Alkermes plc.
Form 8-K
November 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): November 1, 2018

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 (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 November 1, 2018, Alkermes plc (the "Company") issued a press release announcing the outcome of the joint meeting of the U.S. Food and Drug Administration's Psychopharmacologic Drugs Advisory Committee and Drug Safety and Risk Management Advisory Committee regarding the Company's new drug application for ALKS 5461 for the adjunctive treatment of major depressive disorder. 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 review and potential approval by the U.S. Food and Drug Administration (the "FDA") of the ALKS 5461 NDA and the anticipated timing of such review and approval; and the potential therapeutic and commercial value of ALKS 5461. 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: whether the preclinical and clinical results of ALKS 5461 studies will meet the regulatory requirements for approval by the FDA; whether the FDA's bases for the Refusal to File letter for the ALKS 5461 NDA, later rescinded by the FDA, or other bases will cause the FDA to require more data or information prior to approval of ALKS 5461; whether ALKS 5461 will be approved by the FDA in a timely manner or at all; whether the FDA will impose conditions on the marketing of ALKS 5461, such as a risk evaluation and mitigation strategy; whether future clinical trials for ALKS 5461, if any, 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; 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 (the "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 November 1, 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: November 1, 2018 By: /s/ David J. Gaffin
David J. Gaffin
Senior Vice President, Chief Legal Officer, Chief Compliance Officer and Secretary

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