

**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) January 3, 2023

**JAZZ PHARMACEUTICALS PUBLIC LIMITED
COMPANY**

(Exact name of registrant as specified in its charter)

Ireland
(State or Other Jurisdiction
of Incorporation)

001-33500
(Commission
File No.)

98-1032470
(IRS Employer
Identification No.)

Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland D04 E5W7
(Address of principal executive offices, including zip code)

011-353-1-634-7800
(Registrant's telephone number, including area code)

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:

- 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, nominal value \$0.0001 per share	JAZZ	The Nasdaq Stock Market LLC

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.

In November and December 2022, Jazz Pharmaceuticals plc (the “Company”) received notices from Teva Pharmaceuticals, Inc.; Padagis US LLC; Apotex Inc.; API Pharma Tech LLC and InvaGen Pharmaceuticals, Inc.; Lupin Limited; Taro Pharmaceutical Industries Ltd.; Zenara Pharma Private Limited and Biophore Pharma, Inc.; MSN Laboratories Pvt. Ltd. and MSN Pharmaceuticals, Inc.; Alkem Laboratories Ltd.; and Ascent Pharmaceuticals, Inc. (the “ANDA Filers”), that they have each filed with the U.S. Food and Drug Administration (“FDA”) an Abbreviated New Drug Application (“ANDA”), for a generic version of Epidiolex® (cannabidiol) oral solution. As of the date of this filing, we are not aware of other ANDA filers. The notices from the ANDA Filers each included a “paragraph IV certification” with respect to certain of the Company’s patents listed in FDA’s Orange Book for Epidiolex on the date of the receipt of the notice. The listed patents relate generally to the composition and method of use of Epidiolex, and methods of treatment using Epidiolex. A paragraph IV certification is a certification by a generic applicant that alleges that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product.

On January 3, 2023, the Company filed a patent infringement suit against the ANDA Filers in the United States District Court for the District of New Jersey. The complaint alleges that by filing their ANDAs, the ANDA Filers have infringed certain of the Company’s Orange Book listed patents, and seeks an order that the effective date of FDA approval of the ANDAs shall be a date no earlier than the expiration of the last to expire of the asserted patents. As a result of this lawsuit, a stay of approval of up to 30 months will be imposed by FDA on the ANDA Filers’ ANDAs. Epidiolex also has Orphan Drug Exclusivity for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older through September 28, 2025 and for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients between 1 and 2 years of age and for the treatment of seizures associated with tuberous sclerosis complex through July 31, 2027.

SIGNATURES

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.

JAZZ PHARMACEUTICALS PUBLIC LIMITED
COMPANY

By: /s/ Neena Patil
Name: Neena Patil
Title: Executive Vice President and Chief Legal
Officer

Date: January 4, 2023