

Jazz Pharmaceuticals plc
Form 8-K
December 11, 2012

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

December 10, 2012

Date of Report (Date of earliest event reported)

JAZZ PHARMACEUTICALS PUBLIC LIMITED
COMPANY

(Exact name of Registrant as specified in its charter)

Edgar Filing: Jazz Pharmaceuticals plc - Form 8-K

Ireland
(State or Other Jurisdiction of

001-33500
(Commission

98-1032470
(IRS Employer

Incorporation)

File No.)

Identification No.)

Fourth Floor, Connaught House, One Burlington Road, Dublin 4, Ireland

(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))

Item 8.01. Other Events.

On December 10, 2012, Jazz Pharmaceuticals, Inc. (the Company), a subsidiary of Jazz Pharmaceuticals plc (the Registrant), received notice from Amneal Pharmaceuticals, LLC (Amneal) that Amneal has submitted an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (the FDA) seeking regulatory approval to market a generic version of Xyrem[®] (sodium oxybate) oral solution 500 mg/ml. The notice from Amneal included a Paragraph IV certification with respect to the following patents listed in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), U.S. Patent Nos. 6,780,889; 7,262,219; 7,668,730; 7,765,106; 7,765,107; 7,851,506; 7,895,059; and 8,263,650, alleging that these patents are invalid and/or not infringed by the manufacture, use, sale, offer for sale and/or importation of Amneal's proposed generic product.

The Company is currently reviewing the details of Amneal's notice and Paragraph IV certification. Under the Hatch-Waxman Act, the Company has 45 days from receipt of the notice to determine if it will file a patent infringement suit. If the Company brings such a suit, a stay of approval will be imposed by the FDA on Amneal's ANDA for 30 months after the date of the Company's receipt of Amneal's notice or until a district court decision with respect to the validity or infringement of the Company's patents that is adverse to the Company, whichever is earlier.

The Company intends to vigorously enforce its intellectual property rights, but cannot predict the outcome of this matter.

Previous Paragraph IV certification notices for Xyrem have been received from Roxane Laboratories, Inc., as described in more detail in the Legal Proceedings section of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 filed with the Securities and Exchange Commission on November 9, 2012 (the September 2012 Quarterly Report). To the extent that the Company receives additional Paragraph IV certification notices from other companies with respect to ANDAs submitted to the FDA seeking regulatory approval to market a generic version of Xyrem[®], the Company intends to disclose such additional notices through its Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K filed with the Securities and Exchange Commission rather than through the filing of Current Reports on Form 8-K.

For a discussion of risks related to the ANDA filing that is the subject of this Current Report on Form 8-K and the prior ANDA filing, see the Risk Factors section of the September 2012 Quarterly Report, including the risk factors under the headings Risks Relating to Xyrem and the Significant Impact of Xyrem Sales and Risks Related to Our Intellectual Property.

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/ Suzanne Sawochka Hooper
Name: Suzanne Sawochka Hooper
Title: Executive Vice President and General
Counsel

Date: December 11, 2012