

JAZZ PHARMACEUTICALS INC
Form 8-K
July 18, 2007

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 13, 2007

Date of Report (Date of earliest event reported)

JAZZ PHARMACEUTICALS, INC.

(Exact name of Registrant as specified in its charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

001-33500
(Commission File No.)

05-0563787
(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)

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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))
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Item 1.01 Entry into a Material Definitive Agreement.

On July 13, 2007, Jazz Pharmaceuticals, Inc. entered into (i) a civil settlement agreement (the "Civil Settlement Agreement") with the United States of America, acting through the United States Department of Justice, the United States Attorney's Office for the Eastern District of New York, the Office of Inspector General of the Department of Health and Human Services ("HHS-OIG"), the United States Office of Personnel Management and the United States Department of Defense TRICARE Management Activity to resolve the previously-disclosed governmental investigation related to the promotion of Xyrem® (sodium oxybate) and (ii) a non-prosecution agreement with the United States Attorney's Office for the Eastern District of New York (the "Non-prosecution Agreement") under which the United States Attorney's Office agreed that Jazz Pharmaceuticals would not be prosecuted for the matters that were the subject of the investigation. Orphan Medical, Inc., which was acquired by Jazz Pharmaceuticals in June 2005, entered into (i) a plea agreement with the United States Attorney's Office for the Eastern District of New York (the "Plea Agreement"), under which Orphan Medical pled guilty, on July 13, 2007, to one felony count of introducing a misbranded drug into interstate commerce and (ii) the Civil Settlement Agreement. Jazz Pharmaceuticals expects that it and Orphan Medical will also enter into agreements with Medicaid participating states.

Pursuant to the Civil Settlement Agreement and the Plea Agreement, payments totaling approximately \$20.0 million will be made over the period from July 20, 2007 through January 15, 2012. This amount includes payments to Federal healthcare programs and Medicaid participating states, as well as restitution and fines. In addition, under the Non-prosecution Agreement, Jazz Pharmaceuticals has agreed to guarantee payment by Orphan Medical of the amounts due under the Plea Agreement. The total payments due under the Civil Settlement Agreement and the Plea Agreement are payable as follows: \$1.0 million in 2007; \$2.0 million in 2008; \$2.5 million in 2009; \$3.0 million in 2010; \$3.0 million in 2011 and \$8.5 million in 2012. All remaining amounts due under the Civil Settlement Agreement could be accelerated if Jazz Pharmaceuticals is acquired, or in the event of an uncured default resulting from the failure to make payments when due. In addition, all or a portion of the remaining amounts due under the Civil Settlement Agreement could be accelerated if Jazz Pharmaceuticals has net income in any year. Orphan Medical, which no longer directly markets products, may be excluded from participation in Federal healthcare programs as a result of the settlement.

Jazz Pharmaceuticals has also entered into a five-year corporate integrity agreement with HHS-OIG (the "Corporate Integrity Agreement") pursuant to which Jazz Pharmaceuticals has agreed, among other things, to keep in place and continue its current compliance program, including a compliance committee, a compliance officer, a code of conduct, comprehensive compliance policies, training and monitoring, a compliance hotline, an open door policy and a disciplinary process for compliance violations. Jazz Pharmaceuticals will provide periodic reports to HHS-OIG and its compliance program will be reviewed by an independent review organization.

The settlement is neither an admission of liability by Jazz Pharmaceuticals nor a concession by the United States that its claims are not well founded. Participation in Federal healthcare programs by Jazz Pharmaceuticals, which was not prosecuted, will not be affected by the settlement. In the event of an uncured material breach or deliberate violation, as the case may be, of the Civil Settlement Agreement, the Corporate Integrity Agreement or the Non-prosecution Agreement, Jazz Pharmaceuticals could be excluded from participation in Federal healthcare programs and/or subject to prosecution.

The Plea Agreement was approved by the United States District Court for the Eastern District of New York on July 13, 2007.

The foregoing description of the Civil Settlement Agreement, the Non-prosecution Agreement, the Plea Agreement and the Corporate Integrity Agreement is qualified in its entirety by the text of those agreements, which are attached hereto as Exhibits 10.57A, 10.57B, 10.57C and 10.57D, respectively, and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit

Number	Description
10.57A	Civil Settlement Agreement, dated July 13, 2007, among the United States of America acting through the entities named therein, Jazz Pharmaceuticals, Inc., and Orphan Medical, Inc.
10.57B	Non-prosecution Agreement, dated July 13, 2007, between the United States Attorney's Office for the Eastern District of New York and Jazz Pharmaceuticals, Inc.
10.57C	Plea Agreement, dated July 13, 2007, between the United States Attorney for the Eastern District of New York and Orphan Medical, Inc.
10.57D	Corporate Integrity Agreement, dated July 13, 2007, between the Office of Inspector General of the Department of Health and Human Services and Jazz Pharmaceuticals, Inc.

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/ Carol A. Gamble
Carol A. Gamble
Senior Vice President, General Counsel
and Corporate Secretary

Date: July 17, 2007

EXHIBIT INDEX

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