

Jazz Pharmaceuticals plc
Form 8-K
December 21, 2018

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

December 20, 2018

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.)

Edgar Filing: Jazz Pharmaceuticals plc - Form 8-K

Fifth Floor, Waterloo Exchange, Waterloo 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01. Other Events.

Solriamfetol New Drug Application

On December 21, 2018, Jazz Pharmaceuticals plc (the Company) issued a press release announcing that, on December 20, 2018, the U.S. Food and Drug Administration extended the Prescription Drug User Fee Act goal date for its review of the Company's New Drug Application for solriamfetol from December 20, 2018 to March 20, 2019. A copy of the press release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

Agreement with Porton Biopharma Limited

Jazz Pharmaceuticals France SAS (f/k/a EUSA Pharma SAS, f/k/a Opi S.A.) (Jazz France), a wholly owned subsidiary of the Company, and Porton Biopharma Limited, a limited liability company wholly owned by the UK Secretary of State for Health (PBL), entered into a Contract Variation Agreement dated as of December 20, 2018 (the Amendment) to the Royalty Bearing Licence Agreement and Supply Agreement Re Erwinia-Derived Asparaginase, dated as of July 22, 2005, between PBL (successor to Public Health England by novation) and Jazz France (as amended on December 22, 2009, November 21, 2011, and August 8, 2012, the RBLA). The term of the RBLA expires on December 31, 2020, subject to automatic five-year extensions unless terminated by either party in writing on or before a specified date. The Amendment amends the date by which a written notice of termination may be delivered from December 31, 2018 to February 28, 2019. The material terms of the RBLA remain unchanged. The Company expects to continue discussions with PBL related to an extension of the term of the RBLA after December 31, 2020 and/or entry into a replacement agreement, but the Company cannot predict whether the parties will reach agreement on an extension or other agreement prior to February 28, 2019 or whether PBL will deliver a termination notice to the Company on or before such date.

Pursuant to the RBLA, PBL (i) granted the Company an exclusive license to market, sell and distribute Erwinaze[®], a treatment approved in the U.S. and in certain markets in Europe (where it is marketed as Erwinase[®]) for patients with acute lymphoblastic leukemia who have developed hypersensitivity to *E. coli*-derived asparaginase, on a worldwide basis and (ii) agreed to manufacture Erwinaze for the Company. PBL is the Company's sole supplier for Erwinaze.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	<u>Press Release, dated December 21, 2018.</u>

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to the Company's expectations for continued negotiation with PBL related to an extension of the term of the RBLA beyond December 31, 2020 or entry into a replacement agreement, 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 by such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, the risks that: the Company and PBL may be unable to reach agreement on an extension of the Company's right to market, sell and distribute Erwinaze after December 31, 2020 or PBL may otherwise deliver a termination notice under the RBLA on or before February 28, 2019, in which case the Company would lose its license to sell Erwinaze in any market after December 31, 2020, except under specified terms for a post-expiration period; and the Company may incur significant costs and charges associated with termination of the RBLA; 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 Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 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 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
Executive Vice President and General
Title: Counsel

Date: December 21, 2018