ALNYLAM PHARMACEUTICALS, INC.
Form 8-K
January 08, 2018

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 8, 2018 (January 6, 2018)

Alnylam Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36407**	**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))

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.

On January 6, 2018, Alnylam Pharmaceuticals, Inc. (the Company) and Genzyme Corporation (Genzyme) entered into Amendment No. 2 (the Collaboration Amendment) to the Master Collaboration Agreement dated as of 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) (the Original Collaboration Agreement, together with Amendment No. 1 and including the License Terms appended to the Original Collaboration Agreement, the Master Agreement). In connection and simultaneously with entering into the Collaboration Amendment, the Company and Genzyme also entered into the ALN-AT3 Global License Terms with respect to ALN-AT3 (fitusiran) and any back-up products (the AT3 License Terms) and an Exclusive License Agreement with respect to all TTR products, including ALN-TTR02 (patisiran), ALN-TTRsc02 (a subcutaneously administered investigational RNAi therapeutic in clinical development) and any back-up products (the Exclusive TTR License).

The Collaboration Amendment, together with the AT3 License Terms and the Exclusive TTR License, revise the terms and conditions of the Master Agreement to (i) provide the Company the exclusive right to pursue the further global development and commercialization of all TTR products, including ALN-TTR02 (patisiran), ALN-TTRsc02 and any back-up products, (ii) provide Genzyme the exclusive right to pursue the further global development and commercialization of ALN-AT3 (fitusiran) and any back-up products and (iii) terminate the previous co-development and co-commercialization rights related to ALN-TTRsc, ALN-TTRsc02 and ALN-AT3 (fitusiran) under the Master Agreement. Going forward, the Company will fund all development and commercialization costs for ALN-TTR02 (patisiran) and ALN-TTRsc02. The Company also will fund development and commercialization costs for ALN-AT3 (fitusiran) through the transition period, up to a specified cap, after which Genzyme will fund all development and commercialization costs for ALN-AT3 (fitusiran). Each party will be responsible for its costs associated with the transfer of the respective program to the other party.

In consideration for the rights granted to Genzyme under the Collaboration Amendment and the AT3 License Terms, Genzyme is required to make one milestone payment of $50.0 million following the dosing of the first patient in the ATLAS Phase 3 program for ALN-AT3 (fitusiran). In addition, the Company will be eligible to receive tiered royalties of fifteen to thirty percent based on global annual net sales of ALN-AT3 (fitusiran) and up to fifteen percent based on global annual net sales of back-up products, in each case by Genzyme, its affiliates and its sublicensees. Under the Collaboration Amendment and the Exclusive TTR License, Genzyme will be eligible to receive (i) royalties up to twenty-five percent, increasing over time, based on annual net sales of ALN-TTR02 (patisiran) in territories excluding the United States, Canada and western Europe, provided royalties on annual net sales of ALN-TTR02 in Japan will be twenty-five percent beginning as of the effective date of the Exclusive TTR License, (ii) tiered royalties of fifteen to thirty percent based on global annual net sales of ALN-TTRsc02 (consistent with the royalties due to the Company from Genzyme on ALN-AT3 (fitusiran)), and (iii) tiered royalties of up to fifteen percent based on global annual net sales of back-up products, in each case by the Company, its affiliates and its sublicensees. Except as described above, there will be no additional milestones due to either party with respect to ALN-AT3 (fitusiran), ALN-TTR02 (patisiran) or ALN-TTRsc02.

Genzyme continues to have the right to opt into the Company s other rare genetic disease programs for development and commercialization in territories outside of the United States, Canada, and Western Europe, as well as one right to a global license.

The transaction is subject to customary closing conditions and clearances, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act.

The foregoing description of the Collaboration Amendment, the AT3 License Terms and the Exclusive TTR License does not purport to be complete and is qualified in its entirety by reference to the Collaboration Amendment, the AT3 License Terms and the Exclusive TTR License, copies of which the Company expects to file as exhibits to its

Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.

Item 2.02. Results of Operations and Financial Condition.

On January 7, 2018, the Company announced its pipeline goals for 2018 and the Company s continued advancement towards its Alnylam 2020 guidance. The Company also updated its cash guidance for the year ended December 31, 2017, stating that it now expects to end 2017 with greater than $1.7 billion in cash, cash equivalents,

marketable securities, and restricted cash. The information in this Item 2.02 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, 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 of 1933, as amended (the Securities Act), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 7.01. Regulation FD Disclosure.

On January 7, 2018, the Company issued a press release concerning the Collaboration Amendment, a copy of which is being furnished as Exhibit 99.2 to this Report on Form 8-K. The information in this Item 7.01 and Exhibit 99.2 attached hereto is intended to be furnished and shall not be deemed filed for purposes of Section 18 of 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., dated January 7, 2018, announcing 2018 pipeline goals and updating 2017 year-end cash guidance
99.2	Press Release of Alnylam Pharmaceuticals, Inc., dated January 7, 2018, concerning Collaboration Amendment

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 8, 2018

By: /s/ Michael P. Mason
Michael P. Mason

Vice President, Finance and Treasurer