

ALNYLAM PHARMACEUTICALS, INC.

Form 8-K

January 15, 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): January 15, 2009 (January 9, 2009)

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 January 9, 2009, Alnylam Pharmaceuticals, Inc. ("Alnylam") entered into a License and Collaboration Agreement (the "Agreement") with Cubist Pharmaceuticals, Inc. ("Cubist") to develop and commercialize therapeutic products ("Licensed Products") based on certain of Alnylam's RNA interference ("RNAi") technology for the treatment of respiratory syncytial virus ("RSV"). Licensed Products include Alnylam's ALN-RSV01, which is currently in Phase II clinical development for the treatment of RSV infection in adult lung transplant patients, as well as several other second-generation RNAi-based RSV inhibitors, which currently are in pre-clinical studies.

Under the terms of the Agreement, Alnylam and Cubist will share responsibility for developing Licensed Products in North America and will each bear one-half of the related development costs. Alnylam's collaboration with Cubist for the development of Licensed Products in North America will be governed by a joint steering committee comprised of an equal number of representatives from each party. Cubist will have the sole right to commercialize Licensed Products in North America with costs associated with such activities and any resulting profits or losses to be split equally between Alnylam and Cubist. Throughout the rest of the world (the "Royalty Territory"), excluding Asia, where Alnylam has previously partnered its ALN-RSV program with Kyowa Hakko Kirin Co., Ltd., Cubist will have an exclusive, royalty-bearing license to develop and commercialize Licensed Products.

In consideration for the rights granted to Cubist under the Agreement, Cubist is obligated to make a \$20.0 million upfront cash payment to Alnylam. Cubist also has an obligation under the Agreement to pay Alnylam milestone payments, totaling up to an aggregate of \$82.5 million, upon the achievement of specified development and sales events in the Royalty Territory. In addition, if Licensed Products are successfully developed, Cubist will be required to pay to Alnylam double digit royalties on net sales of Licensed Products in the Royalty Territory, if any, subject to offsets under certain circumstances. Upon achievement of certain development milestones, Alnylam will have the right to convert the North American co-development and profit sharing arrangement into a royalty-bearing license and, in addition to royalties on net sales in North America, will be entitled to receive additional milestone payments totaling up to an aggregate of \$130.0 million upon achievement of specified development and sales events in North America, subject to the timing of the conversion by Alnylam and the regulatory status of a Licensed Product at the time of conversion. If Alnylam makes the conversion to a royalty-bearing license with respect to North America, then North America becomes part of the Royalty Territory.

Unless terminated earlier in accordance with the Agreement, the Agreement expires on a country-by-country and Licensed Product-by-Licensed Product basis, (a) with respect to the Royalty Territory, upon the latest to occur of: (i) the expiration of the last-to-expire Alnylam patent covering a Licensed Product, (ii) the expiration of the Regulatory-Based Exclusivity Period (as defined in the Agreement) and (iii) ten years from first commercial sale in such country of such License Product by Cubist or its affiliates or sublicensees, and (b) with respect to North America, if Alnylam has not converted North America into the Royalty Territory, upon the termination of the Agreement by Cubist upon specified prior written notice. Alnylam estimates that its fundamental RNAi patents covered under the Agreement will expire both in and outside of the United States generally between 2016 and 2025. Allowed claims covering ALN-RSV01 in the United States would expire in 2026. These patent rights are subject to any potential patent term extensions and/or supplemental protection certificates

extending such term extensions in countries where such extensions may become available. In addition, more patent filings relating to the collaboration may be made in the future. Cubist has the right to terminate the Agreement at any time (i) upon three months prior written notice if such notice is given prior to the acceptance for filing of the first application for regulatory approval of a Licensed Product or (ii) upon nine months prior written notice if such notice is given after the acceptance for filing of the first application for regulatory approval. Either party may terminate the Agreement in the event the other party fails to cure a material breach or upon patent-related challenges by the other party.

During the term of the Agreement, neither party nor its affiliates may develop, manufacture or commercialize anywhere in the world, outside of Asia, a therapeutic or prophylactic product that specifically targets RSV, except for Licensed Products developed, manufactured or commercialized pursuant to the 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: January 15, 2009

By: /s/ Patricia L. Allen
Patricia L. Allen
Vice President of Finance and Treasurer