

Jazz Pharmaceuticals plc
Form 8-K
August 05, 2014

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
August 4, 2014

Date of Report (Date of earliest event reported)

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction

of incorporation)

001-33500
(Commission

File No.)

98-1032470
(IRS Employer

Identification No.)

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Fourth Floor, Connaught House,

1 Burlington Road, Dublin 4, Ireland

(Address of principal executive offices, including zip code)

011-353-1-634-7800

(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 2.01. Completion of Acquisition or Disposition of Assets.

As previously announced, on July 1, 2014, Jazz Pharmaceuticals Public Limited Company (the *Company*), Jazz Pharmaceuticals International II Limited (the *Buyer*), a wholly-owned subsidiary of the Company, and Gentium S.p.A., a majority-owned subsidiary of the Company (the *Gentium*) and together with Buyer and the Company, Jazz Pharmaceuticals, entered into an Assignment Agreement (the *Assignment Agreement*) with Sigma-Tau Pharmaceuticals, Inc. (the *Sigma-Tau*).

Pursuant to the terms of the Assignment Agreement, Sigma-Tau agreed to sell, transfer and assign to Buyer all of Sigma-Tau's right, title and interest in and to the License and Supply Agreement, dated December 7, 2001, as amended, between Gentium and Sigma-Tau (the *License Agreement*), pursuant to which Sigma-Tau held certain rights to market defibrotide in North America, Central America and South America, and Buyer agreed to assume certain liabilities of Sigma-Tau under the License Agreement. Sigma-Tau also agreed to sell, transfer and assign to Buyer all of Sigma-Tau's and its affiliates' right, title and interest in and to certain know-how and certain other assets that, in each case, relate to defibrotide.

On August 4, 2014, the parties closed the transaction contemplated by the Assignment Agreement (the *Closing*). At the Closing, Buyer made an initial upfront payment of \$75 million to Sigma-Tau. Buyer is also obligated to make milestone payments of up to \$175 million to Sigma-Tau (the *Milestone Payments*) comprised of: (i) \$25 million upon the acceptance for filing by the U.S. Food and Drug Administration (the *FDA*) of the first new drug application (the *NDA*) for defibrotide for veno-occlusive disease (the *VOD*); and (ii) up to an additional \$150 million based on the timing of potential FDA approval of defibrotide for VOD. The Company has guaranteed Buyer's payment obligations under the Assignment Agreement, including to make the Milestone Payments and to cover any indemnification claims that are Buyer's responsibility. The terms of the Assignment Agreement, including the consideration, were negotiated between Jazz Pharmaceuticals and Sigma-Tau at arms' length.

The foregoing description of the Assignment Agreement and the transaction contemplated thereby does not purport to be complete and is subject to, and qualified in its entirety by reference to, the full text of the Assignment Agreement, which is filed as Exhibit 2.1 hereto and incorporated herein by reference. The Company has sought confidential treatment for certain portions of the Assignment Agreement pursuant to a confidential treatment request submitted to the Securities and Exchange Commission.

The Assignment Agreement has been included solely to provide investors and security holders with information regarding its terms. It is not intended to be a source of financial, business or operational information, or to provide any other factual information, about the rights acquired pursuant to, or any of the parties to, the Assignment Agreement. The representations, warranties and covenants contained in the Assignment Agreement are made only for purposes of the Assignment Agreement and are made as of specific dates; are solely for the benefit of the parties (except as specifically set forth therein); may be subject to qualifications and limitations agreed upon by the parties in connection with negotiating the terms of the Assignment Agreement, including being qualified by confidential disclosures made for the purpose of allocating contractual risk between the parties, instead of establishing matters as facts; and may be subject to standards of materiality and knowledge applicable to the contracting parties that differ from those applicable to investors or security holders. Investors and security holders should not rely on the representations, warranties and covenants or any description thereof as characterizations of the actual state of facts or condition of the rights acquired pursuant to, or any of the parties to, the Assignment Agreement. Moreover, information concerning the subject matter of the representations, warranties and covenants may change after the date of the Assignment Agreement, as applicable, which subsequent information may or may not be fully reflected in public disclosures.

Relationships

The Company became the indirect majority shareholder of Gentium in January 2014 pursuant to a tender offer and ultimately acquired more than 99% of the outstanding voting securities of Gentium (the *Gentium Acquisition*).

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Sigma-Tau is an affiliate of Sigma-Tau Finanziaria S.p.A., which together with its affiliated entities beneficially owned, based on public filings, approximately 17% of the outstanding voting securities of Gentium immediately prior to the Gentium Acquisition and was also represented on Gentium's board of directors.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits**

Exhibit Number	Description
2.1	Assignment Agreement, dated July 1, 2014, by and among Jazz Pharmaceuticals International II Limited, Sigma-Tau Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and Gentium S.p.A.*

* Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company undertakes to furnish supplemental copies of any of the omitted schedules upon request by the Securities and Exchange Commission. In addition, confidential treatment has been requested as to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to the potential acceptance for filing of and potential approval of an NDA for defibrotide, and other statements that are not historical facts. These forward-looking statements are based on the Company's 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, risks and uncertainties associated with the Company's ability to successfully manage the risks associated with integrating defibrotide into the Company's product portfolio; the possibility that the Company may fail to realize the anticipated benefits (commercial or otherwise) from the acquisition of rights to defibrotide in the Americas from Sigma-Tau; the inherent uncertainty associated with the regulatory approval process, including the risks that the Company may be required to conduct additional time-consuming and costly clinical trials in order to obtain any regulatory approval of defibrotide in the United States and that the Company may otherwise be unable to obtain or maintain any regulatory approvals for defibrotide in the United States; the difficulty and uncertainty of pharmaceutical product development, including the timing and cost thereof; and those other risks detailed from time-to-time under the caption "Risk Factors" and elsewhere in the Company's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the Quarterly Report on Form 10-Q for the quarter ended March 31, 2014 and future filings and reports by the Company, including the Quarterly Report on Form 10-Q for the quarter ended June 30, 2014. The Company undertakes 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 its 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
Name: Suzanne Sawochka Hooper
Title: Executive Vice President and
General Counsel

Date: August 5, 2014

EXHIBIT INDEX

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