

Jazz Pharmaceuticals plc
Form 8-K
November 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

November 13, 2012

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)

001-33500
(Commission)

98-1032470
(IRS Employer)

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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 November 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 May 18, 2012 (the "May 2012 Citizen Petition"). The May 2012 Citizen Petition addressed the legal and scientific bases for requiring in vivo bioequivalence studies for generic formulations of Xyrem (sodium oxybate) oral solution ("Xyrem") and requested that the FDA: publish in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") bioequivalence requirements specifying whether in vitro or in vivo bioequivalence studies, or both, are required for abbreviated new drug applications ("ANDAs") referencing Xyrem; not accept for review, review, or approve any ANDA referencing Xyrem unless and until the FDA has published bioequivalence requirements in the Orange Book specifying whether in vitro bioequivalence studies, in vivo bioequivalence studies, or both, are required for such ANDAs; and require in vivo bioequivalence studies for any sodium oxybate drug product for which approval is sought in an ANDA referencing Xyrem to the extent such drug product differs from Xyrem in manufacturing process, pH, excipients, impurities, degradants or contaminants. The Company is evaluating the FDA's response to the May 2012 Citizen Petition and potential further actions that the Company may take with respect to the issues raised in the petition.

The FDA response with respect to the May 2012 Citizen Petition did not address the Citizen Petition filed by the Company on July 10, 2012 (the "July 2012 Citizen Petition"), which was disclosed on a Current Report on Form 8-K filed by the Company with the U.S. Securities and Exchange Commission on July 10, 2012.

Copies of the May 2012 Citizen Petition, the FDA's response to the May 2012 Citizen Petition and the July 2012 Citizen Petition are available in the Investors & Media section of the Company's website at www.jazzpharma.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: November 13, 2012