Jazz Pharmaceuticals plc
Form 8-K
April 05, 2017

**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**

**April 5, 2017**

**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)**

**Fourth Floor, Connaught House,**

**1 Burlington Road, Dublin 4, Ireland**

**(Former 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.**

*Settlement Agreement*

On April 5, 2017, Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited, subsidiaries of Jazz Pharmaceuticals plc (collectively, Jazz ), entered into a settlement agreement (the Settlement Agreement ) and related agreements with Hikma Pharmaceuticals PLC and its subsidiaries, Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp. and Eurohealth (USA), Inc. (collectively, Roxane ) related to Jazz s ongoing patent infringement litigation (the Litigation ) against Roxane in the U.S. District Court for the District of New Jersey (the District Court ). In the Litigation, Jazz alleges that multiple Jazz patents covering Xyrem® (sodium oxybate) oral solution (the Xyrem Patents ) are or will be infringed by the generic version of Xyrem covered by Roxane s abbreviated new drug application ( ANDA ), which was approved by the U.S. Food and Drug Administration ( FDA ) in January 2017 (the Roxane ANDA ).

Under the Settlement Agreement, the parties have agreed to file a stipulation and order of dismissal of the Litigation with the District Court. Roxane has agreed to release Jazz from all claims asserting that (and not to sue or assert any claim that) the Xyrem Patents are unenforceable, unpatentable, invalid or not infringed by the Roxane ANDA and/or the manufacture, sale or import of the generic product covered by the Roxane ANDA, and Jazz has agreed to release Roxane from all claims asserting that (and not to sue or assert any claim that) the Xyrem Patents are or would be infringed by the Roxane ANDA and/or the manufacture, sale or import of the generic product covered by the Roxane ANDA.

In connection with the Settlement Agreement, Jazz has granted Roxane the right to sell an authorized generic version of Xyrem in the U.S. and its territories, districts, possessions and the Commonwealth of Puerto Rico (the Territory ), for an initial term of six months commencing on January 1, 2023, or earlier under certain circumstances (the Initial Term ). Such circumstances include events related to the market entry of other generic versions of Xyrem, a final decision that all unexpired claims of the Xyrem patents are invalid and/or unenforceable, or a substantial reduction in Xyrem net sales over specified periods of time. Roxane will have the right to extend the Initial Term and continue to sell an authorized generic version of Xyrem for up to a total of five years (the Initial Term, as it may be extended by Roxane, is referred to herein as the Authorized Generic Sales Period ). Jazz will receive a meaningful royalty from Roxane on net sales of the authorized generic version of Xyrem sold by Roxane, with the royalty rate increasing during the Initial Term based on increased net sales of the authorized generic version of Xyrem. There will also be a substantial increase in the royalty rate should the Authorized Generic Sales Period be extended beyond one year. Jazz will also be paid for supply of the authorized generic version of Xyrem and will be reimbursed by Roxane for a portion of the services costs associated with the operation of the Xyrem REMS (as defined below) and distribution of the authorized generic version of Xyrem.

Jazz has also granted Roxane a non-exclusive license under the Xyrem Patents to make, have made and market its generic sodium oxybate product under the Roxane ANDA in the Territory, which license will be effective at the end of the Authorized Generic Sales Period. Roxane has agreed that, other than in accordance with the terms and conditions of the Settlement Agreement and the foregoing arrangements, Roxane will not make, use or sell a generic version of Xyrem for so long as the Xyrem Patents remain in effect.

The Roxane authorized generic product will be distributed through the FDA-approved Risk Evaluation and Mitigation Strategy (the REMS ) for Xyrem. The FDA s approval of Roxane s ANDA includes a waiver that permits Roxane s ANDA product to use a separate REMS from the Xyrem REMS. The Settlement Agreement permits Roxane to develop and implement the separate REMS approved with its ANDA, and permits Jazz to challenge the FDA s waiver decision and the separate REMS approved in connection with Roxane s ANDA, and to raise any other safety issues pertaining to Xyrem.

In accordance with legal requirements, the parties have agreed to submit the Settlement Agreement to the U.S. Federal Trade Commission ( FTC ) and the U.S. Department of Justice ( DOJ ) for review. The Settlement Agreement will remain in effect until the expiration of the last to expire of the Xyrem Patents or the date of a final decision that all unexpired claims of the Xyrem Patents are invalid and/or unenforceable.

