

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