

Alkermes plc.
Form 8-K
November 29, 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 29, 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 29, 2018, Alkermes plc (the Company) issued a press release announcing positive topline results from ENLIGHTEN-2, a phase 3 study that evaluated the weight gain profile of ALKS 3831 compared to olanzapine over six months in patients with stable schizophrenia. 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 (the Securities Act), 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, Section 27A of the Securities Act and Section 21E of the Exchange Act, including, but not limited to, statements concerning: timing and expectations regarding the scientific disclosure and submission for publication of the ENLIGHTEN-2 study results; the potential therapeutic and commercial value of ALKS 3831; timing and expectations regarding interactions with the FDA and submission of an NDA for ALKS 3831; and the adequacy of the ENLIGHTEN clinical development program to serve as the basis of an NDA for ALKS 3831 for schizophrenia. The Company cautions 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 an NDA for ALKS 3831 will be submitted in a timely manner; once an NDA is submitted, whether the preclinical and clinical results of the ALKS 3831 studies will meet the regulatory requirements for approval by the FDA; potential changes in cost, scope and duration of the ENLIGHTEN clinical development and regulatory program; whether ALKS 3831 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	<u>Press release issued by Alkermes plc dated November 29, 2018.</u>

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 29, 2018

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