

ALNYLAM PHARMACEUTICALS, INC.
Form 8-K
April 09, 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 9, 2019 (April 8, 2019)

Alnylam Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

300 Third Street, Cambridge, MA

001-36407
(Commission

File Number)

77-0602661
(IRS Employer

Identification No.)

02142

(Address of Principal Executive Offices)

(Zip Code)

Registrant's telephone number, including area code: (617) 551-8200

Not applicable

(Former Name or Former Address, if Changed Since Last Report)

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. below):

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))

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.

Regeneron Collaboration

Master Agreement

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

Under the terms of the Collaboration, the Company will work exclusively with Regeneron to discover RNAi therapeutics for eye and CNS diseases for an initial five-year research period, subject under certain circumstances to extension for up to an additional two years (the Initial Research Term). Regeneron has an option to extend the Initial Research Term (the Research Term Extension Period, together with the Initial Research Term, the Research Term), subject to payment of a research term extension fee of up to \$400 million. The Collaboration will also cover a select number of RNAi therapeutic programs designed to target genes expressed in the liver, which will include the parties previously-announced collaboration to identify RNAi therapeutics for the chronic liver disease nonalcoholic steatohepatitis. The Company retains broad global rights to all of its other unpartnered liver-directed clinical and preclinical pipeline programs.

Regeneron will lead development and commercialization for all programs targeting eye diseases (subject to limited exceptions), with the Company entitled to certain potential milestone and royalty payments pursuant to the terms of a license agreement, as further described below under the heading *Form of License Agreement* (the Form of License Agreement and each, a License Agreement). The parties will alternate leadership on CNS and liver programs, with the lead party retaining global development and commercial responsibility. For CNS and liver programs, both parties will have the option at lead candidate selection to enter into a co-co collaboration agreement, as further described below under the heading *Form of Co-Co Collaboration Agreement* (the Form of Co-Co Collaboration Agreement and each, a Co-Co Collaboration Agreement), to participate equally in potential future profits of programs led by the other party. If the non-lead party elects to not enter into a Co-Co Collaboration Agreement with respect to a given CNS or liver program, the parties will enter into a License Agreement with respect to such program and the lead party will be the Licensee for the purposes of the License Agreement. If the lead party for a CNS or liver program elects to not enter into the Co-Co Collaboration Agreement, then leadership of the program will transfer to the other party and the former non-lead party will be the Licensee for the purposes of the License Agreement.

In addition, the parties have agreed to evaluate anti-C5 antibody-siRNA combinations for C5 complement-mediated diseases including evaluating the combination of Regeneron's pozelimab (REGN3918), currently in Phase 1 development, and the Company's cemdisiran, currently in Phase 2 development. The Company will retain control of cemdisiran monotherapy development, and Regeneron will lead combination product development. The parties will negotiate and enter into a Co-Co Collaboration Agreement to equally share investment and potential future profits on the monotherapy program, and a License Agreement pursuant to which Regeneron will be solely responsible for all development and commercialization costs and the Company will receive low double-digit royalties and commercial milestones of up to \$325 million on any potential combination product sales, in each case in accordance with the terms set forth in the agreed-upon term sheet attached to the Master Agreement.

The Collaboration will be governed by a joint steering committee that will be comprised of an equal number of representatives from each party.

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In connection with the Master Agreement, Regeneron will make a \$400 million upfront payment to the Company and purchase \$400 million of the Company's equity, as further detailed below under *Equity Placement*. The Company is also eligible to receive up to an additional \$200 million in milestone payments upon achievement of

certain criteria during early clinical development for the eye and CNS programs. The parties plan to advance programs directed to 30 targets under the Collaboration during the Initial Research Term. For each program, Regeneron will provide the Company with \$2.5 million in funding at program initiation and an additional \$2.5 million at lead candidate identification, with the potential for approximately \$30 million in annual discovery funding to the Company as the Collaboration reaches steady state.

