

Alkermes plc.  
Form 8-K  
October 20, 2016

**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 20, 2016**

**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**  
(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**

## Edgar Filing: Alkermes plc. - Form 8-K

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))
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**Item 7.01 Regulation FD Disclosure.**

On October 20, 2016, Alkermes plc issued a press release announcing the positive topline results of FORWARD-5, a phase 3 clinical study of ALKS 5461 in major depressive disorder. This 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**

Certain statements set forth in Item 7.01 above constitute forward-looking statements within the meaning of the Private Securities Litigation Reform of 1995, as amended, including the therapeutic value, development and regulatory plans, 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 projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether preclinical and clinical results for ALKS 5461 will be predictive of future clinical study results and commercial potential of ALKS 5461; whether future clinical trials for ALKS 5461 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; whether the preclinical and clinical results of ALKS 5461 will meet the regulatory requirements for approval; whether regulatory submissions may occur or be submitted in a timely manner; and those risks and uncertainties described in Item 1A under the heading Risk Factors in the company's Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2015, and in any other 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](http://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 they are made. The information contained in this Item 7.01 is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating or revising any forward-looking information contained in this press release.

**Item 8.01 Other Events.**

On October 20, 2016, Alkermes plc issued a press release announcing the positive topline results of FORWARD-5, a phase 3 clinical study of ALKS 5461 in major depressive disorder. In the study, ALKS 5461 2mg/2mg met the prespecified primary endpoint of significantly reducing depression scores compared to placebo, as measured by 6-item Montgomery Åsberg Depression Rating Scale (MADRS-6) scores. ALKS 5461 2mg/2mg also demonstrated statistically significant reductions in 10-item MADRS (MADRS-10) scores compared to placebo. The 1mg/1mg dose of ALKS 5461 showed improvement in depressive symptoms in the study, but did not separate significantly from placebo. The most commonly reported adverse events for ALKS 5461 in the FORWARD-5 study were nausea, dizziness and fatigue.

**Item 9.01 Financial Statements and Exhibits**

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(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Alkermes plc dated October 20, 2016.

**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 20, 2016

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