

ALNYLAM PHARMACEUTICALS, INC.

Form 8-K

September 07, 2017

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): September 7, 2017

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 8.01. Other Events.

On September 7, 2017, Alnylam Pharmaceuticals, Inc. (the Company) announced an update on its fitusiran and givosiran investigational RNAi therapeutic programs. The Company reported a fatal thrombotic event in a patient with hemophilia A without inhibitors in its Phase 2 open label extension study of fitusiran, an RNAi therapeutic in development for the treatment of hemophilia A and B with or without inhibitors. As a result, the Company has suspended dosing in all ongoing fitusiran studies pending further review of the safety event and development of a risk mitigation strategy. In addition, the Company reported that it has reached alignment with the U.S. Food and Drug Administration on a Phase 3 study design for givosiran, an RNAi therapeutic in development for the treatment of acute hepatic porphyrias.

The information in Item 8.01 of this Form 8-K (including Exhibit 99.1) 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

The following exhibit relating to Item 8.01 shall be deemed to be furnished, and not filed:

99.1 Press Release dated September 7, 2017.

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.

Date: September 7, 2017

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ Laurie B. Keating
Laurie B. Keating
Senior Vice President, General Counsel and
Secretary

EXHIBIT INDEX

| Exhibit No. | Description |
|------------------------|--|
| 99.1 | <u>Press Release dated September 7, 2017</u> |