

Alkermes plc.
Form 8-K
January 21, 2016

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 21, 2016**

ALKERMES PUBLIC LIMITED COMPANY

(Exact Name of Registrant as Specified in its Charter)

Ireland
(State or Other Jurisdiction of
Incorporation)

001 35299
(Commission
File Number)

98-1007018
(I.R.S. Employer
Identification No.)

Connaught House
1 Burlington Road
Dublin 4, Ireland
(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: **+353-1-772-8000**

Edgar Filing: Alkermes plc. - Form 8-K

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 21, 2016, Alkermes plc issued a press release announcing the topline results of FORWARD-3 and FORWARD-4, two phase 3 clinical studies of ALKS 5461 in major depressive disorder. This press release is attached hereto as Exhibit 99.1 and is incorporated by reference in this Item 7.01.

The information in this Item 7.01 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as expressly set forth by specific reference in such a filing.

Note Regarding Forward-Looking Statements

Certain statements set forth in Item 7.01 above constitute forward-looking statements within the meaning of the Private Securities Litigation Reform of 1995, as amended, including the therapeutic value, development and regulatory plans, and commercial potential of ALKS 5461. Although Alkermes believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those expressed or implied in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others, whether preclinical and clinical results for ALKS 5461 will be predictive of future clinical study results; whether future clinical trials for ALKS 5461 will be completed on time or at all; potential changes in cost, scope and duration of the ALKS 5461 clinical development program; whether ALKS 5461 could be shown ineffective or unsafe during clinical studies; whether the preclinical and clinical results of ALKS 5461 will meet the regulatory requirements for approval; whether regulatory submissions may occur or are submitted in a timely manner; and those risks described in the Alkermes plc Quarterly Report on Form 10-Q for the period ended Sept. 30, 2015 and the Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2014, and in any other subsequent filings made by Alkermes with the U.S. Securities and Exchange Commission (SEC), which are available on the SEC 's website at www.sec.gov. The information contained in Item 7.01 above is provided by Alkermes as of the date hereof, and, except as required by law, Alkermes disclaims any intention or responsibility for updating or revising any forward-looking information contained therein.

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 PLC

Date: January 21, 2016

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