Alkermes plc.
Form 8-K
April 16, 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): **April 13, 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):

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))

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 o

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. o

Item 7.01 Regulation FD Disclosure.

On April 16, 2018, Alkermes plc (the Company) issued a press release announcing that on April 13, 2018, the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application for ALKS 5461. A copy of such press release is attached hereto as Exhibit 99.1 and is incorporated by reference in this Item 7.01. Exhibit 99.1 contains hypertext links to information on the Company s website and other parties websites. The information on the Company s website and other parties websites is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Current Report on Form 8-K.

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, (the Securities Act) 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 or incorporated by reference in Item 7.01 above constitute forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, but not limited to, statements concerning: potential approval by the FDA of ALKS 5461 and the anticipated timing of such approval; and the therapeutic value and commercial potential 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 will meet the regulatory requirements for approval by the FDA; whether the FDA s bases for the rescinded Refusal to File letter or other bases will cause the FDA to require more data or information prior to approval; whether ALKS 5461 will be approved by the FDA in a timely manner or at all; if approved, whether ALKS 5461 will be commercialized successfully; whether the preclinical and clinical results for ALKS 5461 will be predictive of commercial potential of ALKS 5461; 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 (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 above.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Alkermes plc, dated April 16, 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: April 16, 2018	By:	/s/ David J. Gaffin David J. Gaffin Senior Vice President, Chief Legal Officer and Secretary