ALNYLAM PHARMACEUTICALS, INC.
Form 8-K
January 13, 2014

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 13, 2014 (January 11, 2014)

Alnylam Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50743**	**77-0602661**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

300 Third Street, Cambridge, MA 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))

Item 1.01. Entry Into a Material Definitive Agreement.

Collaboration

On January 11, 2014, Alnylam Pharmaceuticals, Inc. (the Company) entered into a global, strategic collaboration with Genzyme Corporation (Genzyme), to discover, develop and commercialize RNA interference (RNAi) therapeutics as genetic medicines to treat orphan diseases (the Collaboration). The Collaboration is governed by a Master Collaboration Agreement, dated January 11, 2014, by and between the Company and Genzyme (including the License Terms appended thereto, the Master Agreement), which will become effective upon closing of the Equity Transaction (as defined below) (the Effective Date) and will supersede and replace the previous collaboration between the Company and Genzyme entered into in October 2012 to develop and commercialize RNAi therapeutics targeting transthyretin (TTR) for the treatment of transthyretin-mediated amyloidosis (ATTR).

The Collaboration is structured as an exclusive relationship for the worldwide development and commercialization of RNAi therapeutics in the field of genetic medicines, which includes the Company s current 5x15 and future genetic medicine programs that reach Human Proof-of-Principal (POP) Study Completion (as defined in the Master Agreement) (Human POP) by the end of 2019 (collectively, Collaboration Products), subject to extension to the end of 2021 in various circumstances. The Company retains product rights in North America and Western Europe, while Genzyme obtains exclusive rights to develop and commercialize Collaboration Products in the rest of the world (the Genzyme Territory). Genzyme s rights are structured as an opt-in that is triggered upon achievement of Human POP. The Company maintains development control for all programs prior to Genzyme s opt-in and maintains development and commercialization control after Genzyme s opt-in for all programs in its territory.

Upon the Effective Date, Genzyme will opt-in to patisiran (ALN-TTR02), an RNAi therapeutic currently in a Phase III clinical trial for the treatment of ATTR patients with Familial Amyloidotic Polyneuropathy, for the Genzyme Territory, and the Company will retain full product rights in North America and Western Europe. The Company and Genzyme have also agreed to expand their current collaboration on ALN-TTRsc, an RNAi therapeutic currently in a Phase II clinical trial for the treatment of ATTR patients with TTR amyloid cardiomyopathy, where the parties will co-develop and co-promote ALN-TTRsc in North America and Western Europe. The Company will maintain development and commercialization control with ALN-TTRsc and Genzyme will develop and commercialize the product in the Genzyme Territory.

In addition to its regional rights for the Company s current 5x15 programs and the Company s future genetic medicine programs in the Genzyme territory, Genzyme has the right to either (i) co-develop and co-promote ALN-AT3 for the treatment of hemophilia and other rare bleeding disorders in the Company s territory, with the Company maintaining development and commercialization control, or (ii) obtain a global license to ALN-AS1 for the treatment of hepatic porphyrias. Genzyme will exercise this selection right upon Human POP for the ALN-AT3 and ALN-AS1 programs. Finally, Genzyme has obtained the right for a global license to a single, future genetic medicine program that is not one of the currently defined Company 5x15 programs. The Company retains global rights to any RNAi therapeutic genetic medicine program that does not reach Human POP by the end of 2019, subject to certain limited exceptions. Under the terms of the Agreement, the Company retains full rights to all current and future RNAi therapeutic programs outside of the field of genetic medicines, including the right to form new collaborations.

In consideration for the rights granted to Genzyme under the Master Agreement, Genzyme is required to make payments to the Company for each Collaboration Product upon the achievement of specified development, regulatory and commercial milestones for each (i) regional (e.g., patisiran) and co-developed/co-promoted (e.g., ALN-TTRsc) Collaboration Product totaling up to $75 million and (ii) global Collaboration Product up to $200 million, and to pay tiered double-digit royalties up to twenty percent for each regional and global Collaboration Product based on annual net sales, if any, of each Collaboration Product by Genzyme, its affiliates and sublicensees. In the case of co-developed/co-promoted Collaboration Products, the parties will share profits equally and Alnylam will book product sales in North America and Western Europe.

Under the Master Agreement, the parties will collaborate in the development of option products, with the Company leading development for all programs prior to Genzyme s opt-in and also leading development and commercialization for all programs in the Company s territory after Genzyme s opt-in. Development costs for Collaboration Products once Genzyme exercises an option (or as of the Effective Date for patisiran and ALN-TTRsc) will be shared between Genzyme and the Company as follows, subject to the provisions of the relevant License Terms: (a) for all regional Collaboration Products, Genzyme shall be responsible for twenty percent of the global development costs, (b) for all co-develop/co-promote Collaboration Products, Genzyme shall be responsible for fifty percent of the global development costs, and (c) for all global Collaboration Products, Genzyme shall be responsible for one hundred percent of global development costs. If Genzyme does not exercise its option to license rights to a particular program, the Company will retain the exclusive right to develop and commercialize such program throughout the world, including the right to sublicense to third parties.

The Collaboration will be governed by an alliance joint steering committee that will be comprised of an equal number of representatives from each party. There will also be additional committees to manage various aspects of each regional, co-developed/co-promoted and global program. The Company and Genzyme intend to enter into supply agreements to provide for supply of Collaboration Products to Genzyme for clinical studies, and, at Genzyme s request, commercial sales. Genzyme also has certain rights to manufacture Collaboration Products. Additionally, Genzyme has certain limited opt-out rights, as specified in the Agreement, upon which products revert fully back to the Company with no further obligations to Genzyme.

