

Alkermes plc.
Form 8-K
November 27, 2017

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 27, 2017

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.)
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Connaught House, 1 Burlington Road Dublin 4, Ireland (Address of principal executive offices)	(Zip Code)
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(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))

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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 1.01 Entry into a Material Definitive Agreement.

On November 27, 2017, Alkermes Pharma Ireland Limited (the “Company”), a subsidiary of Alkermes plc, entered into a license and collaboration agreement (the “Agreement”) with Biogen Swiss Manufacturing GmbH (“Biogen”), under which the Company granted to Biogen a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize ALKS 8700 and other products or compounds (collectively, the “Products”) under certain of the Company’s intellectual property, for the treatment, prevention or diagnosis of any human disease, disorder or condition (the “Collaboration”). ALKS 8700 is a novel, oral, monomethyl fumarate small drug molecule in phase 3 development for the treatment of relapsing forms of multiple sclerosis.

Under the terms of the Agreement, the Company is entitled to receive from Biogen an up-front cash payment of \$28 million. The Company is also eligible to receive from Biogen additional payments upon achievement of the following milestones: (i) a \$50 million option payment, payable upon Biogen’s decision to continue the Collaboration after having reviewed certain data from the Company’s long-term safety clinical trial and part A of the phase 3 gastrointestinal tolerability clinical trial of ALKS 8700 and (ii) a \$150 million payment upon an approval by the U.S. Food and Drug Administration (“FDA”) on or before December 31, 2021 of a new drug application (“NDA”) for ALKS 8700.

In addition, Biogen is obligated to pay the Company a mid-teens percentage royalty on worldwide net sales of ALKS 8700, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of ALKS 8700. Biogen is also obligated to pay the Company royalties on net sales of Products other than ALKS 8700 at tiered royalty rates calculated as percentages of net sales ranging from high-single digits to low double-digits. All royalties are payable on a Product-by-Product and country-by-country basis until the later of (i) the last-to-expire patent right covering the applicable Product in the applicable country and (ii) a specified period of time from the first commercial sale of the applicable Product in the applicable country. Royalties for all Products and the minimum annual payments for ALKS 8700 are subject to customary reductions.

Until FDA approval of an NDA for ALKS 8700, the Company is responsible for the development of ALKS 8700 for the treatment of multiple sclerosis. Biogen will pay a portion of the ALKS 8700 development costs incurred by the Company in 2017 and will be responsible for all ALKS 8700 development costs incurred by the Company thereafter, subject to annual budget limitations agreed upon between the parties. After the date of FDA approval of an NDA for ALKS 8700 for the treatment of multiple sclerosis, Biogen shall be responsible for all development and commercialization activities, as well as the costs of all such activities, for ALKS 8700 and all other Products. The Company has retained the right to manufacture clinical supplies and commercial supplies of Products, subject to Biogen’s right to manufacture or have manufactured commercial supplies as a back-up manufacturer.

If, based on results of the Company’s long-term safety clinical trial and ALKS 8700 phase 3 gastrointestinal tolerability clinical trial, ALKS 8700 discontinuations due to gastrointestinal adverse events exceeds a certain pre-defined threshold or demonstrates a greater rate of discontinuations as compared to Tecfidera, respectively (in either case, “GI Inferiority”), then (i) Biogen shall have the right to recapture from the Company its \$50 million option payment through certain temporary reductions in royalty rates, (ii) the minimum annual payments Biogen owes to the

Company shall terminate, and (iii) there shall be no reversion of ALKS 8700 to the Company in the event that Biogen terminates the Agreement and does not commercialize ALKS 8700.

The Company and Biogen have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

Unless earlier terminated, the Agreement will remain in effect until the expiry of all royalty obligations. Biogen has the right to terminate the Agreement at will, on a Product-by-Product basis or in its entirety. Either party has the right to terminate the Agreement following any governmental prohibition of the transactions effected by the Agreement, or in connection with an insolvency event involving the other party. Upon termination of the Agreement by either party, if, prior to such termination (i) ALKS 8700 did not meet GI Inferiority or (ii) ALKS 8700 met GI Inferiority but Biogen commercialized ALKS 8700, then, at the Company's request, Biogen will transfer the ALKS 8700 program back to the Company.

The foregoing descriptions of the Agreement are only a summary and are qualified in their entirety by reference to the full and complete terms contained in the Agreement, which the Company intends to file as an exhibit to its Annual Report on Form 10-K for the year ended December 31, 2017.

Item 7.01 Regulation FD Disclosure.

On November 27, 2017, the Company issued a press release announcing that it had entered into the Agreement. A copy of such press release is filed as Exhibit 99.1 hereto and is incorporated by reference in this Item 7.01.

Financial Expectations

The Company expects to recognize the majority of the \$28 million up-front payment from the Collaboration during the fourth quarter of 2017, pending a final determination of the revenue recognition treatment of the up-front payment. As a result, the Company is updating its financial expectations for 2017 for the following line items:

