Alkermes plc.
Form 8-K
July 02, 2018

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): July 2, 2018

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)	(IRS 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):

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On July 2, 2018, Alkermes plc issued a press release announcing that the U.S. Food and Drug Administration has approved ARISTADA INITIO™ (aripiprazole lauroxil), to be given in combination with a single 30 mg dose of oral aripiprazole, for the initiation of ARISTADA® (aripiprazole lauroxil), a long-acting injectable atypical antipsychotic for the treatment of schizophrenia in adults. The 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

The press release attached as Exhibit 99.1 hereto and incorporated by reference in Item 7.01 above contains certain statements that constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform of 1995, as amended, including, but not limited to, statements concerning the timing of the commercial launch of ARISTADA INITIO in the U.S., the commercialization of ARISTADA INITIO and the potential therapeutic and commercial value of ARISTADA INITIO for initiation of ARISTADA for the treatment of schizophrenia. You are cautioned that forward-looking statements are inherently uncertain. Although the company 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: when ARISTADA INITIO will become commercially available; whether the pharmacokinetic and safety results demonstrated in the company's open-label pharmacokinetic, safety and tolerability study of ARISTADA INITIO for initiation of ARISTADA for the treatment of schizophrenia will be predictive of results when commercialized; whether ARISTADA INITIO will be commercialized successfully; whether third-party payers will cover or reimburse ARISTADA INITIO for initiation of ARISTADA for the treatment of schizophrenia; and those risks and uncertainties described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended Dec. 31, 2017 and in subsequent filings made by the company with the U.S. Securities and Exchange Commission ("SEC"), which are available on the SEC's website at www.sec.gov. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking statements contained in Item 7.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Alkermes plc, dated July 2, 2018.

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: July 2, 2018

By: /s/ David J. Gaffin
David J. Gaffin
Senior Vice President, Chief Legal Officer, Chief Compliance Officer and Secretary