Regeneron has the right to terminate the Master Agreement for convenience upon ninety days' notice to the Company. The termination of the Master Agreement does not affect the term of any License Agreement or Co-Co Collaboration Agreement then in effect. In addition, either party may terminate the Master Agreement for a material breach by, or insolvency of, the other party. Unless earlier terminated pursuant to its terms, the Master Agreement will remain in effect with respect to each program until (a) such program becomes a terminated program or (b) the parties enter into a License Agreement or Co-Co Collaboration Agreement with respect to such program.

The Master Agreement includes various representations, warranties, covenants, dispute escalation and resolution mechanisms, indemnities and other provisions customary for transactions of this nature.

Form of License Agreement

Following lead candidate selection for an eye program (except in limited circumstances) or upon a party's election to not enter into a Co-Co Collaboration Agreement following candidate selection for a CNS or liver program, the parties will enter into a License Agreement for the applicable program.

Under the Form of License Agreement, the licensee will be solely responsible for development of collaboration products arising from such program, except that in the event that Regeneron is the licensee, Regeneron may request that the Company perform certain research activities at Regeneron's expense. The licensee is required to use commercially reasonable efforts to develop a collaboration product for the purposes of achieving regulatory approval in each Major Market Country (as defined in the Form of License Agreement).

In addition, the licensee will be solely responsible for all commercialization activities for collaboration products arising out of the applicable program, and the licensee is required to use commercially reasonable efforts to commercialize a collaboration product following receipt of regulatory approval in each Major Market Country (as defined in the Form of License Agreement). Under the Form of License Agreement, the licensee books all sales of collaboration products.

Under the Form of License Agreement, the Company is responsible for the manufacture of all early stage supply requirements, regardless of which party is the licensee. The Company will also be responsible for manufacturing late stage supply requirements if the Company is the licensee. In the event that Regeneron is the licensee, the parties will enter into an early stage supply agreement, pursuant to which Regeneron will pay the Company for the early stage manufacturing costs, and Regeneron may manufacture late stage supply requirements, or the parties can agree to have the Company be responsible for all or some of such manufacturing on Regeneron's behalf. Regeneron will pay the Company for the manufacturing costs associated with any late stage supply requirements performed by the Company on Regeneron's behalf.

Except for the specific activities described above that are performed by the Company at Regeneron's request, 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 Form of 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, consisting of up to \$60 million in development milestones and up to \$90 million in commercial milestones. 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.

The parties have the right to terminate a given License Agreement for the other party's material breach, subject to cure rights, or in the event of the other party's insolvency. Additionally, the licensee may terminate a License Agreement for convenience upon ninety days' notice to the licensor. Unless earlier terminated pursuant to its terms, each License Agreement will remain in effect until the expiration of the last royalty term for the last collaboration product under the applicable License Agreement.

The Form of License Agreement includes various representations, warranties, covenants, dispute escalation and resolution mechanisms, indemnities and other provisions customary for transactions of this nature.

Form of Co-Co Collaboration Agreement

Upon a party's election to enter into a Co-Co Collaboration Agreement following lead candidate selection for a CNS or liver program or, in limited circumstances for an eye program, the parties will enter into a Co-Co Collaboration Agreement for the applicable program.

Under the Form of Co-Co Collaboration Agreement, the parties will each perform development activities in accordance with the plan and budget approved by the joint steering committee. Following the completion of a Phase 2 clinical trial, the lead party is required to use commercially reasonable efforts to obtain regulatory approval of a collaboration product in each Major Market Country (as defined in the Form of Co-Co Collaboration Agreement).

The Form of Co-Co Collaboration Agreement provides for certain opportunities for each party to opt-out of any further development activities under the applicable Co-Co Collaboration Agreement along with the cost-sharing arrangement (the "Opt-Out Right"), subject to continued sharing of costs through defined points. In the event that a party exercises its Opt-Out Right, the opt-out party will no longer have any obligation to perform any development activities with respect to any collaboration product under the applicable Co-Co Collaboration Agreement, except that if the Company exercises its Opt-Out Right, the Company will still be required to, at Regeneron's request, perform certain development activities in accordance with a plan and budget to be reasonably agreed to by the parties.