- **Revenues:** The Company now expects total revenues to range from \$870 million to \$900 million, up from a previous range of \$850 million to \$880 million.
- **GAAP Net Loss:** The Company now expects net loss according to generally accepted accounting principles in the U.S. ("GAAP") to range from \$140 million to \$170 million, or a basic and diluted loss per share of \$0.91 to \$1.10, based on a weighted average basic and diluted share count of approximately 154 million shares outstanding. This compares to previous expectations of GAAP net loss in the range of \$160 million to \$190 million, or a basic and diluted loss per share of \$1.04 to \$1.23, based on a weighted average basic and diluted share count of approximately 154 million shares outstanding.
- **Non-GAAP Net Income:** The Company now expects non-GAAP net income to be in the range of \$5 million to \$35 million. This equates to a non-GAAP basic income per share of \$0.03 to \$0.23, based on a weighted average basic share count of approximately 154 million shares outstanding, and a non-GAAP diluted income per share of \$0.03 to \$0.22, based on a weighted average diluted share count of approximately 161 million shares outstanding. This compares to a previous expectation of the Company's non-GAAP financial measure to be in the range of a non-GAAP net loss of \$15 million to a non-GAAP net income of \$15 million. This equated to a non-GAAP basic loss per share of \$0.10 to a non-GAAP basic income per share of \$0.10, based on a weighted average basic share count of approximately 154 million shares outstanding, and a non-GAAP diluted loss per share of \$0.10 to a non-GAAP diluted income per share of \$0.09, based on a weighted average diluted share count of approximately 161 million shares outstanding.

The Company maintains its financial expectations for all other line items provided in its Current Report on Form 8-K filed with the U.S. Securities and Exchange Commission ("SEC") on Oct. 26, 2017.

The following is a reconciliation of GAAP guidance to non-GAAP guidance:

Alkermes plc and Subsidiaries

2017 Guidance — GAAP to Non-GAAP Adjustments

An itemized reconciliation between projected loss per share on a GAAP basis and projected earnings per share on a non-GAAP basis is as follows:

(In millions, except per share data)	Amount	Shares	(Loss)/Earnings Per Share
Projected Net Loss — GAAP	\$ (155.0)	154	\$ (1.01)
Adjustments:			
Share-based compensation expense	85.0		
Amortization expense	60.0		
Depreciation expense	37.5		
Other-than-temporary impairment of equity method investment	10.5		
Change in the fair value of warrants and equity method investments	2.0		
Non-cash net interest expense	1.0		
Change in the fair value of contingent consideration	(16.0)		
Income tax effect related to reconciling items	(5.0)		
Projected Non-GAAP Net Income	\$ 20.0	161	\$ 0.12

Projected GAAP and non-GAAP measures reflect mid-points within ranges of estimated guidance.

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.

Non-GAAP Financial Measures

Certain statements set forth or incorporated by reference in Item 7.01 above include information about certain financial measures that are not prepared in accordance with GAAP, including non-GAAP net income and non-GAAP diluted earnings per share. These non-GAAP measures are not based on any standardized methodology prescribed by GAAP and are not necessarily comparable to similar measures presented by other companies.

Non-GAAP net income adjusts for one-time and non-cash charges by excluding from GAAP results: share-based compensation expense; amortization; depreciation; non-cash net interest expense; certain other one-time or non-cash items; and the income tax effect of these reconciling items.

The Company's management and board of directors utilize these non-GAAP financial measures to evaluate the company's performance. The Company provides these non-GAAP measures of the Company's performance to investors because management believes that these non-GAAP financial measures, when viewed with the Company's results under GAAP and the accompanying reconciliations, are useful in identifying underlying trends in ongoing operations.

However, non-GAAP net income and non-GAAP basic and diluted earnings per share are not measures of financial performance under GAAP and, accordingly, should not be considered as alternatives to GAAP measures as indicators of operating performance. Further, non-GAAP net income and non-GAAP basic and diluted earnings per share should not be considered measures of our liquidity.

A reconciliation of GAAP to non-GAAP financial measures has been provided in the tables included in this Current Report on form 8-K.

Note Regarding Forward-Looking Statements

Certain statements set forth or incorporated by reference in Item 1.01 and 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: the continued clinical development and the potential therapeutic and commercial value of ALKS 8700 for the treatment of relapsing forms of MS, the regulatory strategy for the filing of an NDA for ALKS 8700 and the adequacy of the Company’s development program for ALKS 8700 to serve as the basis for an NDA, the timing of the submission of an NDA for ALKS 8700 to the FDA, the potential financial benefits that may be achieved under the license and collaboration agreement between the Company and Biogen, and the Company’s future financial and operating performance, business plans or prospects. 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 results from the head-to-head study to evaluate the GI tolerability of ALKS 8700 compared to TECFIDERA will show that ALKS 8700 has favorable GI tolerability; whether preclinical and early clinical results for ALKS 8700 will be predictive of future clinical study results or real-world results; whether clinical trials for ALKS 8700 will be completed on time or at all; changes in the cost, scope and duration of the ALKS 8700 clinical trials; whether ALKS 8700 could be shown ineffective or unsafe during clinical studies, and whether, in such instances, the Company may not be permitted by regulatory authorities to undertake new or additional clinical studies of ALKS 8700; whether regulatory submissions for ALKS 8700 will be submitted on time or at all; whether adverse decisions by regulatory authorities will occur; whether the pharmacokinetic, phase 3 and other studies conducted for ALKS 8700 will meet the FDA’s requirements for approval of an NDA for ALKS 8700; whether the potential financial benefits under the license and collaboration agreement between the Company and Biogen will be achieved; and those risks and uncertainties described in the Alkermes plc Annual Report on Form 10-K for the fiscal year ended Dec. 31, 2016, and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2017 and Sept. 30, 2017 and in subsequent filings made by the company with 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 or incorporated by reference in Item 1.01 or Item 7.01 above.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	<u>Press release issued by Alkermes plc dated November 27, 2017.</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 27, 2017 By: /s/ David
J. Gaffin
David J.
Gaffin
Senior
Vice
President,
Chief
Legal
Officer