Jazz Pharmaceuticals plc Form 8-K September 18, 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): September 17, 2012

## JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

#### Edgar Filing: Jazz Pharmaceuticals plc - Form 8-K

of incorporation)

### File Number) Fourth Floor, Connaught House, 1 Burlington Road,

Identification No.)

**Dublin 4, 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 September 17, 2012, Jazz Pharmaceuticals, Inc., a wholly owned subsidiary of Jazz Pharmaceuticals plc (the Company), received a claim construction order and opinion, also known as a Markman ruling, from the United States District Court for the District of New Jersey in connection with the ongoing patent litigation with Roxane Laboratories, Inc. (Roxane), Civil Action No. 10-6108. The litigation relates to Roxane s abbreviated new drug application filed with the United States Food and Drug Administration requesting approval to market a generic version of Xyrem® (sodium oxybate) oral solution. The Company believes that the Markman ruling is generally favorable to the Company s positions in the litigation going forward.

A Markman ruling is an interim order by a court that determines the meaning of certain patent claim terms as requested by one or more of the parties to a lawsuit, including the court—s determination that certain terms do not require construction. The ruling in this case follows a Markman hearing held on April 26, 2012. Neither the Markman hearing nor the ruling address the new patent related to Xyrem that was issued to Jazz Pharmaceuticals, Inc. on September 11, 2012, titled—Microbiologically Sound and Stable Solutions of Gamma-Hydroxybutyrate Salt for the Treatment of Narcolepsy—(Patent No. 8,263,650).

The Company expects that the next phase of the ongoing litigation will be expert discovery. No trial date has been scheduled. The Company cannot predict the outcome of this matter.

This report contains forward-looking statements, including, but not limited to, statements related to future activity in, and the potential outcome of, the ongoing litigation that is the subject of this report and related matters. 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 associated with the ongoing litigation and related regulatory matters and the Company s ability to protect its intellectual property rights with respect to Xyrem, as detailed 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 and future filings and reports by the Company. The Company undertakes no duty or obligation to update any forward-looking statements contained in this report 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

Name: Suzanne Sawochka Hooper

Title: Executive Vice President and General

Counsel

Date: September 17, 2012