Roxane was the first applicant to submit an ANDA to the FDA requesting approval to market a generic version of Xyrem. To date, six other companies have sent Jazz notices that they had filed ANDAs, and Jazz filed patent infringement lawsuits against each of these companies in the District Court. In the second quarter of 2016, Jazz settled two of these other lawsuits, granting the settling ANDA applicants a license to manufacture, market and sell their generic versions of Xyrem on or after December 31, 2025, or earlier depending on the occurrence of certain events.

The foregoing description of the Settlement Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Settlement Agreement, which will be filed as an exhibit to Jazz Pharmaceuticals plc s Quarterly Report on Form 10-Q for the quarter ending June 30, 2017.

*Rights Agreement*

Item 3.03 below is incorporated herein by reference.

**Item 3.03. Material Modification to Rights of Security Holders.**

On April 5, 2017, Jazz Pharmaceuticals plc (the Company ) entered into a Rights Agreement, dated as of April 5, 2017 (the Rights Agreement ), with Computershare Trust Company, N.A., as rights agent. The Board of Directors of the Company (the Board ) has authorized the issuance of one ordinary share purchase right (a Right ) for each outstanding ordinary share, par value $0.0001 per share, of the Company (the ordinary shares ). The Rights will be issued on April 17, 2017 to the shareholders of record on that date.

The Board has adopted the Rights Agreement to enable all shareholders of the Company to realize the long-term value of their investment in the Company and to guard against attempts to acquire control of the Company at an inadequate price. In general terms, the Rights Agreement works by causing significant dilution to any person or group that acquires 10% (or 20% in the case of a 13G Investor as defined in the Rights Agreement) or more of the outstanding ordinary shares of the Company without the prior approval of the Board. The Rights Agreement is not intended to prevent an acquisition of the Company on terms that the Board considers favorable to, and in the best interests of, all shareholders. Rather, the Rights Agreement aims to provide the Board with adequate time to fully assess any takeover proposal and therefore comply with its fiduciary duties and to encourage anyone seeking to acquire the Company to negotiate with the Board prior to attempting a takeover. The Rights Agreement was adopted in response to the takeover environment in general, particularly in light of the Settlement Agreement with Roxane discussed under Item 1.01 above, and is not in response to any specific approach to the Company or perceived imminent takeover proposal for the Company. The issuance of Rights is not taxable to the Company or to shareholders and will not affect reported earnings per share. A summary of the terms of the Rights Agreement follows.

*The Rights*. The Rights will initially trade with, and will be inseparable from, the ordinary shares. The Rights are evidenced only by certificates or book-entry credits that represent ordinary shares. New Rights will accompany any new ordinary shares the Company issues after the Record Date until the earlier of the Distribution Date described below and any redemption or expiration of the Rights.

*Exercisability*. The Rights will not be exercisable until ten (10) days after the public announcement that a person or group has become an Acquiring Person by obtaining beneficial ownership of 10% (or 20% in the case of a 13G Investor, as defined in the Rights Agreement) or more of our outstanding ordinary shares.

The date when the Rights become exercisable is referred to as the Distribution Date. Until that date, the certificates or book-entry credits that represent ordinary shares will also evidence the Rights, and any transfer of ordinary shares will constitute a transfer of Rights. After that date, the Rights will separate from the ordinary shares and be evidenced by book-entry credits. Any Rights held by an Acquiring Person are void and may not be exercised.

*Exercise Price*. Each Right will allow its holder to purchase from the Company one ordinary share for $600 (the Exercise Price ), once the Rights become exercisable. Prior to exercise, the Right does not give its holder any dividend, voting, or liquidation rights.

*Beneficial Ownership*. Certain synthetic interests in securities created by derivative positions, whether or not such interests are considered to be ownership of the underlying ordinary shares or are reportable for purposes of Regulation 13D of the Securities Exchange Act of 1934, as amended, are treated as beneficial ownership of the number of the Company s ordinary shares equivalent to the economic exposure created by the derivative position, to the extent actual ordinary shares of the Company are directly or indirectly held by counterparties to the derivatives contracts. Swaps

dealers unassociated with any control intent or intent to evade the purposes of the rights plan are excepted from such imputed beneficial ownership.

