

Jazz Pharmaceuticals plc
Form 8-K
April 16, 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

April 12, 2013

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)

001-33500
(Commission)

98-1032470
(IRS Employer)

(of Incorporation)

(File No.)

(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 November 22, 2010, Jazz Pharmaceuticals, Inc., a wholly owned subsidiary of Jazz Pharmaceuticals plc, or the Company, filed a lawsuit in the United States District Court for the District of New Jersey, or the District Court, against Roxane Laboratories, Inc., or Roxane, in response to Roxane's Paragraph IV Certification notice, or Paragraph IV Certification, that it had submitted an abbreviated new drug application, or ANDA, to the United States Food and Drug Administration requesting approval to market a generic version of Xyrem® (sodium oxybate) oral solution. That lawsuit was consolidated with two subsequent lawsuits that Jazz Pharmaceuticals, Inc. filed in the District Court against Roxane, referred to together as the original case. The original case alleges infringement of eight of the Company's patents covering Xyrem.

Two additional patents covering formulations of Xyrem and the uses of Xyrem to treat cataplexy and daytime sleepiness in patients with narcolepsy (Patent Nos. 8,263,650 and 8,324,275), or the 650 patent and the 275 patent, were issued in September 2012 and December 2012, respectively. In October 2012, Jazz Pharmaceuticals, Inc. filed an additional lawsuit in the District Court against Roxane related to the 650 patent, or the 650 case, and in December 2012, Jazz Pharmaceuticals, Inc. filed a lawsuit in the District Court against Roxane related to the 275 patent, or the 275 case.

On April 12, 2013, the District Court issued an order consolidating the original case with the 650 case and the 275 case. Previously, the District Court held a scheduling conference for the purpose of setting discovery and other deadlines for the consolidated case, and a scheduling order is expected shortly. The parties proposed a consolidated schedule, subject to District Court approval, that contemplates fact discovery concerning the 650 and 275 patents remaining open until September 2013, with claim construction, or Markman, briefing scheduled to occur between July and October 2013. Expert discovery on the consolidated case, involving all ten of the patents involved in the consolidated case, is scheduled to begin following the issuance of any Markman order, and is expected to last approximately five and a half months. No trial date for the consolidated case has been scheduled. However, based on the schedule proposed in the scheduling conference, the Company anticipates that trial in the consolidated case could occur as early as mid-2014.

The actual timing of events in the litigation that is the subject of this report may be significantly earlier or later than contemplated by the schedule that was proposed in the recent scheduling conference and the Company's resulting current expectations, and the Company cannot predict the timing or outcome of events in the litigation.

This report contains forward-looking statements, including, but not limited to, statements related to future activity in, and the anticipated timing of, the ongoing litigation and events related thereto that are the subject of this report as well as related matters. These forward-looking statements are based on the Company's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of the contents of the District Court's final scheduling order and these risks and uncertainties, which include, without limitation, risks and uncertainties associated with the ongoing litigation and related regulatory matters and the Company's ability to protect its intellectual property rights with respect to Xyrem, as detailed under the caption Risk Factors and elsewhere in the Company's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and future filings and reports by the Company. The Company undertakes no duty or obligation to update any forward-looking statements contained in this report as a result of new information, future events or changes in its expectations.

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
Suzanne Sawochka Hooper
Executive Vice President and General Counsel

Date: April 15, 2013