ALNYLAM PHARMACEUTICALS, INC.
Form 8-K
February 04, 2013

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): February 4, 2013 (February 3, 2013)

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 February 3, 2013, Alnylam Pharmaceuticals, Inc. (the Company) and The Medicines Company (MedCo), entered into a license and collaboration agreement (the MedCo Agreement) pursuant to which the Company granted to MedCo an exclusive, worldwide license to develop, manufacture and commercialize RNA interference (RNAi) therapeutics targeting proprotein convertase subtilisin/kexin type 9 (PCSK9) for the treatment of hypercholesterolemia and other human diseases, including ALN-PCS02, an intravenously administered RNAi therapeutic which has completed a Phase I clinical trial, and ALN-PCSsc, a subcutaneously administered RNAi therapeutic currently in pre-clinical development (collectively, Licensed Products).

In consideration for the rights granted to MedCo under the MedCo Agreement, MedCo is required to pay to the Company an upfront cash payment of $25.0 million. In addition, MedCo is required to make payments to the Company upon the achievement of specified clinical development, regulatory approval and commercial milestones totaling up to $180.0 million, and to pay scaled double-digit royalties based on annual worldwide net sales, if any, of Licensed Products by MedCo, its affiliates and sublicensees, subject to reduction under specified circumstances.

Under the MedCo Agreement, the parties will collaborate in the further development of Licensed Products. The Company will retain responsibility for the development of Licensed Products until Phase I Completion (as defined in the MedCo Agreement) at its cost, up to an agreed upon initial development cost cap. MedCo will assume all other responsibility for the development and commercialization of Licensed Products, at its sole cost. Initially the collaboration will include the development of both ALN-PCS02 and ALN-PSCsc in parallel, provided that the parties intend to select one of ALN-PCS02 or ALN-PSCsc for ongoing development at a specified development stage, in accordance with the terms of the MedCo Agreement. The collaboration between MedCo and the Company will be governed by a joint steering committee that will be comprised of an equal number of representatives from each party.

The Company will be solely responsible for obtaining supply of finished product reasonably required for the conduct of its obligations under the initial development plan through Phase I Completion, and supplying MedCo with finished product reasonably required for the first Phase II study of a Licensed Product conducted by MedCo, at the Company s expense, provided such costs do not exceed the development costs cap, subject to certain exceptions. After such time, MedCo will have the sole right and responsibility to manufacture and supply Licensed Product for development and commercialization under the MedCo development plan, subject to the terms of the MedCo Agreement. The Company and MedCo intend to enter into a supply and technical transfer agreement to provide for supply of Licensed Products to MedCo within a specified time following the effective date of the MedCo Agreement.

Unless terminated earlier in accordance with the terms of the agreement, the MedCo Agreement expires on a Licensed Product-by-Licensed Product and country-by-country basis upon expiration of the last 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 patent rights

covering a Licensed Product, (2) the expiration of the Regulatory Exclusivity (as defined in the MedCo Agreement), and (3) the twelfth anniversary of the first commercial sale of the Licensed Product in such country. The Company estimates that its fundamental RNAi patents covering Licensed Products under the MedCo Agreement will expire both in and outside of the United States generally between 2015 and 2023. The Company also estimates that its ALN-PCS product-specific patents covering Licensed Products under the MedCo Agreement in the United States and elsewhere would expire at the end of 2033. 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 MedCo Agreement in the event the other party fails to cure a material breach or upon patent-related challenges by the other party. The Company may terminate the agreement in the event that a lead Licensed Product has not been designated by the joint steering committee within a designated time period. In addition, MedCo has the right to terminate the agreement without cause at any time upon four months prior written notice.

During the term of the MedCo Agreement, neither party will, alone or with an affiliate or third party, research, develop or commercialize, or grant a license to any third party to research, develop or commercialize, in any country, any product directed to the PCSK9 gene, other than a Licensed Product, without the prior written agreement of the other party, subject to the terms of the MedCo Agreement.

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: February 4, 2013

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

Vice President, Finance and Treasurer