

Jazz Pharmaceuticals plc
Form 8-K
January 22, 2013

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

January 18, 2013
Date of Report (Date of earliest event reported)

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Exact name of Registrant as specified in its charter)

Ireland	001-33500	98-1032470
(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

Fourth Floor, Connaught House, 1 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 January 18, 2013, Jazz Pharmaceuticals, Inc. (the “Company”), a subsidiary of Jazz Pharmaceuticals plc (the “Registrant”), filed a lawsuit in the United States District Court for the District of New Jersey against Amneal Pharmaceuticals, LLC (“Amneal”) for infringement of seven patents for Xyrem[®](sodium oxybate) oral solution, U.S. Patent Nos. 6,472,431; 6,780,889; 7,262,219; 7,851,506; 7,895,059; 8,263,650; and 8,324,275, six of which are currently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”). The lawsuit concerns an Abbreviated New Drug Application (“ANDA”) filed by Amneal with the U.S. Food and Drug Administration (“FDA”) seeking FDA approval to market a generic version of Xyrem[®](sodium oxybate) oral solution 500 mg/ml prior to the expiration of the identified patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Amneal, 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 Paragraph IV certification notice on December 10, 2012 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.

Previous Paragraph IV certification notices for Xyrem have been received from Roxane Laboratories, Inc. (“Roxane”), as described in more detail in the “Legal Proceedings” section of the Registrant’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”).

For a discussion of risks related to the ANDA filing that is the subject of this Current Report on Form 8-K and the ANDA filed by Roxane, 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: January 22, 2013