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ALNYLAM PHARMACEUTICALS, INC.

Form 8-K November 04, 2009 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 4, 2009 (October 29, 2009)

Alnylam Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware 000-50743 77-0602661

(IRS Employer

(State or Other Jurisdiction (Commission

Identification

of Incorporation) File Number) 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.

Roche Alliance

In July 2007, Alnylam Pharmaceuticals, Inc. (the "Company") and, for limited purposes, Alnylam Europe AG, entered into a license and collaboration agreement (the "LCA") with F. Hoffmann-La Roche Ltd ("Roche Basel") and Hoffmann-La Roche Inc. (together with Roche Basel, "Roche"). Under the LCA, the Company granted Roche a non-exclusive license to the Company's intellectual property to develop and commercialize therapeutic products that function through RNA interference ("RNAi"), subject to the Company's existing contractual obligations to third parties. Under the LCA, the Company and Roche also agreed to collaborate on the discovery of RNAi therapeutic products directed to one or more disease targets ("Discovery Collaboration"), subject to the Company's existing contractual obligations to third parties. On October 29, 2009, the Company and Roche advanced their alliance to initiate this therapeutic collaboration stage. Under this new phase of the collaboration, the Company and Roche will jointly collaborate on the discovery and development of specific RNAi therapeutic products and each party will contribute key delivery technologies in the effort, which is focused on specific disease targets. The Company and Roche intend to co-develop and co-commercialize RNAi therapeutic products in the U.S. market and the Company is eligible to receive additional milestone and royalty payments for products developed in the rest of the world, if any. After a pre-specified period of collaborative activities, each party will have the option to opt-out of the day-to-day development activities in exchange for reduced milestones and royalty payments in the future. The Discovery Collaboration will be governed by the joint steering committee that is comprised of an equal number of representatives from each party.

Cubist Alliance

On January 9, 2009, the Company entered into a License and Collaboration Agreement (the "Cubist Agreement") with Cubist Pharmaceuticals, Inc. ("Cubist") to develop and commercialize therapeutic products ("Licensed Products") based on certain of the Company's RNAi technology for the treatment of respiratory syncytial virus ("RSV") infection. Licensed Products initially included ALN-RSV01, as well as several other second-generation RNAi-based RSV inhibitors.

On November 2, 2009, the Company and Cubist entered into an amendment to the Cubist Agreement (the "Amendment"), which provides that the parties will focus their collaboration and joint development efforts on ALN-RSV02, a second-generation compound, for use in pediatric patients. Consistent with the original Cubist Agreement, the Company and Cubist will each bear one-half of the related development costs for ALN-RSV02. Pursuant to the terms of the Amendment, the Company will continue to develop ALN-RSV01 for adult transplant patients in its sole discretion and at its sole expense. Cubist has the right to resume the collaboration on ALN-RSV01 again in the future, which right may be exercised for a specified period of time following the completion of the Company's planned Phase IIb trial of ALN-RSV01 in adult lung transplant patients infected with RSV, subject to the payment by Cubist of an opt-in fee representing reimbursement of an agreed upon percentage of the Company's future development expenses for ALN-RSV01.

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Item 2.02. Results of Operations and Financial Condition.

On November 4, 2009, the Company announced its financial results for the quarter ended September 30, 2009. 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 2.02. 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 5.02. Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers; Compensatory Arrangements of Certain Officers.

The Company announced that, on October 29, 2009, Edward Scolnick, M.D. informed the Company that he will not stand for re-election as a Director at the Company's 2010 Annual Meeting of Stockholders. Dr. Scolnick will remain on the Company's Board of Directors for the remainder of his term.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

99.1 Press Release dated November 4, 2009.

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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 4, 2009 By: /s/ Patricia L. Allen

Patricia L. Allen

Vice President of Finance and Treasurer