

**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
(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 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Alkermes plc, dated April 16, 2018.

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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

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Alkermes Contacts:

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Alkermes Announces FDA Acceptance for Review of New Drug Application for ALKS 5461 for the Adjunctive Treatment of Major Depressive Disorder

— FDA Action Expected by Jan. 31, 2019 —

— Conference Call Scheduled for Today at 8:30 a.m. ET —

DUBLIN, Ireland, April 16, 2018 — Alkermes plc (Nasdaq: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for ALKS 5461, a novel, once-daily, oral investigational medicine for the adjunctive treatment of major depressive disorder (MDD) in patients with an inadequate response to standard antidepressant therapies. FDA's target action date for the ALKS 5461 NDA is Jan. 31, 2019.

FDA's acceptance of the ALKS 5461 NDA and rescission of the Refusal to File letter issued March 30, 2018 follows productive interactions with the Agency in which Alkermes clarified certain aspects of the NDA submission. No additional data or analyses were submitted by Alkermes to FDA.

"FDA's filing of the ALKS 5461 application is a positive step forward for patients suffering from major depressive disorder, a serious disease where inadequate response to existing antidepressants remains a well-known and significant treatment limitation, and where there have been no new pharmacological treatment approaches in 30 years," stated Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President of Medicines Development and Medical Affairs at Alkermes. "We will continue to engage with the FDA throughout the review process, as we work to bring this important medicine to patients."

The NDA filing for ALKS 5461 is based on results from a clinical efficacy and safety package with data from more than 30 clinical trials and more than 1,500 patients with MDD. Throughout the clinical development program, ALKS 5461 demonstrated a consistent profile of antidepressant activity, safety and tolerability in the adjunctive treatment of MDD.

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Conference Call Information

Alkermes will host a conference call at 8:30 a.m. ET (1:30 p.m. BST) on Monday, April 16, 2018, to discuss this update. The conference call may be accessed by visiting Alkermes' website or by dialing +1 888 424 8151 for U.S. callers and +1 847 585 4422 for international callers. The conference call ID number is 6037988. In addition, a replay of the conference call will be available from 11:00 a.m. ET (4:00 p.m. BST) on Monday, April 16, 2018, through 5:00 p.m. ET (10:00 p.m. BST) on Monday, April 23, 2018, and may be accessed by visiting Alkermes' website or by dialing +1 888 843 7419 for U.S. callers and +1 630 652 3042 for international callers. The replay access code is 6037988.

About ALKS 5461

ALKS 5461 is a proprietary, investigational, once-daily oral medicine that acts as an opioid system modulator and represents a novel mechanism of action for the adjunctive treatment of major depressive disorder (MDD) in patients with an inadequate response to standard antidepressant therapies. ALKS 5461 is a fixed-dose combination of buprenorphine, a partial mu-opioid receptor agonist and kappa-opioid receptor antagonist, and samidorphan, a mu-opioid receptor antagonist.

About MDD

According to the *DSM-5® (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition)*, major depressive disorder (MDD) is a condition in which patients exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities consistently for at least a two-week period, and demonstrate impaired social, occupational, educational or other important functioning. An estimated 16.2 million people in the U.S. suffered from MDD in 2016,(1) the majority of whom may not adequately respond to initial antidepressant therapy.(2)

About Alkermes plc

Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction and multiple sclerosis. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in

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Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, 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 this press release.

DSM-5® is a registered trademark of the American Psychiatric Association.

(1) National Institutes of Mental Health: Major Depression. Accessed on April 15, 2018 from <https://www.nimh.nih.gov/health/statistics/major-depression.shtml>.

(2) Rush AJ et al (2007) *Am J. Psychiatry*, 163:11, pp. 1905-1917 (STAR*D Study).

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