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

July 9, 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 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, or the SEC, on May 8, 2012, including the "Risk Factors" included in Part II, Item 1A of the Form 10-Q, and the Current Report on Form 8-K that we filed with the SEC on June 4, 2012, to reflect recent events related to our ongoing interactions with the Food and Drug Administration, or FDA, and related actions that we have taken.

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.

As previously disclosed, in late May 2012, we received a Form FDA 483 at the conclusion of an FDA inspection conducted in May 2012. The May 2012 FDA Form 483 followed a Form FDA 483 that we received in May 2011 and a warning letter from the FDA that we received in October 2011 relating to the matters covered by the 2011 Form FDA 483. The May 2012 Form FDA 483 noted the FDA investigators' observations with respect to our incomplete review of information from Express Scripts Specialty Distribution Services, Inc. and its affiliate CuraScript, Inc., or ESSDS, related to potential Xyrem-related 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. In June 2012, we responded to the May 2012 Form FDA 483 with our plan to address the observations, and we believe that we have now substantially completed the review, investigation and documentation that is necessary to fully address the observations. In particular, we have completed our review of ESSDS information related to potential Xyrem-related adverse events over an approximately nine-year period from late 2002 through May 2011. As a result of this 2012 review, over the entire period that was reviewed, we have identified fewer than 80 previously unreported serious adverse events that are required to be reported to the FDA. Of these events, approximately one-half were "serious and unexpected" cases (including a small number of deaths) that require expedited reporting to the FDA, which we completed in July 2012. We plan to submit the balance of the previously unreported adverse events in our periodic safety update report (PSUR) that is due to be filed with the FDA in September 2012. We have also completed and documented the investigation of serious and unexpected adverse drug experiences in the historical period that was the subject of the May 2012 Form FDA 483. Finally, we have documented and implemented a procedure with respect to the administrative aspect of our current drug safety monitoring procedures that was the subject of the May 2012 FDA Form 483. We are also near completion of the actions that we believe are necessary to fully address the matters raised in the October 2011 warning letter. While we have completed the actions that we believe are required to address the observations in the May 2012 Form FDA 483 and believe that we are near fully addressing the matters raised in the warning letter, we cannot predict the final outcome of the FDA's regulatory compliance review, or the timing thereof.

In July 2012, we held a telephonic meeting with the FDA with respect to our analysis of the effect of previously unreported deaths that we identified in 2011. 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 data did not change the known risks associated with the use of Xyrem. As a result of the July 2012 meeting, we believe that the FDA does not require any further analysis with respect to the historical period that was covered by the analysis.

This analysis arose from our discovery in April 2011 that deaths of patients who had been prescribed Xyrem between 2003 and 2010 had not always been reported to us by ESSDS and therefore to the FDA by us as required. 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. 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. This analysis was the subject of our July 2012 telephonic meeting with the FDA.

Our ongoing review of Xyrem safety information has not resulted in any significant change in our view of the overall safety profile of the product. We are continuing to work with the FDA on both the product label and updated Risk Evaluation and Mitigation Strategy, or REMS, to further enhance and promote the safe use of Xyrem. We cannot predict the final outcome of the FDA's review of our proposed changes to the product label or updated REMS, or the timing thereof.

"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 fully address the matters raised in the May 2012 Form FDA 483 and the warning letter 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 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 REMS, 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 and uncertainties 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 and our June 4, 2012 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: July 9, 2012