

ALKERMES INC
Form 8-K
March 10, 2008

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 7, 2008
ALKERMES, INC.
(Exact Name of Registrant as Specified in its Charter)

PENNSYLVANIA
(State or Other Jurisdiction of
Incorporation)

1-14131
(Commission
File Number)

23-2472830
(I.R.S. Employer
Identification No.)

88 Sidney Street
Cambridge, Massachusetts
(Address of principal executive offices)

02139
(Zip Code)

Registrant's telephone number, including area code: (617) 494-0171

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.

On March 7, 2008, Alkermes, Inc. (Alkermes or the Company) received a letter from Eli Lilly and Company (Lilly) terminating the Development and License Agreement (the Agreement) between Lilly and Alkermes dated April 1, 2001, as amended, relating to the development of inhaled formulations of insulin and other compounds potentially useful for the treatment of diabetes, based on the Company's proprietary AIR[®] pulmonary technology. The termination of the Agreement will become effective 90 days from March 7, 2008.

Under the Agreement, Alkermes was responsible for the formulation and preclinical testing of inhaled formulations of insulin and other compounds that could be used to treat diabetes as well as the development of an inhalation device. Lilly was obligated to pay Alkermes an initial fee, research funding and milestones payable upon the achievement of certain development and commercial goals. Lilly was responsible for conducting clinical trials, obtaining regulatory approvals and marketing any products developed under the Agreement. Alkermes would have received royalties for any such products sold. Lilly had exclusive worldwide rights to make, use and sell products developed under the Agreement. Upon termination of the Agreement, all intellectual property rights licensed to Lilly under the Agreement will return to Alkermes. In connection with this termination, Alkermes also has the right to purchase all regulatory submissions and related data owned by Lilly that were generated under the Agreement.

Pursuant to the Agreement, Lilly has been developing an inhaled form of insulin known as AIR Insulin in partnership with the Company. The product has been in phase III clinical development as a potential treatment for type 1 and type 2 diabetes.

Lilly stated in a press release issued on March 7, 2008 that the termination of the Agreement is not a result of any observations during AIR Insulin trials relating to the safety of the product, but rather was a result of increasing uncertainties in the regulatory environment, and a thorough evaluation of the evolving commercial and clinical potential of the product compared to existing medical therapies.

The termination of the Agreement results in the termination of the Supply Agreement (the Supply Agreement) between the Company and Lilly dated December 14, 2006 for the manufacture of AIR Insulin. Under the Supply Agreement, Alkermes manufactured clinical supplies of the product and was the exclusive commercial manufacturer and supplier of AIR Insulin powder for the AIR Insulin system. The Supply Agreement provided that Lilly would pay Alkermes manufacturing fees for such products and, in the case of commercial sales, a royalty as well. Lilly was also obligated to fund all operating costs of the portion of the Company's commercial-scale production facility used to manufacture AIR Insulin products and to fund the design, construction and validation of a second manufacturing line at the facility.

Alkermes is evaluating the impact of the termination of the Agreement and the Supply Agreement on its business.

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.

ALKERMES, INC.

Date: March 10, 2008

By: /s/ James M. Frates
James M. Frates
Senior Vice President, Chief Financial
Officer and Treasurer