

Jazz Pharmaceuticals plc
Form 8-K
December 13, 2012

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

December 13, 2012

Date of Report (Date of earliest event reported)

**JAZZ PHARMACEUTICALS PUBLIC LIMITED
COMPANY**

(Exact name of Registrant as specified in its charter)

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Ireland
(State or Other Jurisdiction)

001-33500
(Commission)

98-1032470
(IRS Employer)

(of Incorporation)

(File No.)

(Identification No.)

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.

On December 13, 2012, the U.S. Food & Drug Administration (the "FDA") denied the Citizen Petition filed by Jazz Pharmaceuticals, Inc. (the "Company"), a wholly owned subsidiary of Jazz Pharmaceuticals plc, on July 10, 2012 (the "July 2012 Citizen Petition"). The July 2012 Citizen Petition addressed the requirements for submission of any abbreviated new drug application, or ANDA, referencing Xyrem and asked the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the ANDA submitted by Roxane Laboratories, Inc. ("Roxane"), that did not contain a proposed risk management system at the time it was accepted for review, because such ANDA would not have demonstrated, as required by law, that the new generic drug product would have the same labeling and conditions of use as Xyrem. The July 2012 Citizen Petition further requested that the FDA (i) not accept for review any ANDA referencing Xyrem that does not contain, at the time of its submission, a proposed risk management system sufficient to demonstrate that the new generic drug product has the same labeling and conditions of use as Xyrem; and (ii) determine that if any sponsor, including Roxane, of an ANDA referencing Xyrem that did not contain, at the time it was accepted for review, a proposed risk management system later submits, or resubmits, an ANDA that contains a proposed risk management system sufficient to demonstrate that the new generic drug product would have the same labeling and conditions of use of Xyrem, then such ANDA should not be approved for a period of up to thirty months beginning on the date the Company receives notice of any Paragraph IV certifications contained in such new ANDA, to the extent that the Company avails itself of its right to initiate a patent infringement action based on such notice.

The Company is evaluating the FDA's response to the July 2012 Citizen Petition and potential further actions that the Company may take with respect to the issues raised in the petition. The July 2012 Citizen Petition was directed to the filing requirements for an ANDA referencing Xyrem and does not address all of the requirements for approval of any such ANDA, or the effect of other provisions of applicable FDA regulations. The July 2012 Citizen Petition and the FDA's response are also independent of protections provided by the Company's intellectual property and the impact of ongoing and potential additional litigation related to currently filed or potential future ANDAs referencing Xyrem.

Copies of the July 2012 Citizen Petition and the FDA's response to the July 2012 Citizen Petition are available in the Investors & Media section of the Company's website at www.jazzpharmaceuticals.com.

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: December 13, 2012