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): July 15, 2019

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 D04 C5Y6
(Address of principal executive offices)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Ordinary shares, $0.01 par value	ALKS	Nasdaq Global Select Market

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 July 15, 2019, Alkermes plc issued a press release announcing the expansion of its planned new drug application for ALKS 3831 to encompass the treatment of bipolar I disorder in addition to the treatment of 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, and in Exhibit 99.1 furnished herewith, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Alkermes plc dated July 15, 2019.

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: July 15, 2019

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

Exhibit 99.1

Alkermes Contacts:

For Investors:Sandy Coombs +1 781 609 6377
For Media: Gretchen Murphy +1 781 609 6419

Alkermes Expands Planned New Drug Application for ALKS 3831 to Include Treatment of Bipolar I Disorder

— Following Pre-NDA Meeting With FDA, Company Plans to Submit New Drug Application for Schizophrenia and Bipolar I Disorder Indications in the Fourth Quarter of 2019 —

DUBLIN, July 15, 2019 -- Alkermes plc (Nasdaq: ALKS) today provided an update on its regulatory strategy for ALKS 3831 (olanzapine/samidorphan), the company's investigational, novel, once-daily, oral atypical antipsychotic drug candidate designed to provide the efficacy of olanzapine while mitigating olanzapine-associated weight gain. Following a pre-New Drug Application (NDA) meeting with the U.S. Food and Drug Administration (FDA), the company plans to expand the NDA for ALKS 3831 to encompass the treatment of bipolar I disorder in addition to the treatment of schizophrenia. The ALKS 3831 NDA, which the company now plans to submit in the fourth quarter of 2019, will include data from the completed ALKS 3831 ENLIGHTEN clinical development program in patients with schizophrenia as well as pharmacokinetic (PK) bridging data comparing ALKS 3831 and ZYPREXA® (olanzapine).

"Bipolar I disorder is a complicated and often misdiagnosed disease, characterized by severe shifts in mood and energy that can impact a person's ability to complete day-to-day activities. Antipsychotics are a mainstay treatment option for many people living with bipolar I disorder; however, new treatments with differentiated efficacy and tolerability profiles are needed," said Roger S. McIntyre, M.D., Professor of Psychiatry and Pharmacology at the University of Toronto, Head of the Mood Disorders Psychopharmacology Unit at the University Health Network in Toronto and Director for the Depression and Bipolar Support Alliance (DBSA). "A potential new medication like ALKS 3831 would be a meaningful addition to the bipolar I disorder treatment landscape."

"As a longstanding leader dedicated to developing new medicines to treat schizophrenia and other serious mental health disorders, we are gratified to now extend that commitment to people living with bipolar I disorder," said Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President of Medicines Development and Medical Affairs at Alkermes. "We are pleased to have met with FDA to align on this regulatory review pathway for ALKS 3831 for the treatment

of bipolar I disorder, based on pharmacokinetic bridging data and results from our ENLIGHTEN program for schizophrenia. Our NDA preparation is well underway and we anticipate submitting a single NDA for ALKS 3831 later this year for the treatment of schizophrenia and bipolar I disorder."

The ALKS 3831 NDA will include data to support an indication for the treatment of manic or mixed episodes associated with bipolar I disorder as a monotherapy or adjunct to lithium or valproate and for maintenance treatment of bipolar I disorder; and an indication for the treatment of schizophrenia. The proposed fixed dosage strengths for ALKS 3831 include 10 mg of samidorphan co-formulated with 5 mg, 10 mg, 15 mg or 20 mg of olanzapine.

About the ENLIGHTEN Clinical Development Program

The ENLIGHTEN clinical development program for ALKS 3831 comprises two key studies in patients with schizophrenia: the ENLIGHTEN-1 study evaluating the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks and the ENLIGHTEN-2 study assessing weight gain with ALKS 3831 compared to olanzapine over six months. The program also includes supportive studies to evaluate the pharmacokinetic and metabolic profile and long-term safety of ALKS 3831, and pharmacokinetic bridging data comparing ALKS 3831 and ZYPREXA.

About ALKS 3831

ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of schizophrenia and bipolar I disorder. ALKS 3831 is composed of samidorphan, a novel, new molecular entity, co-formulated with the established antipsychotic agent, olanzapine, in a single bilayer tablet.

About Bipolar I Disorder

Bipolar disorder is a brain disorder that causes unusual shifts in a person's mood, energy and ability to function. Patients with this brain disorder often experience debilitating mood swings from extreme highs (mania) to extreme lows (depression). Bipolar I disorder is characterized by the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode, and affects approximately one percent of the adult population in the United States in any given year.[1]

About Schizophrenia
Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million American adults have schizophrenia,[2] with men and women affected equally.

About Alkermes
Alkermes plc is a fully integrated, global biopharmaceutical company developing innovative medicines for the treatment of central nervous system (CNS) diseases and oncology. The company has a diversified commercial product portfolio and a substantial clinical pipeline of product candidates for chronic diseases that include schizophrenia, depression, addiction, multiple sclerosis and cancer. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Massachusetts; a research and manufacturing facility in 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: the potential therapeutic and commercial value of ALKS 3831 for the treatment of schizophrenia and the treatment of bipolar I disorder; and timing and expectations regarding interactions with the FDA and submission of an NDA for ALKS 3831, including the expected data to be contained in such NDA, the adequacy of such data to serve as the basis of an NDA for ALKS 3831 for the treatment of schizophrenia and the treatment of bipolar I disorder, and the proposed fixed dosage strengths for ALKS 3831. 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 the 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 and the PK bridging data will meet the regulatory requirements for approval by the FDA for either, or both, of the proposed schizophrenia and bipolar I disorder indications; potential changes in cost, scope and duration of the ENLIGHTEN clinical development program and the broader ALKS 3831 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, 2018 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.

ZYPREXA® is a registered trademark of Eli Lilly & Company.

[1] Merikangas et al. Lifetime and 12-Month Prevalence of Bipolar Spectrum Disorder in the National Comorbidity Survey Replication. *Arch Gen Psychiatry*, 2007 May; 64(5): 543–552. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1931566/

[2] National Institutes of Health. *Schizophrenia.* Accessed on July 8, 2019 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

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