

ALKERMES INC
Form 8-K
May 06, 2010

**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): May 5, 2010

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.)

**852 Winter Street
Waltham, Massachusetts**

(Address of principal executive offices)

02451-1420

(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):

- 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 7.01. Regulation FD Disclosure

On May 6, 2010, Alkermes, Inc. (Alkermes), Amylin Pharmaceuticals, Inc. (Amylin), and Eli Lilly and Co. (Lilly) announced that the U.S. Food and Drug Administration has classified the BYDUREON (exenatide for extended-release injectable suspension) complete response as a Class 2 resubmission and assigned a new Prescription Drug User Fee Act (PDUFA) action date of October 22, 2010. A copy of the press release is attached hereto as Exhibit 99.1. This information, including Exhibit 99.1, 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press release issued by Alkermes, Amylin and Lilly, dated May 6, 2010, announcing classification of the BYDUREON complete response as a Class 2 resubmission and establishment of a new PDUFA action date.

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: May 6, 2010

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