JAZZ PHARMACEUTICALS INC
Form 8-K
October 20, 2010

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

October 18, 2010

Date of Report (Date of earliest event reported)

JAZZ PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**001-33500**	**05-0563787**

(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

3180 Porter Drive, Palo Alto, California 94304

(Address of principal executive offices, including zip code)

(650) 496-3777

(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 October 18, 2010, Jazz Pharmaceuticals, Inc. (the Company) received notice from Roxane Laboratories, Inc. (Roxane) that it has filed with the U.S. Food and Drug Administration (the FDA) an Abbreviated New Drug Application (ANDA) for a generic version of Xyrem® (sodium oxybate oral solution) 500 mg/ml. The Company believes that the ANDA by Roxane is the ANDA identified by the Company in its press release issued on October 5, 2010. The notice from Roxane included a paragraph IV certification with respect to all of the Company s patents listed in the FDA s Orange Book on the date of the Company s receipt of the notice. A paragraph IV certification is a certification by a generic applicant that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product.

The Company is currently reviewing the details of Roxane s notice. Under the Hatch-Waxman Act, the Company has 45 days from receipt of the notice to determine if it will file a patent infringement suit. If the Company brings such a suit, a stay of approval of up to 30 months will be imposed by the FDA on Roxane s ANDA.

The Company intends to vigorously enforce its intellectual property rights, but cannot predict the outcome of this matter.

For a discussion of risks related to the ANDA filing, see the Risk Factors section of the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 filed by the Company on August 11, 2010, including the risk factors under the headings If generic products that compete with any of our products are approved, sales of our products may be adversely affected. and Risks Related to Our Intellectual Property.

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, INC.

By: /s/ BRUCE C. COZADD
Bruce C. Cozadd
Chairman and Chief Executive Officer

Date: October 20, 2010