

ALNYLAM PHARMACEUTICALS, INC.

Form 8-K

March 06, 2008

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**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): March 6, 2008 (February 29, 2008)

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, Massachusetts

02142

(Address of Principal Executive Offices)

(Postal 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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Item 8.01 Other Events.

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Item 8.01 Other Events.

On February 29, 2008, Alnylam Pharmaceuticals, Inc. announced positive results from its ALN-RSV01 Phase II experimental infection study, referred to as the GEMINI study. The GEMINI study was designed to evaluate the safety, anti-viral activity and tolerability of ALN-RSV01, an RNAi therapeutic for the treatment of respiratory syncytial virus, or RSV, infection. Results from the GEMINI study demonstrated statistically significant anti-viral efficacy in humans and showed:

ALN-RSV01 was generally safe and well tolerated;

subjects receiving ALN-RSV01 experienced a 38.1% reduction in infection rate as measured by plaque assay ($P < 0.01$), with similar reductions in infection rate obtained with other measurements of viral infection, including RT-qPCR, spin-enhanced culture, and RSV antigen assay, and an overall infection rate by any of these measures reflecting a statistically significant anti-viral effect for ALN-RSV01 ($P < 0.025$);

treatment with ALN-RSV01 resulted in a 95% increase in the number of subjects who remained free of infection ($P < 0.01$); 12 of 42 subjects receiving placebo were uninfected as compared with 24 of 43 subjects treated with ALN-RSV01;

consistent trends favoring an ALN-RSV01 treatment effect as measured by viral dynamics, including viral area under the curve, viral load, peak viral load, duration of viral shedding, and mean daily viral load; and

an absence of significant difference in clinical symptoms between subjects receiving ALN-RSV01 and those receiving placebo.

The results of the study were presented at the International Symposium on Respiratory Viral Infections meeting, held February 28 – March 2, 2008 in Singapore.

The GEMINI study was a double-blind, placebo-controlled, randomized study of ALN-RSV01 or placebo in 88 adult subjects experimentally infected with a wild type clinical strain of RSV. The goal of the GEMINI study was to measure the safety and anti-viral activity of ALN-RSV01, with efficacy measures including the viral infection rate and the effects of treatment on viral dynamics and clinical symptoms. The study was performed using ALN-RSV01 or placebo administered intranasally for five consecutive days – two days prior and three days after viral inoculation. The GEMINI study was designed to detect a statistically significant difference in infection rate between ALN-RSV01 and placebo.

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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.

Dated: March 6, 2008

ALNYLAM PHARMACEUTICALS, INC.

By: /s/ Patricia L. Allen

Name: Patricia L. Allen

Title: Vice President of Finance and
Treasurer