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	**001-33500**	**98-1032470**
(State or Other Jurisdiction of Incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

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 Number	Description
99.1	Press Release, dated December 21, 2018.

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
Title: Executive Vice President and General Counsel

Date: December 21, 2018

Jazz Pharmaceuticals Receives New PDUFA Goal Date for Solriamfetol for Excessive Daytime Sleepiness Associated with Narcolepsy or Obstructive Sleep Apnea

DUBLIN, December 21, 2018 – Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced that the U.S. Food and Drug Administration (FDA) has extended the review period for its new drug application (NDA) for solriamfetol as a treatment to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy or obstructive sleep apnea (OSA). The updated Prescription Drug User Fee Act (PDUFA) goal date is now March 20, 2019.

The FDA determined that an NDA submission made by Jazz during the course of discussions regarding draft labeling for solriamfetol constitutes a major amendment to the NDA, resulting in a three-month extension of the PDUFA goal date to provide time for a full review of the submission.

“We appreciate the opportunity to work with the FDA to complete the review process as soon as possible,” said Jed Black, M.D., senior vice president, Sleep and CNS Medicine at Jazz Pharmaceuticals and adjunct professor, Stanford University Medical Center, Stanford Center for Sleep Sciences and Medicine. “We are committed to addressing unmet needs in sleep medicine and look forward to offering solriamfetol as a meaningful treatment option for patients living with excessive daytime sleepiness associated with narcolepsy or OSA.”

Jazz Pharmaceuticals will host a brief investor conference call and live audio webcast on Friday, December 21, 2018 at 8:30 a.m. EST (1:30 p.m. GMT) to discuss the PDUFA goal date extension and a business update. The live webcast may be accessed from the Investors section of the company’s website at www.jazzpharmaceuticals.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary. Investors may participate in the conference call by dialing +1 855 353 7924 in the U.S., or +1 503 343 6056 outside the U.S., and entering passcode 6766127.

A replay of the conference call will be available through December 28, 2018 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 6766127. An archived version of the webcast will be available for at least one week in the Investors section of the company’s website at www.jazzpharmaceuticals.com.

About Solriamfetol

Solriamfetol is a selective dopamine and norepinephrine reuptake inhibitor (DNRI) in development for treatment of excessive sleepiness in adult patients with narcolepsy, OSA, and Parkinson’s disease. In 2014, Jazz Pharmaceuticals acquired a license to develop and commercialize solriamfetol from Aerial Biopharma. Jazz Pharmaceuticals has worldwide development, manufacturing, and commercialization rights to solriamfetol, excluding certain jurisdictions in Asia. SK Biopharmaceuticals, the discoverer of the compound (also known as SKL-N05), maintains rights in 12 Asian markets, including Korea, China and Japan. Solriamfetol has orphan drug designation in the United States for narcolepsy.

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates with a focus in the areas of sleep and hematology/oncology. In these therapeutic areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Defitelio® (defibrotide sodium) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Erwinase®, Defitelio® (defibrotide) and Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion in countries outside the U.S. For country-specific product information, please visit http://www.jazzpharmaceuticals.com/products. For more information, please visit http://www.jazzpharmaceuticals.com/ and follow us on Twitter at @JazzPharma.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to the company offering solriamfetol as a meaningful treatment option for patients with excessive daytime sleepiness associated with narcolepsy or OSA, and other statements that are not historical facts. These forward-looking statements are based on the company's current plans, objectives, estimates, expectations and intentions 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 time-consuming and uncertain regulatory approval process, including the risk that the solriamfetol NDA may not be approved by the FDA on the anticipated timeline or at all, and that the label for solriamfetol may be more restrictive than anticipated; and the manufacture and effective commercialization of solriamfetol; and other risks and uncertainties affecting the company, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals plc'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. Other risks and uncertainties of which the company is not currently aware may also affect the company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by the company on its website or otherwise. The company undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

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