ALKERMES INC
Form 8-K
January 27, 2011

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 26, 2011
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.)

852 Winter Street	
Waltham, Massachusetts	**02451-1420**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(781) 609-6000**

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))

Item 7.01. Regulation FD Disclosure

On January 26, 2011, Alkermes, Inc. s collaborative partner, Amylin Pharmaceuticals, Inc. (Amylin), announced that the U.S. Food and Drug Administration (FDA) provided written approval of Amylin s study design for a thorough QT (tQT) study for BYDUREON (exenatide extended-release for injectable suspension). With the approval of the study design, Amylin intends to commence the study in February 2011.

Amylin intends to conduct the study in healthy volunteers using a crossover design, including placebo, a positive control and continuous infusion of exenatide, the active ingredient in BYDUREON. Target plasma concentrations of exenatide to be evaluated in the study will be in the range of 300 to 500 pg/mL.

Amylin plans to submit the results of this study to the FDA in the second half of 2011. The filing will likely be considered a Class 2 resubmission requiring a six-month review. The study was requested by the FDA in the complete response letter for BYDUREON received by Amylin in October 2010.

BYDUREON (pronounced by-DUR-ee-on) is the proposed brand name for exenatide once weekly, an investigational, extended-release medication for type 2 diabetes designed to deliver continuous therapeutic levels of exenatide in a single weekly dose. BYDUREON is a once-weekly formulation of exenatide, the active ingredient in BYETTA® (exenatide) injection. BYETTA has been available in the U.S. since June 2005 and is used in more than 70 countries worldwide to improve glycemic control in adults with type 2 diabetes. BYDUREON and BYETTA belong to the glucagon-like peptide-1 (GLP-1) receptor agonist class of medications.

The New Drug Application (NDA) for BYDUREON was submitted in May 2009 and is based on data that include the DURATION-1 head-to-head clinical study, safety data from DURATION-2 and more than seven years of clinical experience with BYETTA. The agency issued complete response letters to Amylin in March 2010 and in October 2010. The second complete response letter requested a tQT study to evaluate the potential effect of BYDUREON on heart rhythm and the results of the completed DURATION-5 clinical study to evaluate the efficacy, and the labeling of the safety and effectiveness, of the commercial formulation of BYDUREON.

The information set forth in this Item 7.01 is based, in its entirety, on Amylin's public disclosures made in connection with its earnings release today. The information set forth in this Item 7.01 shall not be deemed filed for purposes of Section 18 of the Exchange Act, or incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Note Regarding Forward-Looking Statements

Certain statements set forth in this Item 7.01 constitute forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, but not limited to: statements by Amylin concerning the design of the tQT study; expected commencement date and duration of the tQT study; whether Amylin will submit the results of the tQT study to the FDA in a timely manner or at all; and whether the FDA will classify the submission as a Class 2 resubmission. You are cautioned that forward-looking statements are inherently uncertain. In addition, although Alkermes, Inc. (the Company) believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the Company has not independently verified any of these statements and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether advancement of BYDUREON will be delayed due to actions or decisions by Amylin with regard to development and regulatory strategy, timing and funding which are out of Alkermes control; whether Amylin and/or the FDA will change the design of the tQT study; whether the tQT study will be completed on time or at all; whether the results of the tQT study will demonstrate that exenatide causes an effect on heart rhythm; decisions by the FDA or foreign regulatory authorities regarding the NDA submission for BYDUREON; and those risks described in Part 1, Item 1A, Risk Factors of our Annual Report on Form 10-K for the year ended March 31, 2010. The information contained in this Item 7.01 is provided by the Company as of the date hereof, and, except as required by law, the Company disclaims any intention or responsibility for updating any forward-looking information contained in this Item 7.01.

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: January 26, 2011

By: /s/ Michael J. Landine
Michael J. Landine
Senior Vice President, Corporate Development