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): August 29, 2023

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 1.01 Entry into a Material Definitive Agreement.

On August 29, 2023, Alkermes, Inc. and Alkermes Pharma Ireland Limited, subsidiaries of Alkermes plc (together, "Alkermes"), entered into a Confidential Settlement and License Agreement (the "Settlement Agreement") with Teva Pharmaceuticals USA, Inc. ("Teva", and together with Alkermes, the "parties") relating to Alkermes' product VIVITROL® (naltrexone for extended-release injectable suspension). The Settlement Agreement resolves patent litigation brought by Alkermes against Teva related to the infringement of Orange Book-listed United States Patent No. 7,919,499 with respect to Teva's Abbreviated New Drug Application ("ANDA") No. 213195. Pursuant to the terms of the Settlement Agreement, Alkermes will grant Teva a non-exclusive, royalty-free, non-transferable, non-sublicensable limited license to make, have made, use, import, sell and offer for sale Teva's product made under ANDA No. 213195 in the United States beginning on January 15, 2027, or earlier under certain circumstances.

The Settlement Agreement obligates the parties to promptly file a joint Stipulated Consent Judgment and Injunction to dismiss pending legal proceedings. The Settlement Agreement is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice. The description of the Settlement Agreement contained herein does not purport to be complete and is qualified in its entirety by reference to the Settlement Agreement, which Alkermes intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2023.

Item 7.01 Regulation FD Disclosure.

On August 30, 2023, Alkermes issued a press release announcing the Settlement Agreement, a copy of which is furnished herewith as Exhibit 99.1 and is incorporated herein by reference. This Item 7.01 and 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 dated August 30, 2023.
104	Cover page interactive data file (embedded within the Inline XBRL document).

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: August 30, 2023

By: /s/ David J. Gaffin
David J. Gaffin
Secretary

Exhibit 99.1

Alkermes Contacts:
For Investors: Sandy Coombs +1 781 609 6377
For Media: Marisa Borgasano +1 781 609 6659

Alkermes Announces Settlement With Teva Related to VIVITROL® Patent Litigation

— Company Grants Teva a License to Market Generic VIVITROL Beginning in January 2027 —

DUBLIN, August 30, 2023 -- Alkermes plc (Nasdaq: ALKS) announced today that the company entered into a settlement agreement with Teva Pharmaceuticals USA, Inc. ("Teva") to resolve the ongoing patent litigation between the parties in the U.S. District Court for the District of New Jersey related to VIVITROL® (naltrexone for extended-release injectable suspension). Pursuant to the terms of the settlement agreement, the company has granted Teva a license under U.S. Patent No. 7,919,499 to market a generic version of VIVITROL in the United States beginning January 15, 2027, or earlier under certain customary circumstances.

Additional details regarding the settlement agreement were not disclosed. The company and Teva will submit the settlement agreement for review to the United States Federal Trade Commission and the United States Department of Justice.

This patent litigation was initiated by the company in September 2020 in response to Teva's abbreviated new drug application seeking United States Food and Drug Administration approval of a generic version of VIVITROL in the United States prior to the expiration of Alkermes' U.S. Patent No. 7,919,499, an Orange Book-listed patent for VIVITROL that expires in 2029. The parties completed a trial in March 2023. In connection with the settlement, the company and Teva will file a proposed Stipulated Consent Judgment and Injunction with the U.S. District Court for the District of New Jersey requesting that the Court dismiss the pending litigation between the parties.

About Alkermes plc
Alkermes plc is a fully-integrated, global biopharmaceutical company developing innovative medicines in the fields of neuroscience and oncology. The company has a portfolio of proprietary commercial products focused on alcohol dependence, opioid dependence, schizophrenia and bipolar I disorder, and a pipeline of product candidates in development for neurological disorders and cancer. Headquartered in Dublin, Ireland, Alkermes plc has a research and development 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 terms of the settlement agreement with Teva, expectations regarding the impact of the settlement agreement and submission of the settlement agreement for review to the United States Federal Trade Commission and the United States Department of Justice. 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, including the unfavorable outcome of other litigation, including so-called “Paragraph IV” litigation and other patent litigation, related to VIVITROL, which may lead to competition from generic drug manufacturers; the outcome of any review of the settlement agreement by the United States Federal Trade Commission and United States Department of Justice; and those risks and uncertainties described under the heading “Risk Factors” in the company’s most recent Annual Report on Form 10-K 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.

###