

JAZZ PHARMACEUTICALS INC

Form 8-K

November 22, 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

November 22, 2010

Date of Report (Date of earliest event reported)

JAZZ PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

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(State or Other Jurisdiction

(Commission

(IRS Employer

of Incorporation)

File No.)

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 November 22, 2010, Jazz Pharmaceuticals, Inc. (the Company) filed a lawsuit in the United States District Court for the District of New Jersey against Roxane Laboratories, Inc. (Roxane) for infringement of all of the Company's patents for Xyrem® (sodium oxybate oral solution) currently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). The lawsuit concerns an Abbreviated New Drug Application (ANDA) filed by Roxane with the U.S. Food and Drug Administration (FDA) seeking FDA approval to market a generic version of Xyrem prior to the expiration of the identified patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Roxane, FDA approval of Roxane's ANDA will be stayed until the earlier of (i) 30 months from the Company's October 18, 2010 receipt of Roxane's Paragraph IV certification notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

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 September 30, 2010 filed by the Company on November 5, 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: November 22, 2010