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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 11, 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 October 11, 2019, Alkermes plc (the "Company") received notice from the U.S. Food and Drug Administration ("FDA") of its tentative approval of VUMERITY™ (diroximel fumarate) for the treatment of relapsing forms of multiple sclerosis. The tentative approval letter stated that final approval of VUMERITY is subject to the expiration of a period of patent protection and/or exclusivity. The Company believes this period relates to the term of a patent of the reference listed drug product that is scheduled to expire on October 20, 2019. The tentative approval letter is posted to the FDA Approved Drugs Product website, available at *www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/211855Orig1s000TAltr.pdf*.

The Company filed the new drug application for VUMERITY through the 505(b)(2) regulatory pathway in December 2018 and certified to the applicable patents of the reference listed drug product assuming a PDUFA (Prescription Drug User Fee Act) target action date in December 2019 and with the goal of enabling a commercial launch of VUMERITY as soon as possible thereafter.

Note Regarding Forward-Looking Statements

Certain statements set forth in Item 7.01 above constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including, but not limited to, statements concerning the final approval of VUMERITY by the FDA, and the timing and factors contributing to such potential approval, including the expected timing for expiration of a certain patent. 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: whether the patent term of that certain patent referred to in Item 7.01 above is the only issue of patent protection and/or exclusivity that is referenced in the FDA's tentative approval letter; whether expiry of the patent period will be sufficient for final approval of VUMERITY; whether the FDA may identify additional barriers to final approval of VUMERITY; and those risks and uncertainties described 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 Item 7.01 above.

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 17, 2019

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