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	**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):

☐ 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	Press release issued by Alkermes plc dated November 29, 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: November 29, 2018

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

Exhibit 99.1

Alkermes Contacts:
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Alkermes Announces Positive Topline Results From ENLIGHTEN-2 Phase 3 Study of ALKS 3831 in Patients With Schizophrenia

— ALKS 3831 Met Both Co-Primary Endpoints, Demonstrating a Favorable Weight Profile Compared to Olanzapine —

— Company Plans to Submit New Drug Application (NDA) to U.S. Food and Drug Administration (FDA) in Mid-2019 —

— Company to Hold Conference Call Today at 8:30 a.m. ET —

DUBLIN, Ireland, Nov. 29, 2018 — Alkermes plc (Nasdaq: ALKS) today announced positive topline results from ENLIGHTEN-2, a pivotal phase 3 study of ALKS 3831 (olanzapine/samidorphan), an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of schizophrenia. ENLIGHTEN-2 is the second of two key phase 3 studies in the ALKS 3831 registration program and was designed to confirm ALKS 3831's favorable weight profile compared to olanzapine, an antipsychotic agent with established efficacy but limited in its clinical use by a high incidence and magnitude of weight gain. ENLIGHTEN-2 was a multicenter, double-blind, randomized, phase 3 study that evaluated the weight gain profile of ALKS 3831 compared to olanzapine over six months in 561 patients with stable schizophrenia. In the study, ALKS 3831 met the pre-specified co-primary endpoints, demonstrating both a lower mean percent weight gain from baseline at six months compared to the olanzapine group (p=0.003) and a lower proportion of patients who gained 10% or more of their baseline body weight at six months compared to the olanzapine group (p=0.003). With the successful completion of ENLIGHTEN-2, Alkermes plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in mid-2019.

In addition to meeting the co-primary endpoints, the study also met its pre-specified key secondary endpoint, with the ALKS 3831 treatment group demonstrating a lower proportion of patients who gained 7% or more of their baseline body weight at six months compared to the olanzapine group (p=0.001). Consistent with the phase 2 study of ALKS 3831, the weight gain curves for the ALKS 3831 and olanzapine treatment groups began to separate after Week 4 and continued to diverge for the remainder of the study. For the ALKS 3831 treatment group, weight stabilized at Week 6 and remained flat for the rest of the six-month treatment period.

“These unequivocal results from ENLIGHTEN-2 provide evidence of a clinically meaningful, differentiated weight profile for ALKS 3831 compared to olanzapine. Importantly, ALKS 3831 favorably shifted the weight gain distribution curve compared to olanzapine, both in terms of mean weight gain and patients experiencing extreme weight gain,” said Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President of Medicines Development and Medical Affairs at Alkermes. “These findings build on the positive safety and efficacy profile seen throughout the ENLIGHTEN development program, and underscore the potential of ALKS 3831 to provide an important benefit for people living with schizophrenia. With these data now in hand, we will meet with the FDA and plan to submit a New Drug Application in mid-2019.”

“Significant unmet patient need remains in schizophrenia despite the number of treatment options available. A new agent that offers the robust efficacy of olanzapine but with a favorable weight profile that stabilizes within weeks of treatment initiation would be an important and differentiated addition to the treatment armamentarium for schizophrenia,” said Christoph Correll, M.D., Professor of Psychiatry and Molecular Medicine at Hofstra Northwell School of Medicine. “People living with schizophrenia deserve treatment options that do not sacrifice tolerability for efficacy. A new therapeutic option with the profile demonstrated by ALKS 3831 in this study would be clinically meaningful for patients and their healthcare providers.”

Detailed results from the study:

- *Co-primary endpoint*: Mean percent change from baseline body weight at six months. Patients in the olanzapine treatment group (n=272) had a 57% higher mean percent weight change at six months compared to patients receiving ALKS 3831 (n=266), (6.59% for olanzapine vs. 4.21% for ALKS 3831, p=0.003).

