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 30, 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 30, 2019, Alkermes plc (the "Company") issued a joint press release with Biogen Inc. announcing positive topline results from EVOLVE-MS-2, a large, randomized, five-week phase 3 study of the gastrointestinal tolerability of diroximel fumarate (formerly BIIB098) and dimethyl fumarate in patients with relapsing-remitting multiple sclerosis. A copy of such press release is furnished as Exhibit 99.1 hereto and is incorporated by reference into this Item 7.01. Exhibit 99.1 contains hypertext links to information on the Company's website and on other external websites. The information on the Company's website and such other websites is not incorporated by reference into this Item 7.01 and does not constitute a part of this Current Report on Form 8-K.

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 INDEX

Exhibit No.	Description
99.1	Press release issued by Alkermes plc on July 30, 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 30, 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

Biogen Contacts:
For Investors: Joe Mara, +1 781 464 2442, IR@biogen.com
For Media: David Caouette, + 617 679 4945, public.affairs@biogen.com

Diroximel Fumarate Demonstrated Significantly Improved Gastrointestinal Tolerability Profile Compared to Dimethyl Fumarate in Patients with Multiple Sclerosis

— Diroximel Fumarate Demonstrated Statistically Superior Gastrointestinal (GI) Tolerability on EVOLVE-MS-2 Study's Primary Endpoint Assessing Self-Reported GI Events —

— Discontinuations Due to GI Events were Less than 1% for Diroximel Fumarate —

DUBLIN, Ireland and CAMBRIDGE, Mass., July 30, 2019 -- Alkermes plc (Nasdaq: ALKS) and Biogen Inc. (Nasdaq: BIIB) today announced positive topline results from EVOLVE-MS-2, a large, randomized, double-blind, five-week, Phase 3 study of diroximel fumarate, an investigational, novel oral fumarate with a distinct chemical structure, for relapsing-remitting multiple sclerosis (RRMS), compared to TECFIDERA® (dimethyl fumarate). Diroximel fumarate was statistically superior to dimethyl fumarate on the study's pre-specified primary endpoint, with patients treated with diroximel fumarate self-reporting significantly fewer days of key gastrointestinal (GI) symptoms with intensity scores ≥2 on the Individual Gastrointestinal Symptom and Impact Scale (IGISIS), as compared to dimethyl fumarate ($p = 0.0003$).

The most common adverse events (AEs) reported in the study for both treatment groups were flushing, diarrhea and nausea (32.8%, 15.4% and 14.6% for diroximel fumarate; 40.6%, 22.3% and 20.7% for dimethyl fumarate). The overall proportion of patients with AEs leading to study discontinuation were 1.6% for diroximel fumarate and 6.0% for dimethyl fumarate. Of those, the proportion of patients who discontinued due to GI adverse events during the five-week treatment period were 0.8% for diroximel fumarate and 4.8% for dimethyl fumarate. Further analysis of the data from the EVOLVE-MS-2 study is ongoing and will be presented at a future scientific forum.

“As part of our leadership in multiple sclerosis, Biogen has long understood that the disease differs from person to person, as well as throughout the course of the disease. We are committed to offering a range of options to patients to meet their needs,” said Michael Ehlers, executive vice president, research & development at Biogen. “These data build on the foundation we have created with TECFIDERA, the most prescribed oral MS therapy worldwide, and further demonstrate the potential of diroximel fumarate as a novel oral fumarate within our MS portfolio.”

“Diroximel fumarate demonstrated statistically superior GI tolerability compared to dimethyl fumarate on the EVOLVE-MS-2 study’s primary endpoint, as well as a low discontinuation rate of less than 1% due to GI adverse events. These results reinforce the safety and tolerability profile diroximel fumarate has consistently demonstrated across the EVOLVE-MS development program, underscoring the potential importance of diroximel fumarate for the treatment of people living with relapsing-remitting MS. We look forward to the FDA’s completion of its review of the diroximel fumarate NDA in the fourth quarter,” said Craig Hopkinson, M.D., chief medical officer and senior vice president of medicines development and medical affairs at Alkermes.

