

Jazz Pharmaceuticals plc
Form 8-K
July 28, 2016

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

July 27, 2016

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.)

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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.

IPR Decisions. On July 27, 2016, the Patent Trial and Appeal Board (the PTAB) of the U.S. Patent and Trademark Office issued final inter partes review (IPR) decisions that the claims of six patents related to the distribution system for Xyrem® (sodium oxybate) oral solution (Xyrem) are unpatentable; as a result, these patents cannot be enforced. The PTAB decisions were issued in connection with petitions for IPR filed by Amneal Pharmaceuticals LLC and Par Pharmaceutical, Inc. in January 2015. Jazz Pharmaceuticals plc (the Company) is reviewing the decisions to determine whether a request for rehearing by PTAB is warranted, and the Company expects to appeal these decisions to the United States Court of Appeals for the Federal Circuit.

ANDA Litigation. In November 2010, Jazz Pharmaceuticals, Inc., a wholly owned subsidiary of 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) seeking a permanent injunction to prevent Roxane from introducing a generic version of Xyrem that would infringe the Company's patents. Additional patents covering Xyrem were subsequently issued, and additional lawsuits were filed against Roxane to include these additional patents in the litigation. All of the lawsuits filed against Roxane between 2010 and 2012 were initially consolidated by the District Court into a single consolidated case. Subsequent lawsuits were consolidated by the District Court into a second consolidated case. At status conferences held in June and July 2016, the District Court determined that it would try all of the patents at issue in the first and second Roxane consolidated cases together, including patents that were previously bifurcated and stayed, and indicated that trial in this consolidated case will be set for the second quarter of 2017.

We cannot predict the outcome of any request for rehearing or appeal of the July 27, 2016 IPR decisions, the specific timing or outcome of events or matters discussed in this Current Report, or the impact of the IPR decisions on ongoing litigation proceedings, related regulatory matters or other aspects of our Xyrem business.

For a description of the matters reported in this Current Report prior to the events reported herein, see *Legal Proceedings* in Part II, Item 1 of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (the Form 10-Q). For a description of risks and uncertainties associated with the events reported in this Current Report, other ongoing litigation, related regulatory matters and the Company's ability to protect its intellectual property rights with respect to Xyrem, see the information set forth 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 Form 10-Q and future filings and reports by the Company.

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: July 28, 2016