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 17, 2017
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.

Sodium Oxybate ANDA Approval.

On January 17, 2017, the U.S. Food and Drug Administration ("FDA") announced that it has approved an abbreviated new drug application ("ANDA") for a generic version of Xyrem® (sodium oxybate), a branded pharmaceutical product manufactured, marketed and sold by Jazz Pharmaceuticals plc (the "Company"). In connection with this approval, the FDA indicated that it has waived the requirement that Xyrem and generic sodium oxybate products utilize a single, shared system risk evaluation and mitigation strategy ("REMS") and approved the generic version of Xyrem with a separate REMS. The Company was not involved in the development of the generic sodium oxybate REMS, which was not publicly available as of January 17, 2017.

Based on publicly available information, the FDA "has determined that the generic sodium oxybate REMS has the same elements to assure safe use as the Xyrem REMS and operationalizes those elements in a comparable manner to the approved Xyrem REMS." The Company will evaluate whether the FDA's waiver of the requirement for a single, shared system REMS in connection with approval of the ANDA meets the conditions for such a waiver under applicable law and, to the extent that the Company determines that the waiver was not permissible under applicable law, intends to evaluate potential challenges to the FDA's waiver decision. The Company cannot predict whether or when the Company may pursue any such challenges or whether any such challenges would be successful.

In connection with FDA approval of the current Xyrem REMS in February 2015, the FDA indicated that it 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 request, seek to require or ultimately require modifications to the Xyrem REMS in connection with approval of the generic sodium oxybate REMS (or otherwise) or seek to otherwise impose or ultimately impose additional requirements to the Xyrem REMS, or the potential timing, terms or propriety thereof. Any such modifications or additional requirements could make it more difficult or expensive for the Company to distribute Xyrem, make distribution easier for generic competitors, impair the safety profile of Xyrem and/or negatively affect sales of Xyrem.

Citizen Petition Response.

In September 2016, Jazz Pharmaceuticals, Inc., a wholly owned subsidiary of the Company, submitted a Citizen Petition to the FDA requesting that, for safety reasons, the FDA refuse to approve any sodium oxybate ANDA with a proposed package insert or REMS that omits the portions of the Xyrem package insert and the Xyrem REMS that instruct prescribers on adjusting the dose of the product when it is co-administered with divalproex sodium (also known as valproate or valproic acid) (the "Citizen Petition"). On January 17, 2017, the FDA granted the Citizen Petition with respect to the Xyrem package insert. The FDA concluded that it will not approve any sodium oxybate ANDA referencing Xyrem that does not include in its labeling the portions of the currently approved Xyrem package insert related to the drug-drug interaction with divalproex sodium. The FDA stated that it did not need to reach the question of whether the drug-drug interaction information could have been excluded from the generic sodium oxybate REMS materials. The Company cannot predict whether or when one or more of the ANDA filers may pursue a challenge to the FDA's response to the Citizen Petition or whether any such challenges would be successful.

Intellectual Property Litigation.

The Company owns patents that cover the distribution, method of use and formulation of Xyrem, including patents relating to the safe and effective use of Xyrem by decreasing the dose of Xyrem when used concomitantly with divalproex sodium (the "DDI Patents"). As previously disclosed, the Company has filed lawsuits against each of the companies that has filed an ANDA with the FDA seeking approval to market a generic version of Xyrem alleging infringement of the Company's patents and seeking a permanent injunction to prevent these ANDA filers from introducing a generic version of Xyrem that would infringe the Company's patents. The federal district court in which the Company's patent litigation is ongoing has set trial on the Company's pending patent litigation in the consolidated matter against the first ANDA filer, other than litigation related to the Company's distribution system patents, for the second quarter of 2017. The Company cannot predict the timing or outcome of this consolidated case or other ongoing or future litigation involving the ANDA filers or whether the Company will be successful in maintaining the validity of the applicable patents and protecting the patents from infringement. In particular, the Company cannot predict whether it will be able to maintain the validity of its distribution system patents or DDI Patents or

obtain a judicial determination that the generic sodium oxybate package insert or REMS will infringe the distribution system patents or DDI Patents. For a description of ongoing legal proceedings as of November 8, 2016, see “Legal Proceedings” in Part II, Item 1 of the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2016. Since the date of the Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, litigation related to the distribution patents was bifurcated from the consolidated case against the first ANDA filer and stayed.

The timing of any potential commercial launch of a generic version of Xyrem is uncertain. While the FDA has approved a generic version of Xyrem, the Company does not believe a launch is likely to occur prior to a district court, or potentially an appellate court, decision in the Company’s ongoing patent litigation. In the event of commercialization prior to an appellate court decision in the Company’s favor, the Company believes that any company that has launched a generic version of Xyrem would be liable to the Company for damages, which could be significant. As previously disclosed, the Company expects that the commercialization of a generic version of Xyrem would have a material adverse effect on the Company’s business, financial condition, results of operations and growth prospects. For a discussion of this risk, see the risk factor under the heading “*If generic versions of Xyrem or other sodium oxybate products that compete with Xyrem are approved and launched, sales of Xyrem would be adversely affected*” and other risks described in Part II, Item 1A of the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to the Company’s evaluation of whether the FDA’s waiver of the requirement for a single, shared system REMS in connection with approval of the ANDA for a generic version of Xyrem meets the conditions for such a waiver under applicable law and, if not, potential challenges thereto by the Company, the potential that the FDA will require modifications to the Xyrem REMS or impose additional requirements to the Xyrem REMS, potential challenges to the FDA’s response to the Citizen Petition by one or more of the ANDA filers, the Company’s belief that a potential commercial launch of a generic version of Xyrem prior to a federal district court, or potential appellate court, decision in ongoing patent litigation is unlikely and the Company’s belief that in the event of an appellate court decision in the Company’s favor, any company that has launched a generic version of Xyrem would be liable to the Company for damages, which could be significant, and other statements that are not historical facts. 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 related to the potential introduction of a generic version of Xyrem; changed or increased regulatory restrictions, including changes to the Xyrem REMS and other regulatory actions by the FDA; the inherent risks and uncertainties associated with the ongoing patent and potential future litigation and regulatory challenges and the Company’s ability to protect its intellectual property rights with respect to Xyrem; the risk that any company or companies may decide, before applicable ongoing patent litigation is concluded, to launch a generic sodium oxybate product at risk of potentially being held liable for damages; any failure to comply with the Xyrem REMS obligations to the satisfaction of the FDA; and those other risks detailed from time to time under the caption “Risk Factors” and elsewhere in the Company’s Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the Quarterly Report on Form 10-Q for the quarter ended September 30, 2016 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/ Suzanne Sawochka Hooper
Suzanne Sawochka Hooper
Executive Vice President and General Counsel

Date: January 17, 2017