

Jazz Pharmaceuticals plc
Form 8-K
March 06, 2014

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

March 5, 2014

Date of Report (Date of earliest event reported)

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.)

Edgar Filing: Jazz Pharmaceuticals plc - Form 8-K

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 (the Company), filed a lawsuit in the United States District Court for the District of New Jersey (the District Court) against Roxane Laboratories, Inc. (Roxane) in response to Roxane's Paragraph IV Patent Certification notice that it had submitted an abbreviated new drug application to the United States Food and Drug Administration requesting approval to market a generic version of Xyrem® (sodium oxybate) oral solution. Additional patents covering Xyrem have issued since the original suit was filed, and cases involving these patents have been consolidated with the original action. The consolidated case alleges infringement of ten of the Company's patents relating to Xyrem, of which four relate to the Company's distribution system associated with the use of Xyrem. These patents include U.S. Patent Nos. 7,688,730, 7,765,106, 7,765,107 and 7,895,059, also referred to as the 730 patent family.

On March 5, 2014, the District Court issued an order granting the Company's motion to bifurcate and stay claims related to the 730 patent family. As a result of this order, discovery and other litigation activities with respect to the 730 patent family have been suspended, and these claims will be litigated separately from the other claims in the consolidated case. We cannot predict the timing of the resumption of the litigation with respect to patents in the 730 patent family.

Although no trial date for the consolidated case has been scheduled, based on the current scheduling order, we anticipate that trial in the consolidated case with respect to the other six patents in suit could occur as early as late in the fourth quarter of 2014. However, the actual timing of events may be significantly earlier or later than contemplated by the current scheduling order.

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 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, 2013 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

Name: Suzanne Sawochka Hooper

Title: Executive Vice President and General Counsel

Date: March 6, 2014