Shares held by Affiliates and Associates (each as defined in the Rights Agreement) of an Acquiring Person, and Notional Ordinary Shares (as defined in the Rights Agreement) held by counterparties to a Derivatives Contract (as defined in the Rights Agreement) with an Acquiring Person, will be deemed to be beneficially owned by the Acquiring Person.

Consequences of a Person or Group Becoming an Acquiring Person.

*Flip In.* If a person or group becomes an Acquiring Person, all holders of Rights except the Acquiring Person may, for $600, purchase ordinary shares of the Company with a market value of $1,200, based on the market price of the ordinary shares prior to such acquisition.

*Reduction in Exercise Price.* After a person or group becomes an Acquiring Person, but before an Acquiring Person owns 50% or more of our outstanding ordinary shares, the Board may provide that each Rights holder, other than the Acquiring

Person, will have the right to receive, upon exercise of a Right, one ordinary share for a purchase price of $1.00 per ordinary share. If the Board makes such a determination, the option of a Rights holder to so exercise Rights shall be in addition to, but not in duplication of, any rights of holders to exercise Rights as described in Flip In above.

*Flip Over.* If our Company is later acquired in a merger or similar transaction after the Distribution Date, all holders of Rights except the Acquiring Person may, for $600, purchase shares of the acquiring company with a market value of $1,200, based on the market price of the acquiring company s stock, prior to such transaction.

*Expiration.* The Rights will expire on April 5, 2018.

*Redemption.* The Board may redeem the Rights without consideration therefor at any time before any person or group becomes an Acquiring Person. If the Board redeems any Rights, it must redeem all of the Rights.

*Anti-Dilution Provisions.* The Board may adjust the purchase price of the ordinary shares, the number of ordinary shares issuable and the number of outstanding Rights to prevent dilution that may occur from a stock dividend, a stock split, or a reclassification of the ordinary shares. No adjustments to the Exercise Price of less than 1% will be made.

*Amendments.* The terms of the Rights Agreement may be amended by the Board without the consent of the holders of the Rights. After a person or group becomes an Acquiring Person, the Board may not amend the Rights Agreement in a way that adversely affects holders of the Rights.

The foregoing description of the Rights Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Rights Agreement, which has been filed as Exhibit 4.1 to this Current Report on Form 8 K. A copy of the Rights Agreement is available free of charge from the Company upon request.

**Item 8.01 Other Events.**

On April 5, 2017, the Company issued a press release relating to the Settlement Agreement with Roxane. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits.**

***(d) Exhibits***

| **Exhibit Number** | **Description** |
|---|---|
| 4.1 | Rights Agreement, dated as of April 5, 2017, between Jazz Pharmaceuticals plc and Computershare Trust Company, N.A., which includes form of Ownership Statement as Exhibit A and the Summary of Rights to Purchase Ordinary Shares as Exhibit B. |
| 99.1 | Press Release issued by Jazz Pharmaceuticals plc dated April 5, 2017. |

**Forward-Looking Statements**

*This Current Report on Form 8-K contains forward-looking statements, including, but not limited to, statements related to the anticipated results and actions to be taken under the Settlement Agreement and the transactions contemplated thereby, review of the Settlement Agreement by the FTC and DOJ, the anticipated dismissal of the Litigation, the Rights 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 in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties related to: approval of the Settlement Agreement and dismissal of related pending litigation by the District Court; review of the Settlement Agreement by the FTC and DOJ; regulatory restrictions and requirements applicable to Xyrem; ongoing patent litigation and related proceedings; protecting and enhancing the Company s intellectual property rights; whether additional third parties may seek to market generic versions of Xyrem, including the risk that any company or companies may decide, before applicable ongoing patent litigation is concluded, to launch a generic sodium oxybate product at risk of potentially being held liable for damages; potential challenges to the Rights Agreement under applicable law; 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 Annual Report on Form 10-K for the year ended December 31, 2016 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
Suzanne Sawochka Hooper
Executive Vice President and General Counsel

Date: April 5, 2017

**EXHIBITS**

| Exhibit Number | Description |
|---|---|
| 4.1 | Rights Agreement, dated as of April 5, 2017, between Jazz Pharmaceuticals plc and Computershare Trust Company, N.A., which includes form of Ownership Statement as Exhibit A and the Summary of Rights to Purchase Ordinary Shares as Exhibit B. |
| 99.1 | Press Release issued by Jazz Pharmaceuticals plc dated April 5, 2017. |