ALNYLAM PHARMACEUTICALS, INC.
Form 8-K
November 13, 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): November 13, 2012 (November 12, 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 November 12, 2012, Alnylam Pharmaceuticals, Inc. (the Company) announced that it has restructured its relationship with Tekmira Pharmaceuticals Corporation (TPC) and Protiva Biotherapeutics, Inc., a wholly-owned subsidiary of TPC (Protiva, and, together with TPC, Tekmira) with a new license agreement and that the parties have resolved all litigation between them pursuant to a settlement agreement. In addition, the Company has elected to independently manufacture its lipid nanoparticle (LNP) -based RNAi therapeutic products and to buy-down certain future potential milestone payments and a significant portion of future potential royalties for its ALN-VSP, ALN-PCS, and ALN-TTR programs.

Cross-License Agreement

On November 12, 2012, the Company, Tekmira and Protiva entered into a Cross-License Agreement (the Cross-License Agreement). In connection with the execution of the Cross-License Agreement, the parties agreed to terminate certain prior agreements, including: (i) the Amended and Restated License and Collaboration dated May 30, 2008 between the Company and TPC (the Prior TPC Agreement); (ii) the Amended and Restated Cross-License Agreement dated May 30, 2008 between the Company and Protiva (the Prior Protiva Agreement, and, together with the Prior TPC Agreement, the Prior License Agreements); and (iii) the Development, Manufacturing and Supply Agreement dated January 2, 2009 between the Company and TPC (the Manufacturing Agreement). The Company and Tekmira also agreed to supersede the rights and obligations under the Supplemental Agreement dated July 27, 2009 between the Company, TPC, Protiva, AlCana Technologies, Inc. (AlCana) and the University of British Columbia (UBC), as between themselves, with the rights and obligations set forth in the Cross-License Agreement.

Under the Cross-License Agreement, the parties have consolidated certain intellectual property related to LNP technology for the systemic delivery of RNAi therapeutics. Specifically, certain patents and patent applications, including the MC3 lipid family, will be assigned by the Company to Tekmira. The Company retains rights to use this intellectual property for the research, development and commercialization of RNAi therapeutic products, including the rights to sublicense this intellectual property on a product-by-product basis. Tekmira has also granted the Company a worldwide license to its LNP technology for the research, development and commercialization of LNP-based RNAi therapeutics, which license shall be exclusive for up to eight targets designated by the Company, and otherwise shall be non-exclusive. The Company has the right to sublicense on a product-by-product basis.

In addition, the Company has elected to buy out its manufacturing obligations to TPC with respect to its LNP-based pipeline programs. Pursuant to the terms of the Cross-License Agreement, the Company will make a one-time payment of $30 million to Tekmira for the termination of, and release of the Company from, all of the Company s obligations under the Manufacturing Agreement, including without limitation the obligations to obtain materials and/or services from TPC. The Company will also have the right to manufacture and have manufactured its LNP-based RNAi therapeutics, which right may be sublicensed to the Company s collaborators.

Further, the Company has elected to buy-down certain future potential milestone and royalty payments due to Tekmira for certain of its RNAi therapeutics, formulated using LNP technology. Specifically, pursuant to the Cross-License Agreement, the Company will make a one-time payment of $35 million to Tekmira, which amount shall constitute payment for the termination of the Prior License Agreements and the parties rights and obligations thereunder, as well as the buy-down of certain milestone payments and the significant reduction of royalty rates for ALN-VSP, ALN-PCS and ALN-TTR. Under the Cross-License Agreement, Tekmira will be eligible to receive an aggregate of $10 million in contingent milestone payments related to advancement of ALN-VSP and ALN-TTR, which now represent the only potential milestones for ALN-VSP, ALN-PCS and ALN-TTR LNP-based RNAi therapeutics. Specifically, Tekmira is eligible to receive a $5 million milestone payment upon each of (i) the initiation of a Phase III clinical trial of an LNP-based ALN-TTR therapeutic, and (ii) the manufacture of ALN-VSP clinical trial material for use in China.

Consistent with the Prior License Agreements, under the Cross-License Agreement, Tekmira is eligible to receive up to an aggregate of $16.0 million in milestone payments for any future RNAi therapeutic formulated using Tekmira LNP technology, excluding ALN-VSP, ALN-PCS and ALN-TTR, together with low single-digit royalty payments on annual product sales, if any.

Under the Cross-License Agreement, Tekmira maintains the three exclusive and five non-exclusive licenses previously granted by the Company under the Prior License Agreements to research, develop and commercialize RNAi therapeutics directed to up to eight gene targets. In addition, the Company has granted Tekmira a non-exclusive license for two additional gene targets, on the same terms and conditions as the prior non-exclusive licenses. In connection with the Settlement Agreement described below, Tekmira also acquired from AlCana its existing options for three additional non-exclusive licenses, which have been included under the Cross-License Agreement. Tekmira may sublicense these rights on a product-by-product basis. The Company has waived its right under the Prior License Agreements to opt-in to the Tekmira research program directed to PLK1.

Under the Cross-License Agreement, the Company is eligible to receive from Tekmira up to an aggregate of $8.5 million in milestone payments for RNAi therapeutics directed to nine of the targets for which the Company has granted licenses to Tekmira, together with single-digit royalties on annual product sales, if any, of RNAi therapeutic products directed to all thirteen of the targets for which the Company has granted licenses to Tekmira.