Under the Form of Co-Co Collaboration Agreement, the lead party has the sole right to commercialize the collaboration products under the applicable Co-Co Collaboration Agreement in accordance with the plan and budget approved by the joint steering committee. Following receipt of regulatory approval in the applicable country, the lead party is required to use commercially reasonable efforts to obtain regulatory approval of a collaboration product in each Major Market Country (as defined in the Form of Co-Co Collaboration Agreement). Under the Form of Co-Co Collaboration Agreement, the lead party books all sales of a collaboration product.

Under the Form of Co-Co Collaboration Agreement, the parties have similar rights and obligations with respect to early stage and late stage manufacturing to those set forth in the Form of License Agreement.

Under the Form of Co-Co Collaboration Agreement, the parties share equally all costs of, and profits from, development and commercialization activities. In the event that a party exercises its Opt-Out Right, the lead party will be responsible for all costs and expenses incurred in connection with the development and commercialization of the collaboration products under the applicable Co-Co Collaboration Agreement, subject to continued sharing of costs through defined points. Once a party exercises its Opt-Out Right, following the first commercial sale of the applicable collaboration product under a Co-Co Collaboration Agreement, the lead party is 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 Opt-Out Right, subject to customary reductions and a reduction for opt-out transition costs.

Each party has the right to terminate a given Co-Co Collaboration Agreement for the other party's material breach, subject to cure rights, or in the event of the other party's insolvency. Additionally, if a party exercises its Opt-Out

Right, the lead party may terminate its obligations to develop and commercialize the collaboration products under the applicable Co-Co Collaboration Agreement, in which case the lead party will attempt to license, sell, grant or transfer to a third party the right to develop and commercialize the collaboration products under the applicable Co-Co Collaboration Agreement, and the parties will share any proceeds according to a defined allocation percentage. Unless earlier terminated pursuant to its terms, each Co-Co Collaboration Agreement will remain in effect until (a) if neither party has exercised its Opt-Out Right, the first date on which the lead party is no longer developing or

commercializing any collaboration products under the applicable Co-Co Collaboration Agreement or (b) if a party has exercised its Opt-Out Right, the date of expiration of the last royalty term for the last collaboration product under the applicable Co-Co Collaboration Agreement.

The Form of Co-Co Collaboration Agreement includes various representations, warranties, covenants, dispute escalation and resolution mechanisms, indemnities and other provisions customary for transactions of this nature.

Equity Placement

The Company has agreed to sell to Regeneron 4,444,445 shares of its common stock, par value \$.01 per share (the Common Stock), for aggregate cash consideration of \$400 million, or \$90.00 per share, pursuant to the terms of a Stock Purchase Agreement, dated April 8, 2019 (the Stock Purchase Agreement), by and between Regeneron and the Company (the Equity Transaction). If at the time of closing of the Equity Transaction (which will occur no earlier than the conclusion of the Company's 2019 annual meeting of stockholders) a sufficient number of authorized shares of Common Stock under the Company's Restated Certificate of Incorporation is not available, the \$400 million of equity under the Stock Purchase Agreement will instead be issued in the form of 1,481,482 shares of the Company's Series A Redeemable Convertible Preferred Stock, par value \$.01 per share (the Preferred Stock), at a purchase price of \$270.00 per share, that will convert automatically into Common Stock on a 1-for-3 basis upon stockholder approval of additional authorized shares of Common Stock. This sale does not involve a public offering and is therefore exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended (the Securities Act). Based on 106,437,145 shares of Common Stock outstanding as of April 8, 2019, following the Equity Transaction Regeneron will beneficially own approximately 4.0% of the outstanding shares of Common Stock (on a pro forma, and if Preferred Stock is issued, on an as converted, basis). The Stock Purchase Agreement contains customary representations, warranties, and covenants of each of the parties thereto. Subject to customary 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.