EVOLVE-MS-2 was a Phase 3, multicenter, double-blind, active-controlled, five-week study designed to evaluate the GI tolerability, including duration and severity, of diroximel fumarate 462 mg twice daily compared to dimethyl fumarate 240 mg twice daily in 506 patients with RRMS. The study’s primary endpoint assessed the number of days patients reported GI symptoms with a symptom intensity score ≥2 on the IGISIS rating scale spanning 0 (not at all) through 10 (extreme). The IGISIS was completed twice daily and evaluated the intensity of key GI symptoms, including nausea, vomiting, upper and lower abdominal pain, and diarrhea.

“With a chronic disease like MS, interrupting or stopping treatment due to GI side effects can often provoke the return of disease activity. Physicians and patients should work together to choose a medication that provides the right balance of efficacy, safety and tolerability to help manage patients’ MS and meet their treatment goals,” said Robert Naismith, M.D., professor of neurology, Washington University School of Medicine in St. Louis. “These topline results suggest that diroximel fumarate offers a differentiated GI tolerability profile and may represent an important new option for people living with relapsing MS.”

The EVOLVE-MS-2 study is part of the EVOLVE-MS diroximel fumarate clinical development program, which is being conducted as part of a worldwide development and commercialization agreement between Alkermes and Biogen. Diroximel fumarate is currently under review with the U.S. Food and Drug Administration (FDA) with a PDUFA (Prescription Drug User Fee Act) target action date in the fourth quarter of 2019. Biogen intends to market diroximel fumarate under the conditionally approved brand name VUMERITY™.

About Diroximel Fumarate

Diroximel fumarate is an investigational, novel oral fumarate candidate with a distinct chemical structure in development for the treatment of relapsing forms of MS. Diroximel fumarate is designed to rapidly convert to monomethyl fumarate in the body and, based on bioequivalence data, is referencing TECFIDERA® (dimethyl fumarate) as part of the 505(b)(2) regulatory pathway. Diroximel fumarate is currently under review with the U.S. Food and Drug Administration (FDA) with a PDUFA (Prescription Drug User Fee Act) target action date in the fourth quarter of 2019. If approved by the FDA, Biogen intends to market diroximel fumarate under the conditionally approved brand name VUMERITY™.

About the Diroximel Fumarate EVOLVE-MS Clinical Development Program

The key components of the EVOLVE-MS (**E**ndea**vo**ring to Advance Treatment for Patients **L**i**v**ing with Multip**l**e Sclerosis) clinical development program of diroximel fumarate include the EVOLVE-MS-1 study, a Phase 3, open-label, two-year safety study in relapsing-remitting MS patients, along with pharmacokinetic bridging studies comparing diroximel fumarate and dimethyl fumarate to demonstrate bioequivalence. The EVOLVE-MS clinical development program also includes EVOLVE-MS-2, a Phase 3, five-week randomized, prospective, double-blind, multi-center study assessing the GI tolerability of diroximel fumarate and dimethyl fumarate.

About Tecfidera® (dimethyl fumarate)

TECFIDERA is the most prescribed oral medication for relapsing multiple sclerosis (MS) in the world and has been shown to reduce the rate of MS relapses, slow the progression of disability and impact the number of MS brain lesions, while demonstrating a well-characterized safety profile in people with relapsing forms of MS. TECFIDERA is approved in 69 countries and more than 398,000 patients have

been treated with it, representing more than 740,000 patient-years of exposure across clinical trial use and patients prescribed TECFIDERA. Of these, 6,335 patients (12,985 patient-years) were from clinical trials.**1**[i] TECFIDERA is indicated in the U.S. for the treatment of patients with relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. TECFIDERA is approved in the European Union for relapsing-remitting MS.

