ALKERMES INC
Form 8-K
November 04, 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): November 4, 2008

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

PENNSYLVANIA	**1-14131**	**23-2472830**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

88 Sidney Street	**02139**
Cambridge, Massachusetts	(Zip Code)
(Address of principal executive offices)	

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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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

Alkermes, Inc. is working with Amylin Pharmaceuticals, Inc., or Amylin, to develop exenatide once weekly, a long-acting formulation of exenatide. Amylin submitted data from its *in vitro in vivo* correlation studies to the U.S. Food and Drug Administration, or FDA, to demonstrate comparability between exenatide once weekly manufactured by Alkermes in its facility and used in previous clinical studies and exenatide once weekly manufactured on a commercial scale in Amylin s Ohio facility. Amylin has recently received feedback from the FDA that such data have not met FDA requirements to demonstrate comparability. Amylin is in active discussions with the FDA regarding options to enable a New Drug Application, or NDA, submission by the end of the first half of 2009. If Amylin is required to initiate a new clinical study, the timing of the NDA submission would depend on the parameters of the new study, and the submission could be delayed beyond the previously stated filing timeline of by the end of the first half of 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.

ALKERMES, INC.

Date: November 4, 2008

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