

**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): September 9, 2020

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.)

**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 8.01 Other Events.

On September 9, 2020, Alkermes, Inc. and Alkermes Pharma Ireland Limited, each an indirect wholly-owned subsidiary of Alkermes plc (collectively with its subsidiaries, “Alkermes”), filed a patent infringement lawsuit in the United States District Court, District of New Jersey against Teva Pharmaceuticals USA, Inc. (“Teva USA”) and Teva Pharmaceutical Industries Ltd. in response to Teva USA’s Paragraph IV certification notice (the “Notice Letter”) regarding the Abbreviated New Drug Application (“ANDA”) submitted by Teva USA to the U.S. Food and Drug Administration (the “FDA”) seeking approval from the FDA to engage in the commercial manufacture, use or sale of a generic version of VIVITROL® (naltrexone for extended-release injectable suspension), in the United States.

The Notice Letter referenced a Paragraph IV certification against one Alkermes patent related to VIVITROL, U.S. Patent No. 7,919,499 (“the ‘499 patent”), which is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the Orange Book). The Notice Letter alleges that the ‘499 patent, which expires in October 2029, is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Teva USA’s proposed product.

Alkermes intends to vigorously defend its intellectual property. The filing of the lawsuit within 45 days of receipt of the Notice Letter triggered a stay of FDA approval of the ANDA for up to 30 months in accordance with the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act).

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: September 9, 2020

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