# 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**

**May 30, 2012**
**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.)** |

**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.**

This Current Report on Form 8-K is being filed to (i) update the disclosures included in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q for the quarter ended March 31, 2012 that we filed with the Securities and Exchange Commission on May 8, 2012, including the "Risk Factors" included in Part II, Item 1A of the Form 10-Q, to reflect recent events related to our ongoing interactions with the Food and Drug Administration, or FDA, following the previously disclosed Form FDA 483 and associated warning letter we received in 2011, including the receipt of a second Form FDA 483 in May 2012 at the conclusion of an FDA inspection, and (ii) provide an update with respect to the anticipated closing of the planned acquisition of EUSA Pharma, Inc.

References in this Current Report on Form 8-K to "Jazz Pharmaceuticals," "we," "us," and "our" refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries, including its predecessor, Jazz Pharmaceuticals, Inc., except that all such references prior the effective time of the merger with Azur Pharma Public Limited Company on January 18, 2012 are references to Jazz Pharmaceuticals, Inc. and its consolidated subsidiaries.

Regulatory Update

In April 2011, we learned that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or ESSDS, and therefore to the FDA by us as required. Under the Xyrem risk management plan, Xyrem is distributed solely through ESSDS. Promptly after learning of this unreported information, we reported to the FDA all of the previously unreported cases that we and ESSDS had identified and began our investigation of data from ESSDS. We also began to immediately take specific steps to strengthen our own procedures, and those between us and ESSDS, to seek to ensure that all adverse events are reported to us, and to the FDA, in an appropriate and timely manner.

The information we initially received concerning the previously unreported cases of death did not specify the cause of death in most cases. We gathered additional information and completed earlier this year an analysis with respect to these cases under a plan that we had discussed with the FDA. The analysis showed that the mortality rates in patients receiving a Xyrem prescription have not increased over time since product launch, and, overall, the inclusion of the new cases does not change the known mortality risks observed among patients prescribed Xyrem. We are continuing to work with the FDA on both the product label and an updated risk management plan to further enhance and promote the safe use of Xyrem.

In May 2011, we received a Form FDA 483 at the conclusion of an FDA inspection conducted in late April and early May 2011, which included the investigator's observations concerning our adverse event reporting system. The Form FDA 483 covered the failure to report serious adverse events, including certain cases of deaths as described above, and also noted deficiencies in certain of our drug safety procedures. After receipt of this Form FDA 483, we continued our efforts to improve our systems, and those used by us and ESSDS, to address the deficiencies noted in the Form FDA 483, and those efforts are continuing.

In October 2011, we received a warning letter from the FDA relating to the matters covered by the Form FDA 483. We responded to the warning letter in November 2011, and provided an update in January 2012, advising the FDA of the efforts that we had taken to date and are continuing to take, including our progress with respect to, and the timing of, our further investigation of ESSDS information related to potential adverse events in the historical period covered by the Form FDA 483 and warning letter. This further investigation of data from the historical period is continuing and while, in our assessment, the results of our preliminary work with respect to the analysis are consistent with the previously known safety profile of Xyrem, we cannot predict the final outcome of this investigation. We have strengthened our procedures and are continuing to take appropriate corrective actions to address the matters covered in the warning letter. While we believe that we have made substantial progress in addressing the matters raised by the warning letter, in late May 2012, we received a Form FDA 483 at the conclusion of an FDA inspection conducted in May 2012. This Form FDA 483 noted the FDA investigators' observations with respect to our incomplete review of ESSDS information related to potential adverse events prior to 2011 and determination of whether there are additional adverse events that are required to be reported to the FDA based on such review; our investigation of serious unexpected adverse drug experiences, including insufficient documentation to demonstrate the past investigation; and our lack of a written procedure relating to one administrative aspect of our current drug safety monitoring procedures.

While we responded to the warning letter and intend to respond to the May 2012 Form FDA 483 in a timely manner, and we anticipate that we will be able to promptly complete the actions that we believe are required to address the matters raised in the warning letter and the observations in the May 2012 Form FDA 483, we cannot predict the final outcome of the FDA's regulatory compliance review, or the timing thereof.

Planned Acquisition of EUSA Pharma

We have satisfied all requirements with respect to antitrust approvals in the U.S. and other required jurisdictions in connection with our planned acquisition of EUSA Pharma. While the closing of the transaction remains subject to customary closing conditions, we continue to expect that we will complete the acquisition in June 2012.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to future interactions with, and potential actions by, the FDA, our ability to promptly complete the actions that we believe are required to address the matters raised in the warning letter and the observations in the May 2012 Form FDA 483, the results of our further investigation of ESSDS information related to potential adverse events in the historical period covered by the 2011 Form FDA 483 and warning letter, the anticipated closing of the acquisition of EUSA Pharma and other statements that are not historical facts. These forward-looking statements are based on our 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, the risks that: any failure to demonstrate our substantial compliance with applicable regulatory requirements to the FDA's satisfaction, or significant unexpected results from our further investigation of potential serious adverse events as discussed in this Current Report on Form 8-K, could have a material and adverse effect on our business, financial condition and results of operations; we cannot assure you that the FDA will agree with our proposed updates to the Xyrem label or risk management plan, whether the FDA will open an evaluation based on the FDA's Adverse Event Reporting System database, or whether the FDA will take or require us to take other actions that could be costly or time-consuming and/or negatively affect the commercial success of Xyrem; and we cannot assure you that regulatory authorities in other countries where Xyrem is sold will not take similar actions; and other risks related to regulatory obligations and oversight and our ability to complete the planned acquisition of EUSA Pharma on the proposed terms and schedule, including risks and uncertainties related to the satisfaction of the closing conditions, as detailed from time-to-time under the caption "Risk Factors" and elsewhere in our Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, as updated by this Current Report on Form 8-K. We undertake 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 our 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: June 4, 2012