The term of the Cross-License Agreement generally ends upon the expiration of the last-to-expire royalty term. Royalties are payable on a product-by-product and country-by-country basis commencing on the first commercial sale of a product in a country and continuing during any period in which (a) in the case of Company products, a valid claim within the Tekmira Royalty-Bearing Patents (as defined in the Cross-License Agreement) covers the applicable Company product in such country of sale, or (b) in the case of Tekmira products, a valid claim within the Company patents covers the applicable Tekmira product in such country of sale. The Company estimates that its fundamental RNAi patents covered under the Cross-License Agreement will expire both in and outside the United States generally between 2019 and 2021,

and that the Tekmira LNP patents covered under the Cross-License Agreement will expire both in and outside the United States generally between 2020 and 2030, subject in each case to any potential patent term extensions and/or supplemental protection certificates extending such term extensions in countries where such extensions may become available. Either party may terminate a license it granted to the other in the event that the other party fails to cure a material breach of its obligations relating to that license. Furthermore, either party may terminate the Cross-License Agreements in the event the other party fails to cure a material breach of an obligation under the agreement. In addition, either party may terminate the Cross-License Agreement upon patent-related challenges by the other party.

Settlement Agreement

On November 12, 2012, the Company, TPC, Protiva and AlCana entered into a Settlement Agreement and General Release (the Settlement Agreement) resolving all ongoing litigation, as well as the interference proceeding between the Company and Protiva. The terms of the Settlement Agreement include mutual releases and dismissal with prejudice of all claims and counterclaims in the following litigation between the parties: (i) *Tekmira Pharmaceuticals Corp., et al. v. Alnylam Pharmaceuticals, Inc., et al.*, Civ. A. No. 11-1010-BLS2, pending in the Business Litigation Section of the Massachusetts Superior Court for Suffolk County; (ii) *Tekmira Pharmaceuticals Corp. v. Michael Hope, et al*., No. S117660, pending in the Supreme Court of British Columbia, Canada; (iii) *Alnylam Pharmaceuticals, Inc., et al. v. Tekmira Pharmaceuticals Corp.*, Civ. A. No. 1:12-CV-10087, pending in the United States District Court for the District of Massachusetts; and (iv) *Alnylam Pharmaceuticals, Inc., et al. v. Tekmira Pharmaceuticals Corp*., Court File No. T-1783-12, pending in the Federal Court of Canada. In addition, as part of the Settlement Agreement, the parties have agreed to a covenant not to sue one another in the future on matters released under the Settlement Agreement, as well as substantial liquidated damages to be paid by any party that breaches such covenant. The parties have also agreed to resolve any future disputes that may arise over the next three years through binding arbitration.

Pursuant to the Settlement Agreement, the Company and Tekmira also agreed to resolve the interference proceeding declared by the Unites States Board of Patent Appeals and Interferences between the Company and Protiva, captioned *Protiva Biotherapeutics, Inc. v. Alnylam Pharmaceuticals, Inc.*, Patent Interference No. 105792.

Item 1.02. Termination of a Material Definitive Agreement.

As more fully described above, on November 12, 2012, in connection with the restructuring of their relationship and the execution of the Cross-License Agreement, the Company, TPC and Protiva agreed to terminate the Prior TPC Agreement, the Prior Protiva Agreement and the Manufacturing Agreement.

Item 7.01. Regulation FD Disclosure.

On November 12, 2012, the Company announced that it has restructured its relationship with Tekmira and settled all outstanding litigation with Tekmira. As a result of the payments to

be made by the Company in connection with this restructuring, the Company will incur a $65 million charge to operating expenses during the quarter ended December 31, 2012. In addition, as a result of these payments, the Company has updated its cash guidance and now expects to end 2012 with greater than $215 million in cash, cash equivalents and marketable securities.

The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 and Item 9.01 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

99.1 Press Release dated November 12, 2012.

Forward-Looking Statements

Various statements in this release concerning the Company s future expectations, plans and prospects, including without limitation, statements regarding the Company s views with respect to the outcome of this settlement and the restructuring of its relationship with Tekmira, its expectations regarding the payment to and receipt from Tekmira of future milestones and royalties, its plans with respect to the manufacture of LNP-based RNAi therapeutics, its expected cash position as of December 31, 2012, and its expectations regarding its Alnylam 5x15 product strategy, constitute forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including, without limitation, the Company s ability to successfully advance RNAi therapeutics, in particular ALN-VSP, ALN-PCS and ALN-TTR, resulting in the potential achievement of milestone and royalty events and thus the benefit to the Company of the buy-down of such payments, the Company s ability to manufacture or have manufactured its LNP-based RNAi therapeutics for clinical and commercial use, obtaining, maintaining and protecting intellectual property and the Company s dependence on Tekmira for the protection of and access to certain LNP intellectual property, obtaining regulatory approval for products, competition from others using technology similar to the Company s and others developing products for similar uses, the Company s ability to raise additional capital, and the Company s ability to establish and maintain strategic business alliances and new business initiatives, as well as those risks more fully discussed in the Risk Factors section of its most recent quarterly report on Form 10-Q on file with the Securities and Exchange Commission. In addition, any forward-looking statements represent the Company s views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company does not assume any obligation to update any forward-looking statements.

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: November 13, 2012

By: /s/ Michael P. Mason
Michael P. Mason
Vice President, Finance and Treasurer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated November 12, 2012.