ALNYLAM PHARMACEUTICALS, INC.
Form 8-K
April 03, 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): April 3, 2018 (March 28, 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 March 28, 2018, Alnylam Pharmaceuticals, Inc. (the Company) and Agilent Technologies, Inc. (Agilent) entered into a Manufacturing Services Agreement (the Agreement) providing for the commercial supply of patisiran drug substance by Agilent.

Pursuant to the Agreement, Agilent has agreed to manufacture and supply to the Company, and the Company has agreed to purchase from Agilent, subject to any conflicting obligations under the Company s third-party agreements, a specified percentage of the active pharmaceutical ingredients required for patisiran for commercial sale (the Product). The Company will be required to provide rolling forecasts for the Product on a quarterly basis, a portion of which will be considered a binding, firm order. The firm order portion will be adjusted after the first-year post-marketing authorization of the Product in the United States. Agilent will be required to reserve sufficient capacity (including labor, materials and equipment) to ensure that it can supply the Product in the amounts specified under such firm orders, including a certain percentage of the remaining, non-binding portions of each forecast, as well as a specified number of batches each year. Under the Agreement, pricing of the Product is to be determined in each statement of work. The Company will be required to provide an initial payment to cover raw material purchases and reserve appropriate resources. Final payment for any batch of Product shall only be made by the Company following acceptance of the Product.

The Agreement has an initial term of five years, which is subject to automatic renewal terms of two years absent earlier termination by either party during a renewal term in accordance with the terms of the Agreement.

The Company may terminate the Agreement or any purchase order thereunder (subject, in certain instances, to penalties), (a) upon sixty days prior written notice: (i) if Agilent is or will be unable to perform the services in accordance with agreed upon terms; (ii) in the event Agilent fails to obtain or maintain any material licenses or approvals; or (iii) if Agilent materially breaches certain of its obligations relating to maintenance of its business, subject to Agilent s right to cure such breach; and (b) upon thirty days prior written notice if the Company determines patisiran is not commercially viable.

Each party also has the right to terminate the Agreement for other customary reasons such as material breach and bankruptcy.

The Agreement contains provisions relating to compliance by Agilent with current Good Manufacturing Practices, certain business operating standards, cooperation with regulatory efforts, audit rights, indemnification and limitations of liability, confidentiality, dispute resolution, assignment and other customary matters for an agreement of this kind.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which the Company expects to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.

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 3, 2018

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

Vice President, Finance and Treasurer