

ALNYLAM PHARMACEUTICALS, INC.

Form 8-K

September 12, 2007

**Table of Contents**

**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): September 12, 2007 (September 6, 2007)  
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))
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**TABLE OF CONTENTS**

Item 1.01. Entry into a Material Definitive Agreement.

SIGNATURE

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**Table of Contents**

**Item 1.01. Entry into a Material Definitive Agreement.**

**Limited Liability Company Agreement**

On September 6, 2007, Alnylam Pharmaceuticals, Inc. ( "Alnylam" ) entered into a joint venture with Isis Pharmaceuticals, Inc., a Delaware corporation ( "Isis" ), to create a new Delaware limited liability company, Regulus Therapeutics LLC ( "Regulus" ), which will focus on the discovery, development and commercialization of microRNA ( "miRNA" ) therapeutics. Alnylam and Isis each own approximately one half of Regulus.

Under the terms of the Limited Liability Agreement among Alnylam, Isis and Regulus (the "LLC Agreement" ), Regulus will be operated as an independent company and governed by a managing board comprised of an equal number of directors appointed by each of Alnylam and Isis. In consideration for Alnylam's and Isis' initial interests in Regulus, Alnylam and Isis each agreed to grant Regulus exclusive licenses to their intellectual property for certain miRNA therapeutic applications as well as certain patents in the miRNA field. In addition, Alnylam agreed to make an initial cash contribution to Regulus of \$10 million, resulting in Alnylam and Isis making approximately equal aggregate initial capital contributions to Regulus. Additional capital contributions to Regulus by Alnylam and Isis are expected to be made pursuant to a mutually approved operating plan. Subject to specified exceptions, and exclusive of distributions made in connection with the dissolution of Regulus, any allocations or distributions by Regulus of property or income will be made on a pro rata basis to Alnylam and Isis in accordance with their percentage interests.

The LLC Agreement will remain in effect until such time as Regulus is dissolved in accordance with the terms of the LLC Agreement, as described below. Subject to certain conditions, each of Alnylam and Isis have the right to initiate a buy-out of Regulus' assets, including Regulus' intellectual property and rights to licensed intellectual property. The LLC Agreement provides that following such initiation of a buy-out, Alnylam and Isis will mutually determine whether to sell Regulus to Alnylam, Isis or a third party, provided, however, that if Alnylam and Isis are unable to negotiate such a sale, Regulus will distribute and assign its rights, interests and assets to Alnylam and Isis in accordance with their percentage interests, except for Regulus' intellectual property and license rights, to which each of Alnylam and Isis will receive co-exclusive rights, subject to certain specified exceptions. Subject to certain conditions, following such a distribution, Alnylam and Isis can gain exclusive rights to Regulus' research programs and development projects, if any.

The LLC Agreement provides for the dissolution of Regulus upon the earlier of (A) the written consent of both Alnylam and Isis, (B) the bankruptcy or dissolution of either Alnylam or Isis, subject to certain exceptions, or (C) the occurrence of an event specified under non-waivable provisions of applicable laws or regulations. In the event of dissolution, Regulus' net proceeds and assets generally will be distributed to Alnylam and Isis pro rata in accordance with their percentage interests in Regulus.

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**Table of Contents**

**License and Collaboration Agreement**

On September 6, 2007, in connection with the execution of the LLC Agreement, Alnylam, Isis and Regulus entered into a license and collaboration agreement (the "Collaboration Agreement") to pursue the discovery, development and commercialization of therapeutic products directed to miRNAs.

*Intellectual Property Assignment and Licenses*

Under the terms of the Collaboration Agreement, Alnylam and Isis each assigns to Regulus specified patents and contracts covering miRNA-specific technology. In addition, each of Alnylam and Isis grants to Regulus an exclusive, worldwide license under its rights to other miRNA-related patents and know-how to develop and commercialize therapeutic products containing compounds that are designed to interfere with or inhibit a particular miRNA, subject to Alnylam's and Isis' existing contractual obligations to third parties. Regulus is also granted the right to request a license from Alnylam and Isis to develop and commercialize therapeutic products directed to other miRNA compounds, which license is subject to Alnylam's and Isis' approval and to each such party's existing contractual obligations to third parties. Regulus also grants to Alnylam and Isis an exclusive license to technology developed or acquired by Regulus for use solely within Alnylam's and Isis' respective fields (as defined in the Collaboration Agreement), but specifically excluding the right to develop, manufacture or commercialize the therapeutic products for which Alnylam and Isis granted rights to Regulus.

*Development and Commercialization*

After a sufficient portfolio of data is obtained with respect to each miRNA compound drug candidate developed by Regulus, Regulus may elect to continue to pursue the development and commercialization of products directed to such miRNA compound and related miRNA compounds, in which event Regulus would be obligated to pay each of Alnylam and Isis a royalty on net sales of any such resulting products.

If Regulus decides not to continue to pursue the development and commercialization of products directed to particular miRNA compounds, either Alnylam or Isis may pursue development and commercialization of such Regulus products. Development and commercialization of such products by either Alnylam or Isis would be subject to the payment to Regulus of a specified upfront fee, royalties on net sale, milestone payments upon achievement of specified regulatory events, and a portion of income received from sublicensing rights.

The commercializing party is obligated to use commercially reasonable efforts to develop and commercialize a therapeutic product containing such miRNA compound drug candidate.

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**Table of Contents**

*Coordination*

The Board of Directors of Regulus is responsible for overseeing the management of Regulus while each party is responsible for its own development and commercialization activities. Certain decisions of Regulus must be approved by each of Alnylam and Isis under the LLC Agreement.

*Termination*

The Collaboration Agreement ends if, prior to first commercial sale of any product, all development activities cease under the collaboration. The Collaboration Agreement otherwise expires, on a product-by-product and country-by-country basis, upon the later of expiration of marketing exclusivity for such product or a specified number of years from first commercial sale. If Regulus, Alnylam or Isis commits an uncured material breach of the Collaboration Agreement, the Collaboration Agreement may be terminated with respect to the breaching party or a buy-out may be initiated under the LLC Agreement, depending on the nature of the breach.

**Services Agreement**

In connection with the execution of the LLC Agreement and License Agreement, on September 6, 2007, Alnylam also executed a Services Agreement (the "Services Agreement") with Isis and Regulus. Under the terms of the Services Agreement, Alnylam and Isis agreed to provide to Regulus, for the benefit of Regulus, certain research and development ("R&D") and general and administrative services, as set forth in an operating plan mutually agreed upon by Alnylam and Isis. The Services Agreement provides that Alnylam and Isis generally will be paid by Regulus for R&D services. Subject to certain exceptions, the Services Agreement will terminate upon the termination or expiration of the LLC Agreement or the License Agreement.

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**Table of Contents**

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: September 12, 2007

By: /s/ John M. Maraganore, Ph.D.  
John M. Maraganore, Ph.D.  
President and Chief Executive Officer