Jazz Pharmaceuticals plc
Form 8-K
July 10, 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

Date of Report (Date of earliest event reported): July 10, 2012

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**001-33500**	**98-1032470**
(State or other jurisdiction	**(Commission**	**(IRS Employer**

of incorporation)	File Number)	Identification No.)

45 Fitzwilliam Square

Dublin 2, Ireland

(Address of principal executive offices, including zip code)

011-353-1-634-4183

(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 July 10, 2012, Jazz Pharmaceuticals, Inc., a wholly owned subsidiary of Jazz Pharmaceuticals plc (the Company), submitted a Citizen Petition to the U.S. Food and Drug Administration (the FDA) addressing the requirements for submission of any abbreviated new drug application (ANDA) referencing Xyrem (sodium oxybate) oral solution (Xyrem). The petition asks the FDA to rescind the acceptance of any previously-accepted ANDA referencing Xyrem, including the ANDA filed 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 petition further asks the FDA not to 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. Finally, the petition asks the FDA to 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, 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, in accordance with 21 U.S.C. 355(j)(5)(B)(iii), to the extent that the Company avails itself of its right to initiate a patent infringement action based on such notice.

The Citizen Petition arises from the Company s belief, based on non-confidential disclosures made by Roxane in the ongoing litigation between the Company and Roxane, that: Roxane s ANDA did not, at the time it was submitted in July 2010, include a proposed risk management system, Roxane did not submit to the FDA as part of its ANDA any materials relating to its proposed sodium oxybate risk management system until a brief outline of such system was submitted in April 2011, and Roxane did not submit any materials that could have potentially constituted a substantially complete proposal for a risk management system until at least October 2011, if at all. The Company believes that the FDA s premature acceptance of Roxane s ANDA caused the thirty-month stay under the Hatch-Waxman Act and the related patent litigation between the parties to begin prematurely in a manner contrary to the law.

The Company cannot predict when or if the FDA will respond to, or otherwise take any action with respect to, the Citizen Petition, or the effect of any such response or action on the ongoing litigation between the Company and Roxane. A copy of the Citizen Petition is available in the Investors & Media Other Information 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: July 10, 2012