- *Co-primary endpoint*: Proportion of patients who gained 10% or more of baseline body weight at six months. Patients in the olanzapine treatment group had two times the risk of gaining 10% or more of their baseline body weight at six months compared to patients receiving ALKS 3831. The proportion of patients who gained 10% or more of their baseline body weight was 29.8% for olanzapine vs. 17.8% for ALKS 3831, (p=0.003).
- *Key secondary endpoint*: Proportion of patients who gained 7% or more of baseline body weight at six months. Patients in the olanzapine treatment group had two times the risk of gaining 7% or more of their baseline body weight at six months compared to patients receiving ALKS 3831. The proportion of patients who gained 7% or more of their baseline body weight was 42.7% for olanzapine vs. 27.5% for ALKS 3831, (p=0.001).
- Additional weight analyses. Additional analyses focused on the proportion of patients who experienced weight gain of at least 2%, 5% and 15% of their baseline body weight at six months. Similar findings were observed, demonstrating a favorable profile at each of these weight gain cutoffs for ALKS 3831 compared to olanzapine.
- Safety. Overall, 64.2% of patients who received ALKS 3831 completed the study, compared to 63.8% of patients who received olanzapine. The most common adverse events reported in the ALKS 3831 treatment group were weight gain, somnolence and dry mouth. The most common adverse events reported in the olanzapine treatment group were weight gain, somnolence and increased appetite. Serious adverse events occurred in 3.6% of ALKS 3831 patients and 2.5% of olanzapine patients during the treatment period.

Alkermes expects to submit the results from the ENLIGHTEN-2 study to a peer-reviewed journal for publication and present full study results, including other endpoints and effects on metabolic parameters, at an upcoming scientific meeting.

About the ENLIGHTEN-2 Study

ENLIGHTEN-2 was a multicenter, randomized, double-blind, phase 3 study that evaluated the weight gain profile of ALKS 3831 compared to olanzapine over six months in patients with stable schizophrenia. A total of 561 patients were randomized in a 1:1 manner to receive either ALKS 3831 or olanzapine for six months, and the 538 patients who were dosed and had at least one post-baseline weight assessment were included in the full study population. The co-primary endpoints of the ENLIGHTEN-2 study were the percent change from baseline in body weight at six months and the proportion of subjects with 10% or more weight gain from baseline at six months. The key secondary endpoint evaluated the proportion of patients with 7% or more weight gain from baseline at six months.

All participants who completed the double-blind portion of the study were eligible to continue in an open-label, long-term safety study and receive ALKS 3831 for an additional 12 months. The objective of the extension phase of the study is to assess the long-term safety, tolerability and durability of effect of ALKS 3831.

Conference Call

Alkermes will host a conference call today, Nov. 29, 2018, at 8:30 a.m. ET (1:30 p.m. GMT), to discuss these topline results. The conference call may be accessed 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. The conference call will also be webcast on the Investors section of Alkermes' website at www.alkermes.com. The webcast will be archived on the Investors section of the Alkermes website for at least 90 days.

About the ENLIGHTEN Clinical Development Program

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

Positive topline data from ENLIGHTEN-1, the first key phase 3 study from the ENLIGHTEN development program, were reported in June 2017. This study evaluated the antipsychotic efficacy, safety and tolerability of ALKS 3831 compared to placebo over four weeks in 403 patients experiencing an acute exacerbation of schizophrenia. ENLIGHTEN-1 met its prespecified primary endpoint, with ALKS 3831 demonstrating statistically significant reductions from baseline in Positive and Negative Syndrome Scale (PANSS) scores compared to placebo ($p<0.001$). Data from the study also showed that the olanzapine comparator arm achieved similar improvements from baseline PANSS scores compared to placebo ($p=0.004$). The most common adverse events for both the ALKS 3831 and olanzapine treatment groups were weight gain, somnolence and dry mouth.

About ALKS 3831

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

Weight gain is a common and clinically relevant metabolic side effect of atypical antipsychotic medications, and olanzapine, commercially available as ZYPREXA®, has one of the highest incidences and greatest amounts of weight gain among the widely prescribed products in this class of drugs.[1] ALKS 3831 is designed to provide the strong antipsychotic efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties.

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

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1 Komossa, K. et al. Olanzapine versus other atypical antipsychotics for schizophrenia. *Cochrane Database of Systematic Reviews*. 2010, Issue 3. Art. No.: CD006654.

2 National Institutes of Health. *Schizophrenia*. Accessed on Nov. 28, 2018 from http://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=67&key=S#S.

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