ALNYLAM PHARMACEUTICALS, INC.
Form 8-K
October 22, 2012

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): October 22, 2012 (October 18, 2012)

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.

On October 18, 2012, Alnylam Pharmaceuticals, Inc. (the Company) and Genzyme Corporation (Genzyme), entered into a License and Collaboration Agreement (the Genzyme Agreement) pursuant to which the Company granted to Genzyme an exclusive license in Japan and the Asia-Pacific region (the Genzyme Territory) to develop and commercialize specified RNA interference (RNAi) therapeutics targeting transthyretin (TTR) for the treatment of transthyretin-mediated amyloidosis (ATTR) and other human diseases. The Genzyme Agreement covers ALN-TTR02 and ALN-TTRsc, and may in the future cover additional TTR-specific RNAi therapeutic compounds that comprise the Company s TTR program (together, Licensed Products), subject, in the case of Improvement Products (as defined in the Genzyme Agreement), to specified additional terms and conditions. The Company retains all development and commercialization rights worldwide outside of the Genzyme Territory.

In consideration for the rights granted to Genzyme under the Genzyme Agreement, Genzyme is required to pay to the Company an upfront cash payment of $22.5 million. In addition, Genzyme is required to make payments to the Company upon the achievement of specified development and regulatory milestones totaling up to $50.0 million, and to pay tiered royalties expected to yield an effective royalty rate percentage ranging from the mid-teens to mid-twenties based on annual net sales, if any, of Licensed Products in the Genzyme Territory by Genzyme, its affiliates and sublicensees.

Under the Genzyme Agreement, the parties will collaborate in the development of Licensed Products, with Genzyme assuming primary responsibility for the development and commercialization of Licensed Products in the Genzyme Territory and the Company retaining primary responsibility for the development and commercialization of Licensed Products in the rest of the world. The collaboration between Genzyme and the Company will be governed by a joint steering committee that will be comprised of an equal number of representatives from each party. Under the agreement, Genzyme is establishing a development plan for the ALN-TTR program relating to the development activities to be undertaken in the Genzyme Territory. Genzyme is responsible, at its expense, for all development activities under the development plan that are reasonably necessary for the regulatory approval and commercialization of an RNAi therapeutic for the treatment of ATTR in the Genzyme Territory. The Company and Genzyme intend to enter into a supply agreement to provide for supply of Licensed Products to Genzyme for clinical studies, and, at Genzyme s request, commercial sales. Genzyme may elect, at any time during the term of the Genzyme Agreement, to manufacture Licensed Products itself or arrange for a third party to manufacture the product.

Genzyme also has a right of first negotiation in the event that the Company desires to grant any third party rights to develop and/or commercialize a Licensed Product for the treatment of ATTR or other human diseases outside of the Genzyme Territory.

Unless terminated earlier in accordance with the terms of the agreement, the Genzyme Agreement expires on a Licensed Product-by-Licensed Product and country-by-country basis upon the last to expire royalty term for any Licensed Product in any country, where a royalty term is defined as the latest to occur of (1) the expiration of the last valid claim of certain Company patents or joint patents covering a Licensed Product, (2) the expiration of the Regulatory Exclusivity (as

defined in the Genzyme Agreement), and (3) twenty-five years from first commercial sale of such Licensed Product in such country (or twelve years from the first commercial sale of such Licensed Product in such country if Genzyme so elects). The Company estimates that its fundamental RNAi patents covering ALN-TTR compounds under the Genzyme Agreement will expire both in and outside of the United States generally between 2016 and 2021. The Company also estimates that its patents covering ALN-TTR compounds under the Genzyme Agreement in the United States and elsewhere would expire in 2032. These patent rights are subject to potential patent term extensions and/or supplemental protection certificates extending such terms in countries where such extensions may become available. In addition, more patent filings relating to the collaboration may be made in the future. Either party may terminate the Genzyme Agreement in the event the other party fails to cure a material breach or in the event that development ends after a specified time period without regulatory approval of a Licensed Product. The Company may terminate the agreement upon patent-related challenges by Genzyme. Genzyme has the right to terminate the agreement without cause at any time upon six months prior written notice. In addition, Genzyme may terminate the agreement upon forty-five days prior written notice if Genzyme determines that specified success criteria have not been met following the completion of a Phase II clinical study.

During the period from the effective date of the Genzyme Agreement until the first commercial sale of a Licensed Product in a country in the Genzyme Territory, and thereafter during any period as to which Genzyme is paying the Company any royalties on net sales of any Licensed Product in such country, neither party will, alone or with an affiliate or third party, develop or commercialize in such country, any product for the treatment of ATTR, other than a Licensed Product or an agreed complementary product, without the prior written agreement of the other party.

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: October 22, 2012

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

Vice President, Finance and Treasurer