Alkermes plc.
Form 8-K
October 16, 2015

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): **October 15, 2015**

ALKERMES PUBLIC LIMITED COMPANY

(Exact Name of Registrant as Specified in its Charter)

Ireland	**001 35299**	**98-1007018**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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**

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 July 13, 2015, Otsuka Pharmaceutical Development & Commercialization, Inc. (Otsuka) filed a Citizen Petition with the U.S. Food and Drug Administration (the FDA) which requested that the FDA refuse to approve the New Drug Application (the NDA) for ARISTADA (aripiprazole lauroxil) or delay approval of such application until Otsuka s exclusivity rights covering long-acting aripiprazole expire in December 2017.

The FDA approved ARISTADA on October 5, 2015.

Concurrent with the FDA s approval of ARISTADA on October 5, 2015, the FDA denied Otsuka s Citizen Petition, a copy of which can be found at www.regulations.gov by searching for aripiprazole lauroxil .

On October 15, 2015, Otsuka Pharmaceutical Co., Ltd., Otsuka, and Otsuka America Pharmaceutical, Inc. filed an action for declaratory and injunctive relief with the United States District Court for the District of Columbia against the FDA, the U.S. Department of Health and Human Services, and other related parties to, among other things, reverse the decision of the FDA approving ARISTADA extended-release injectable suspension for the treatment of schizophrenia, which Alkermes plc and its affiliates (collectively, Alkermes) have already launched, and delay the FDA from approving the NDA for ARISTADA until December 2017.

Alkermes believes Otsuka s action is without merit and intends to seek the court s approval to intervene in, and become a party to, this matter. Alkermes will vigorously defend ARISTADA against such action.

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 Act of 1995, as amended, including, but not limited to, statements concerning the merit of Otsuka s action for declaratory and injunctive relief and Alkermes ability to intervene in such action. Alkermes cautions that forward-looking statements are inherently uncertain. 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 the United States District Court for the District of Columbia will deny Alkermes motion to intervene and/or grant Otsuka s action for declaratory and injunctive relief and those risks described in the Alkermes plc 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: October 16, 2015

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