As a condition to consummating the transactions contemplated by the Stock Purchase Agreement, the Company and Regeneron have entered into an investor agreement dated April 8, 2019 (the Investor Agreement). Under the Investor Agreement, until the expiration or termination of the Research Term under the Master Agreement (subject to extension by one year if the Research Term or Master Agreement is terminated by Regeneron at will, or by up to two years if as of the expiration or termination of the Research Term, Regeneron owns more than 19.99% of the Company's outstanding shares (on an as-converted basis)), Regeneron and its affiliates will be bound by certain standstill provisions. The standstill provisions include agreements not to acquire more than 30% of the Company's outstanding shares of Common Stock and Preferred Stock (on an as-converted basis), call stockholder meetings, nominate directors other than those approved by the Company's Board of Directors, subject to certain limited exceptions, or propose or support a proposal to acquire the Company.

Further, under the Investor Agreement, Regeneron has agreed to vote, and cause its affiliates to vote, all shares of the Company's voting securities Regeneron is entitled to vote in a manner as recommended by the Company's Board of Directors, except with respect to certain change of control transactions, liquidation or dissolution of the Company, or, after the standstill term, any contested election of directors.

Under the Investor Agreement, Regeneron has agreed not to dispose of any of the purchased shares or any shares of Common Stock beneficially owned by it immediately after the closing of the Master Agreement, until the earlier of (i) the four-year anniversary of the closing of the Equity Transaction and (ii) the termination of the Collaboration (the Lock-Up Period), subject to limited exceptions. Following the expiration of the Lock-Up Period, if at any time Regeneron beneficially owns at least 9.9% of the Company's outstanding shares (on an as-converted basis), then until such time as Regeneron beneficially owns less than 5% of the Company's outstanding shares (on an as-converted basis), Regeneron will not dispose of any shares except (a) pursuant to a registered underwritten public offering

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pursuant to the Investor Agreement, (b) in a manner consistent with the volume limitations set forth in Rule 144 under the Securities Act, or (c) as otherwise approved by the Company.

Under the Investor Agreement, following the Lock-Up Period, Regeneron will have three demand rights to require the Company to conduct a registered underwritten public offering with respect to the shares of Common Stock beneficially owned by Regeneron (or issued or issuable upon conversion of the Preferred Stock, if applicable)

immediately after the closing of the Equity Transaction. In addition, following the Lock-Up Period, subject to certain conditions, Regeneron will be entitled to participate in registered underwritten public offerings by the Company if other selling stockholders are included in the registration. The rights and restrictions under the Investor Agreement are subject to termination upon the occurrence of certain events.

Amendment of Genzyme Agreements

Collaboration Amendment

On April 8, 2019, the Company and Genzyme Corporation (Genzyme) entered into Amendment No. 3 (the Collaboration Amendment) to the Master Collaboration Agreement dated January 11, 2014 (the Original Collaboration Agreement), as amended by Amendment No. 1 to the Master Collaboration Agreement dated July 1, 2015 (Amendment No. 1) and Amendment No. 2 to the Master Collaboration Agreement dated January 6, 2018 (Amendment No. 2) (the Original Collaboration Agreement, together with Amendment No. 1 and Amendment No. 2 and including the License Terms appended to the Original Collaboration Agreement, the Master Agreement). Pursuant to the Collaboration Amendment, the Company and Genzyme have agreed to conclude the research and option phase under the Master Agreement.

In connection and simultaneously with entering into the Collaboration Amendment, the Company and Genzyme also entered into the A&R ALN-AT3 Global License Terms with respect to ALN-AT3 (fitusiran) and certain back-up products (the A&R AT3 License Terms). The A&R AT3 License Terms amend and restate the ALN-AT3 Global License Terms entered into by the Company and Genzyme on January 6, 2018 to modify certain of the business terms. The material collaboration terms for fitusiran, as previously announced, will continue unchanged.

In connection with entering into the Collaboration Amendment and the A&R AT3 License Terms, the Company has agreed to advance, at its cost, a selected investigational asset in an undisclosed rare genetic disease through the end of IND-enabling studies. Following completion of such studies, the Company will transition, at its cost, such asset to Genzyme. Thereafter, Genzyme will fund all potential future development and commercialization costs for such asset. If this asset is approved, the Company will be eligible to receive tiered double-digit royalties on global net sales.

