

Jazz Pharmaceuticals plc
Form 8-K
October 11, 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

October 11, 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.)

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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.

On October 11, 2018, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited, subsidiaries of Jazz Pharmaceuticals plc (collectively, Jazz), settled ongoing patent litigation against Amneal Pharmaceuticals LLC (Amneal) related to Amneal's abbreviated new drug application (ANDA) seeking to market a generic version of Xyrem® (sodium oxybate) oral solution.

In connection with the settlement, Amneal will have a non-exclusive right to sell a limited volume of an authorized generic version of Xyrem (the Amneal AG Product) for a term beginning on July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025. Jazz is entitled to receive a meaningful royalty on net sales of the Amneal AG Product as well as payment for the supply of the Amneal AG Product and reimbursement for a portion of the services costs associated with distribution of the Amneal AG Product through the Xyrem Risk Evaluation and Mitigation Strategy. In addition, Jazz granted Amneal a non-exclusive license to make, have made and market its own generic sodium oxybate product under Amneal's ANDA effective December 31, 2025, or earlier under certain circumstances.

The settlement with Amneal represents settlement of all patent infringement litigation against the nine companies that have sent Jazz notices that they had filed ANDAs requesting approval to market a generic version of Xyrem. It is possible that additional companies may file ANDAs seeking to market a generic version of Xyrem or new drug applications referencing Xyrem.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to the settlement of ongoing patent litigation against Amneal, the possibility that additional companies may file ANDAs for generic versions of Xyrem or new drug applications referencing Xyrem, and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals plc'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 related to: court approval of the settlement with Amneal and dismissal of related pending litigation; review of the settlement agreement with Amneal by the U.S. Federal Trade Commission and U.S. Department of Justice; regulatory restrictions and requirements applicable to Xyrem; protecting and enhancing Jazz's intellectual property rights; whether additional third parties seek to introduce generic versions of Xyrem or other sodium oxybate products, including the risk that a company that obtains and maintains U.S. Food and Drug Administration approval of an ANDA for a generic version of Xyrem or a new drug application for another sodium oxybate product could introduce such product before Jazz's patents expire or before the entry dates specified in Jazz's settlement agreements with ANDA filers, including if it is determined that Jazz's patents are invalid or unenforceable, or if such company decides, before applicable patent litigation is concluded, to launch a sodium oxybate product at risk of potentially being held liable for damages; and those other risks detailed 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 Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 and future filings and reports by Jazz Pharmaceuticals plc. Jazz Pharmaceuticals plc 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: October 11, 2018