, by and between Regeneron and Alnylam (including the form of License Agreement (a "License Agreement") and Co-Co (Co-Commercialization) Collaboration Agreement (a "Co-Co Collaboration Agreement") appended thereto), which will become effective upon closing of the Equity Transaction (as defined below) (the "Effective Date"); and is subject to customary closing conditions and clearances, including clearance under the Hart-Scott Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act").

Under the Master Agreement, Regeneron will make an upfront payment of $400 million to Alnylam within 10 business days of the Effective Date. As discussed further below, pursuant to the terms of the Equity Transaction, Regeneron will also purchase $400 million of Alnylam equity on the Effective Date. In addition, Alnylam is eligible to receive up to $200 million in clinical proof-of-principle milestones for eye or CNS programs. For each program, Regeneron will provide Alnylam with a specified amount of funding at program initiation and at lead candidate designation.

Under the Collaboration, the parties plan to perform discovery research until designation of lead candidates, with Regeneron having certain final decision-making rights over the discovery plan. Following designation of a lead candidate, the parties may further advance such lead candidate under either a License Agreement or a Co-Co Collaboration Agreement structure. The initial target nomination and discovery period is five years (which may under certain situations automatically be extended for up to seven years in the aggregate) (the "Research Term"). In addition, Regeneron has an option to extend the Research Term for an additional five-year period for a research extension fee ranging from $200 million to $400 million. The actual amount of the research extension fee will be determined based on the acceptance of one or more Investigational New Drug applications (or their equivalent in certain other countries) for programs in the eye and CNS. The terms of the Master Agreement generally contemplate six targets selected per year. During the Research Term, Alnylam is required to work exclusively with Regeneron in the field of oligonucleotide therapeutics for use in the eye and CNS, subject to certain exceptions.

At the stage of designation of a lead candidate for CNS programs and liver programs, the parties have alternating rights to be a lead party for collaboration products. At the stage of designation of a lead candidate for eye programs, Regeneron has the sole right to take the product forward as a licensee. The lead party is required to take the program forward under the License Agreement structure unless the other party exercises its rights to opt-in to a Co-Co

Collaboration Agreement, in which case the lead party is required to take the program forward under the Co-Co Collaboration Agreement structure. Alnylam does not have rights to opt-in to a Co-Co Collaboration Agreement for eye programs.

Under a License Agreement, the lead party is designated as the licensee and has the right to develop and commercialize the collaboration product under such program. The licensee will be responsible for its own costs and expenses incurred in connection with the development and commercialization of the collaboration products under the License Agreement. The licensee will pay to the licensor certain development and/or commercialization milestone payments totaling up to $150 million for each collaboration product. In addition, following the first commercial sale of the applicable collaboration product under a License Agreement, the licensee is required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the licensor based on the aggregate annual net sales of the collaboration product, subject to customary reductions.

For CNS programs and liver programs, as soon as a party is designated as a lead party, the other company has rights to opt-in to a Co-Co Collaboration Agreement as a participating party. Under a Co-Co Collaboration Agreement, the party designated as the lead party has operational responsibility and final decision-making authority on development and commercialization of the program and the parties will split profits and share costs equally, subject to certain co-funding opt-outs at specified clinical trial phases or under other conditions. If a party exercises its co-funding opt-out right, following the first commercial sale of the applicable collaboration product under a Co-Co Collaboration Agreement, the lead party will be required to make certain tiered royalty payments, ranging from low double-digits up to 20%, to the other party based on the aggregate annual net sales of the collaboration product and the timing of the exercise of the co-funding opt-out right, subject to customary reductions. If the non-lead party does not initially opt-in to a Co-Co Collaboration Agreement, the lead party has the right to take the program forward under a License Agreement structure.

Under the Collaboration, when Regeneron is the licensee under a License Agreement or the lead party under a Co-Co Collaboration Agreement, Alnylam will be responsible for the manufacture and supply of the product to Regeneron for Phase 1 and Phase 2 clinical trials. Additionally, Regeneron will have the opportunity to combine its proprietary antibodies with the silencing RNA ("siRNA") therapeutics developed under the Collaboration.

Within three months of the Effective Date, the parties plan to negotiate and enter into a Co-Co Collaboration Agreement for an siRNA therapeutic targeting the C5 component of the human complement pathway being developed by Alnylam, with Alnylam as the lead party, and a License Agreement for a combination product consisting of such siRNA therapeutic and a fully human monoclonal antibody targeting C5 being developed by Regeneron, with Regeneron as the licensee. The C5 siRNA Co-Co Collaboration Agreement would generally match the financial terms set forth in the form of the Co-Co Collaboration Agreement attached to the Master Agreement. The C5 siRNA License Agreement would contain a flat low double-digit royalty on net sales of the combination product only subject to customary reductions, and there could be up to $325 million in commercial milestones.

Regeneron has the right to terminate the Master Agreement for convenience upon 90 days' notice to Alnylam. Either party may also terminate the Master Agreement for a material breach by the other party. The termination of the Master Agreement does not affect the term of any License Agreement or Co-Co Collaboration Agreement then in effect.