TECFIDERA is contraindicated in patients with a known hypersensitivity to dimethyl fumarate or any of the excipients of TECFIDERA. Rare cases of progressive multifocal leukoencephalopathy, a rare opportunistic viral infection of the brain which has been associated with death or severe disability, have been seen with TECFIDERA patients in the setting of prolonged lymphopenia although the role of lymphopenia in these cases is uncertain. Other serious side effects include a decrease in mean lymphocyte counts during the first year of treatment, which then plateaued, and liver function abnormalities, which resolved upon treatment discontinuation. In clinical trials, the most common adverse events associated with TECFIDERA were flushing and gastrointestinal (GI) events.

Please click here for Important Safety Information and full Prescribing Information, including Patient Information for TECFIDERA in the U.S., or visit your respective country's product website.

About Alkermes plc
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.

About Biogen
At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological and

neurodegenerative diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp, and today has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, commercializes biosimilars of advanced biologics and is focused on advancing neuroscience research programs in multiple sclerosis and neuroimmunology, neuromuscular disorders, movement disorders, Alzheimer's disease and dementia, ophthalmology, immunology, neurocognitive disorders, acute neurology and pain.
We routinely post information that may be important to investors on our website at www.biogen.com. To learn more, please visit www.biogen.com and follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Alkermes 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 continued clinical development and the potential therapeutic and commercial value of diroximel fumarate for the treatment of relapsing forms of MS; plans for presentation of the EVOLVE-MS-2 data at an upcoming scientific forum; the timing and potential outcome of the FDA review of the NDA for diroximel fumarate; the differentiated GI tolerability profile of diroximel fumarate in the future treatment of patients with relapsing forms of MS; and the potential financial, commercial and therapeutic benefits that may be achieved through collaboration with Biogen under the license and collaboration agreement between Alkermes and Biogen. Alkermes cautions that forward-looking statements are inherently uncertain. Although Alkermes 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 preclinical and early clinical results for diroximel fumarate will be predictive of future clinical study results or real-world results; whether clinical trials for diroximel fumarate will be completed on time or at all; whether diroximel fumarate could be shown ineffective or unsafe during clinical studies, and whether, in such instances, Alkermes or Biogen may not be permitted by regulatory authorities to undertake

new or additional clinical studies of diroximel fumarate; whether regulatory submissions for diroximel fumarate will be submitted on time or at all; whether adverse decisions by regulatory authorities will occur; whether the data included in the NDA for diroximel fumarate will meet the FDA's requirements for approval; whether the potential financial, commercial and therapeutic benefits of collaboration with Biogen under the license and collaboration agreement between Alkermes and Biogen will be achieved; and those risks described in the Alkermes Annual Report on Form 10-K for the year ended Dec. 31, 2018 and in subsequent filings made by Alkermes 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, Alkermes disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to the potential benefits, safety and efficacy of diroximel fumarate; potential clinical effects of diroximel fumarate; results from the EVOLVE-MS-2 study; the clinical development program for diroximel fumarate; potential regulatory approval and the timing thereof; clinical trial results and plans; Biogen's research and development program for the treatment of MS; the treatment of MS; the potential of Biogen's commercial business and pipeline programs, including diroximel fumarate; the anticipated benefits and potential of Biogen's collaboration arrangements with Alkermes; and risks and uncertainties associated with drug development and commercialization. These forward-looking statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "except," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation the occurrence of

adverse safety events and/or unexpected concerns that may arise from additional data or analysis; risks of unexpected costs or delays; regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of Biogen's drug candidates, including diroximel fumarate; actual timing and content of submissions to and decisions made by the regulatory authorities regarding Biogen's drug candidates, including diroximel fumarate; regulatory submissions may take longer or be more difficult to complete than expected; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Biogen's drug candidates, including diroximel fumarate; unexpected concerns may arise from additional data, analysis or results obtained during clinical trials; failure to protect and enforce Biogen's data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; uncertainty of success in the development and potential commercialization of VUMERITY; risks relating to the potential launch of VUMERITY, including preparedness of healthcare providers to treat patients, the ability to obtain and maintain adequate reimbursement for VUMERITY and other unexpected difficulties or hurdles; product liability claims; and third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this press release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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[i] Combined post-marketing data based on prescriptions and clinical trials exposure to TECFIDERA as of April 30, 2019.