

Jazz Pharmaceuticals plc
Form 8-K
March 02, 2015

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

February 27, 2015
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 February 27, 2015, the U.S. Food and Drug Administration (the “FDA”) notified Jazz Pharmaceuticals, Inc. (“JPI”), a wholly owned subsidiary of Jazz Pharmaceuticals plc (the “Company”), of (i) the FDA’s approval of the risk evaluation and mitigation strategy (“REMS”) for Xyrem[®] (sodium oxybate) oral solution in the form submitted by JPI in November 2014, which includes provisions requiring distribution through a single pharmacy, and (ii) the FDA’s denial of JPI’s dispute resolution appeal as moot as a result of approval of the Xyrem REMS. The Company expects to timely implement the final approved Xyrem REMS and to submit ongoing assessments as set forth in the FDA’s Xyrem REMS approval notice.

In the approval notice, the FDA states its conclusion that the Xyrem REMS meets the applicable statutory standards. Under the Federal Food, Drug, and Cosmetic Act (the “Act”), the FDA will require a REMS if it determines a REMS is necessary to ensure that the benefits of the drug outweigh the risks of the drug. The FDA may require a REMS to include elements to assure safe use (“ETASU”) to mitigate a specific serious risk listed in the labeling of the drug. The ETASU must be commensurate with the specific serious risks listed in the labeling of the drug, not be unduly burdensome on patient access to the drug, and, to the extent practicable, be structured so as to minimize the burden on the health care delivery system.

The approval notice includes statements from the FDA that (i) the approval action should not be construed or understood as agreement with the Company that dispensing to a single pharmacy is the only way to ensure that the benefits of Xyrem outweigh its risks and that the FDA has continuing concerns that limiting the distribution of Xyrem to one pharmacy imposes burdens on patient access and the healthcare delivery system, and (ii) as with all REMS, the FDA intends to evaluate the Xyrem REMS on an ongoing basis and will require modifications as may be appropriate. The Company cannot predict whether the FDA will seek to require or ultimately require modifications to the Xyrem REMS, including with respect to the distribution system, or seek to otherwise impose or ultimately impose additional requirements to the Xyrem REMS, or the potential timing, terms or propriety thereof.

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to timely implementation of the final approved Xyrem REMS and submission of ongoing assessments under the REMS by the Company, possible future FDA actions to modify the Xyrem REMS or to otherwise impose additional requirements to the Xyrem REMS and other statements that are not historical facts. These forward-looking statements are based on the Company’s current understandings and expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated and any possibilities noted in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, (i) risks and uncertainties associated with future actions by the FDA with respect to the Xyrem REMS, including the risk that the FDA may seek to require modifications or impose additional requirements to the Xyrem REMS and the risks that any such modifications or additional requirements could potentially make it more difficult or expensive for the Company to distribute Xyrem, make it easier for future generic competitors, and/or negatively affect sales of Xyrem and (ii) risks and uncertainties associated with the pressure that the Company faces to develop a single shared REMS with potential generic competitors for Xyrem or to license or share aspects of the Xyrem REMS, the possibility that the FDA may assert that its waiver authority permits it to allow a generic competitor for Xyrem to market a generic drug with a separate REMS that includes different, but comparable, ETASU, the possibility that the Federal Trade Commission, other governmental authorities or others could claim or determine that the Company is using the Xyrem REMS in an anticompetitive manner (including in light of FDA’s statement in the approval notice that the Xyrem REMS could be used in an anticompetitive manner inconsistent with applicable provisions of the Act) or has engaged in other anticompetitive practices, and other risks with respect to the Xyrem REMS in the context of potential generic competition and more broadly. These and other risks are included 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 year ended December 31, 2014 and future filings and reports by the Company. The Company undertakes no duty or

obligation to update any forward-looking statements contained in this Current Report on Form 8-K 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/ Matthew P. Young
Name: Matthew P. Young
Title: Executive Vice President and Chief Financial Officer

Date: March 2, 2015