The foregoing description of the Collaboration is qualified in its entirety by reference to the full text of the Master 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 June 30, 2019 (the "2Q19 Form 10-Q").

Purchase of Equity of Alnylam Pharmaceuticals, Inc.; Investor Agreement

In connection with the Collaboration described above, Regeneron and Alnylam have entered into a Stock Purchase Agreement (the "Stock Purchase Agreement") and an Investor Agreement (the "Investor Agreement"), each dated April 8, 2019. Pursuant to the terms of the Stock Purchase Agreement, Regeneron has agreed to purchase from Alnylam 4,444,445 shares of Alnylam common stock, par value $0.01 per share ("Common Stock"), or, if Stockholder Approval (as defined below) is not obtained at Alnylam's 2019 Annual Meeting of Stockholders (currently scheduled to be held on April 25, 2019), 1,481,482 shares of Alnylam Series A Redeemable Convertible Preferred Stock, par value $0.01 per share ("Preferred Stock"), in each case, for aggregate cash consideration of approximately $400 million (the "Equity Transaction").

If issued, each share of Preferred Stock will automatically convert, following receipt of approval by Alnylam's stockholders to increase the number of shares of authorized Common Stock issuable under Alnylam's certificate of incorporation by at least the number of shares of Common Stock issuable under the Stock Purchase Agreement

("Stockholder Approval"), into three shares of Common Stock. If any shares of Preferred Stock are outstanding at the expiration of the Lock-Up Period (as defined below), Regeneron will have a right to request Alnylam to redeem such shares at a price per share equal to three times the volume-weighted average price of a share of Common Stock for the 15 trading days prior to the date of Regeneron's request for such redemption.

Pursuant to the Stock Purchase Agreement, as a condition to closing, Alnylam must file (i) if Stockholder Approval is not timely obtained, a certificate of designations in respect of the Preferred Stock; or (ii) if Stockholder Approval is timely obtained, a certificate of amendment to its certificate of incorporation to increase the number of authorized shares of Common Stock thereunder by at least the number of shares of Common Stock issuable under the Stock Purchase Agreement. The Stock Purchase Agreement also contains customary representations, warranties, and other customary covenants of each of the parties. Subject to the satisfaction or waiver of the closing conditions, including the expiration or early termination of the applicable pre-merger waiting period under the HSR Act, the Equity Transaction is expected to close during the second quarter of 2019.

Under the Investor Agreement, Regeneron has agreed to certain standstill provisions whereby Regeneron is obligated, during the research term of the Collaboration and under certain circumstances for up to two years thereafter, to refrain from seeking to directly or indirectly exert control of Alnylam or acquiring more than 30% of outstanding shares of Common Stock (including any shares of Common Stock issuable upon conversion of outstanding Preferred Stock), subject to certain exceptions. In addition, Regeneron has agreed, subject to limited exceptions, not to sell or otherwise transfer any of the shares purchased by it under the Stock Purchase Agreement (the "Shares") or any other shares of Common Stock held by it or its subsidiaries at the closing of the Collaboration for a period ending on the earlier of four years after the Effective Date or the termination of the Master Agreement (the "Lock-Up Period"). After the expiration of the Lock-Up Period, if Regeneron exceeds a specified beneficial ownership threshold, Regeneron will be subject to certain volume restrictions with respect to its sale of shares of Common Stock, unless Alnylam consents otherwise or such sale is made pursuant to a registered underwritten public offering. Regeneron has further agreed to vote all of the voting securities of Alnylam it holds in accordance with the recommendation of Alnylam's board of directors, other than with respect to certain extraordinary matters (including a change in control of Alnylam). The voting agreement expires, among other events, on the date on which Regeneron (together with its affiliated permitted transferees) no longer holds at least 1% of the outstanding shares of Common Stock. The Investor Agreement also provides that, following the Lock-Up Period, Regeneron will have certain demand and piggyback registration rights with respect to the Shares, subject to customary conditions (including underwriter cutbacks). The foregoing rights and restrictions under the Investor Agreement are subject to termination upon the occurrence of certain events, as described therein.

The Stock Purchase Agreement may be terminated at any time prior to closing by mutual consent; by Regeneron if closing has not occurred by September 30, 2019; or by either party if any specified closing condition becomes incapable of fulfillment for a reason other than that party's failure to fulfill its obligations under the Stock Purchase Agreement, or upon the breach by the other party of any covenant or agreement or upon a representation or warranty given by the other party becoming untrue, in each case, so that certain closing conditions cannot be met.

The foregoing description of the Equity Transaction and the Investor Agreement is qualified in its entirety by reference to the full text of the Stock Purchase Agreement and the Investor Agreement, respectively, a copy of each of which will be filed with the SEC as an exhibit to the 2Q19 Form 10-Q.

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: Executive Vice President, General Counsel and Secretary

Date: April 10, 2019