Amended and Restated Investor Agreement

In connection with the Collaboration Amendment, the Company and Genzyme also entered into an Amended and Restated Investor Agreement, dated April 8, 2019 (the A&R Investor Agreement), which amends and restates the Investor Agreement entered into by the Company and Genzyme on February 27, 2014 (the Original Investor Agreement). Pursuant to the A&R Investor Agreement, Genzyme is released from the lock-up restrictions under the Original Investor Agreement and is permitted to sell shares of the Company's Common Stock in transactions approved by the Company or in fully bought block sale transactions satisfying the conditions set forth in the A&R Investor Agreement.

Under the A&R Investor Agreement, until the earlier of (i) the fifth anniversary of the expiration of the last to expire royalty term or the earlier termination of the Master Agreement, as amended by the Collaboration Amendment, and (ii) the date after December 31, 2021 on which the beneficial ownership of Genzyme and its affiliates no longer represents at least 5% of the outstanding shares of Common Stock, Genzyme and its affiliates will be bound by certain standstill provisions. The standstill provisions include agreements not to acquire more than 30% of the outstanding shares of Common Stock, call stockholder meetings, nominate directors other than those approved by the Company's Board of Directors, subject to certain limited exceptions, or propose or support a proposal to acquire the Company.

The A&R Investor Agreement provides that Genzyme will continue to vote, and cause its affiliates to vote, all shares of the Company's voting securities they are entitled to vote, up to a maximum of 20% of the Company's outstanding

shares of Common Stock, in a manner either as recommended by the Company's Board of Directors or proportionally with the votes cast by other stockholders of the Company, except with respect to certain change of control transactions or any liquidation or dissolution of the Company, as in the Original Investor Agreement. Until

Genzyme owns less than 7.5% of the Company's outstanding shares of Common Stock, if the Company issues Common Stock or securities convertible into or exercisable for Common Stock to (i) a third party that holds at least 30% of the Company's outstanding shares of Common Stock or, (ii) in connection with a collaboration or license transaction to a third party that will initially hold at least the percentage of the Company's outstanding shares of Common Stock represented by the shares originally purchased by Genzyme on February 27, 2014, then the Company will offer Genzyme an opportunity to amend the standstill and voting provisions in the A&R Investor Agreement to be consistent with the terms provided to such third party.

Under the A&R Investor Agreement, Genzyme no longer has registration rights or the conditional right to appoint one individual to the Company's Board of Directors. Genzyme continues to be entitled to certain financial information rights until Genzyme and its affiliates no longer beneficially own at least 2.5% of the Company's outstanding shares of Common Stock.

The foregoing description of each of the Master Agreement, the Form of License Agreement, the Form of Co-Co Collaboration Agreement, the Stock Purchase Agreement, the Investor Agreement, the Collaboration Amendment, the A&R AT3 License Terms and the A&R Investor Agreement does not purport to be complete and is qualified in its entirety by reference to each such agreement, copies of which the Company expects to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2019.

Item 3.02. Unregistered Sales of Equity Securities.

The information set forth under the heading *Equity Placement* in Item 1.01 is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

On April 8, 2019, the Company issued a press release concerning the Regeneron Collaboration and the Equity Transaction, and a press release concerning the Genzyme Collaboration Amendment, copies of which are being furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Report on Form 8-K. The information in this Item 7.01 and Exhibits 99.1 and 99.2 attached hereto is intended to be furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

- 99.1 [Press Release of Alnylam Pharmaceuticals, Inc. announcing Regeneron Collaboration and Equity Transaction, dated April 8, 2019](#)
- 99.2 [Press Release of Alnylam Pharmaceuticals, Inc. announcing Amendment of Genzyme Agreements, dated April 8, 2019](#)

SIGNATURE

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 hereunto duly authorized.

ALNYLAM PHARMACEUTICALS, INC.

Date: April 9, 2019

By: /s/ Laurie B. Keating
Laurie B. Keating
Executive Vice President, Chief Legal Officer