In addition, under the Master Agreement, the Company and Genzyme have agreed to enter into exclusive discussions and negotiations regarding a potential collaboration around the delivery of small interfering RNAs (siRNAs) to the central nervous system (CNS) with the objective of enabling the discovery of siRNAs for the treatment of CNS disorders.

The Master Agreement (including the License Terms appended thereto) contains certain termination provisions, including for material breach by the other party. Unless terminated earlier pursuant to its terms, the Master Agreement will terminate upon the last to expire of any of the option periods under the Master Agreement or the License Terms appended thereto.

Equity Placement

The Company has agreed to sell to Genzyme 8,766,338 shares of its common stock, par value $.01 per share (the Common Stock), for aggregate cash consideration of $700 million, or $79.85 per share of Common Stock, pursuant to the terms of a Stock Purchase Agreement, dated January 11, 2014, by and between Genzyme and the Company (the Equity Transaction). 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 75,058,054 shares of Common Stock outstanding as of January 11, 2014 (on a pro forma basis), following the Equity Transaction Genzyme will beneficially own approximately 12% of the outstanding shares of Common Stock. 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 Hart-Scott-Rodino Antitrust Improvements Act of 1976, the Equity Transaction is expected to close during the first quarter of 2014.

As a condition to the closing of the Equity Transaction, Genzyme will enter into an investor agreement with the Company (the Investor Agreement). Under the Investor Agreement, until the earlier of the fifth anniversary of the expiration or earlier termination of the Collaboration and the date on which Genzyme and its affiliates cease to beneficially own 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.

Further, Genzyme will agree 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 liquidation or dissolution of the Company. Until Genzyme owns less than 7.5% of the Company s outstanding shares of Common Stock, subject to Genzyme s limited right to maintain its ownership percentage as described below, if the Company issues Common Stock or securities convertible into or exercisable for Common Stock to a third party that holds at least 30% of the Company s outstanding shares of Common Stock or, 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 purchased by Genzyme at the closing of the Equity Transaction, the Company will offer Genzyme an opportunity to amend the standstill and voting provisions in the Investor Agreement to be consistent with the terms provided to such third party.

Under the Investor Agreement, Genzyme will agree not to dispose of any shares of Common Stock beneficially owned by it immediately after the closing of the Equity Transaction until the earlier of (i) December 31, 2019 (subject to extension by up to two years if Genzyme s option to select additional compounds under the Master Agreement is extended beyond December 31, 2019) and (ii) six months after the expiration or earlier valid termination of the Collaboration, in each case subject to earlier termination in the event certain clinical activities under the Collaboration fail to occur (the Lock-Up Period). Following the expiration of the Lock-Up Period, Genzyme will be permitted to sell such shares of Common Stock subject to certain limitations, including volume and manner of sale restrictions. Notwithstanding the foregoing, following the two-year anniversary of the closing of the Equity Transaction, in the event that the market price per share of the Common Stock is at least 100% higher than the market price per share of the Common Stock at closing of the Equity Transaction (in each case based upon a ten-day trailing average), Genzyme may sell up to 25% of its initial shares of Common Stock, subject to certain restrictions on post-Lock-Up Period dispositions as described above.

Under the Investor Agreement, following the Lock-Up Period, Genzyme 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 Genzyme immediately after the closing of the Equity Transaction. In addition, following the Lock-Up Period, subject to certain conditions, Genzyme will be entitled to participate in registered underwritten public offerings by the Company if other selling stockholders are included in the registration.

The Investor Agreement provides that, until Genzyme owns less than 7.5% of the Company s outstanding shares of Common Stock, subject to Genzyme s limited right to maintain its ownership percentage as described herein, in connection with new issuances of Common Stock, subject to certain exceptions, Genzyme will be entitled to a right of first offer to participate proportionally to maintain its then-current ownership percentage of the Company s Common Stock. If Genzyme is not entitled to a right of first offer with respect to a new issuance, Genzyme will have the opportunity, on a post-transaction basis, to purchase additional shares sufficient to maintain its pre-transaction ownership percentage of the Company s Common Stock (subject to the same 7.5% ownership threshold).

In addition, in the event Genzyme and its affiliates acquire at least 20% or more of the outstanding shares of Common Stock, Genzyme will be entitled to appoint one individual to the Company s Board of Directors. Genzyme will also be entitled to certain information rights, including with respect to financial information in the event Genzyme or its affiliates require such information for its own financial reporting purposes.

The rights and restrictions under the Investor Agreement are subject to termination upon the occurrence of certain events. In connection with the closing of the Equity Transaction, the Company s stockholder rights plan will be amended consistent with the terms of the Investor Agreement.

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 January 13, 2014, the Company issued a press release concerning the Collaboration and the Equity Transaction, a copy of which is being furnished as Exhibit 99.1 to this Report on Form 8-K. The information in this Item 7.01 and Exhibit 99.1 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 (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.

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Document
99.1	Press Release issued by the Company, dated January 13, 2014

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: January 13, 2014

By: /s/ Michael P. Mason
Michael P. Mason
Vice President, Finance and Treasurer

Exhibit Index

Number	Description
99.1	Press Release issued by the Company, dated January 13, 2014