Jazz Pharmaceuticals plc
Form 8-K
July 02, 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

July 1, 2014

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.)**

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 1.01. Entry into a Material Definitive Agreement.

On July 1, 2014, Jazz Pharmaceuticals Public Limited Company (the Company), Jazz Pharmaceuticals International II Limited (Buyer), a wholly-owned subsidiary of the Company, and Gentium S.p.A. (Gentium), a majority-owned subsidiary of the Company, entered into an Assignment Agreement (the Assignment Agreement) with Sigma-Tau Pharmaceuticals, Inc. (Sigma-Tau). Upon the closing of the transaction contemplated by the Assignment Agreement (the Closing), the Company would own worldwide rights to defibrotide.

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, 2011, as amended, between Gentium and Sigma-Tau (the License Agreement), pursuant to which Sigma-Tau has certain rights to market defibrotide in North America, Central America and South America, and Buyer has 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.

Upon the Closing, Buyer will make an initial upfront payment of $75 million to Sigma-Tau (the Initial Payment). 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 (FDA) of the first new drug application (NDA) for defibrotide for veno-occlusive disease (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 Initial Payment and the Milestone Payments and to cover any indemnification claims that are Buyer s responsibility.

Buyer and Sigma-Tau have made customary representations and warranties and agreed to customary covenants in the Assignment Agreement, and, subject to certain limitations, each of Buyer and Sigma-Tau has also agreed to indemnify the other for breaches of representations, warranties, covenants and other specified matters. In addition, Buyer and Sigma-Tau, on behalf of themselves and their affiliates, have agreed to release each other from certain liabilities with respect to the License Agreement or the defibrotide-related know-how and assets. The Closing is subject to certain conditions, including expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

The foregoing description of the Assignment Agreement and the transactions 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 will be filed as an exhibit to a subsequent Current Report on Form 8-K that the Company expects to file in connection with the anticipated Closing. The Company intends to seek confidential treatment for certain portions of the Assignment Agreement pursuant to a confidential treatment request that it intends to submit to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

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). 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**
99.1	Press Release, dated July 2, 2014, titled Jazz Pharmaceuticals Announces Agreement to Acquire Rights to Defibrotide in the Americas From Sigma-Tau Pharmaceuticals, Inc.

Forward-Looking Statements

This Current Report on Form 8-K and the accompanying Exhibit 99.1 contain forward-looking statements, including, but not limited to, statements related to the anticipated closing of the transaction contemplated by the Assignment Agreement and the timing and benefits thereof, the therapeutic and commercial potential of defibrotide, planned future discussions with the FDA concerning the regulatory pathway for submission of an NDA for defibrotide, the potential acceptance for filing of and potential approval of an NDA for defibrotide, potential future development of defibrotide for approval in countries outside the European Union (EU) and in other indications, the Company s pipeline and portfolio growth strategy, including potentially bringing new therapies to market, 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 complete the acquisition of defibrotide rights from Sigma-Tau pursuant to the Assignment Agreement on the proposed terms and schedule, including risks and uncertainties related to the satisfaction of closing conditions; 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 defibrotide rights 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 or in other countries outside of the EU; the difficulty and uncertainty of pharmaceutical product development, including the timing and cost thereof; risks related to effectively commercializing defibrotide, including uncertainty of the future sales of and revenue from defibrotide following regulatory approval, if any, in the United States, and in other indications; the Company s ability to identify and acquire, in-license or develop additional products or product candidates to grow its business; possible restrictions on the Company s ability and flexibility to pursue certain future opportunities as a result of its substantial outstanding debt obligations; risks related to future opportunities and plans; 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. The Company undertakes no duty or obligation to update any forward-looking statements contained in this Current Report on Form 8-K and the accompanying Exhibit 99.1 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/ Matthew P. Young
Name: Matthew P. Young
Title: Senior Vice President and Chief Financial Officer

Date: July 2, 2014

EXHIBIT INDEX

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