Jazz Pharmaceuticals plc Form 8-K April 04, 2019

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 4, 2019

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

001-33500 (Commission

98-1032470 (IRS Employer

of Incorporation) File No.) 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 1.01. Entry into a Material Definitive Agreement.

On April 4, 2019, Jazz Pharmaceuticals plc (the Company) and its subsidiaries Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, Jazz) entered into a civil Settlement Agreement (the Settlement Agreement) with the U.S. Department of Justice (DOJ) and the Office of Inspector General (OIG) of the Department of Health and Human Services (collectively, the U.S. Government). The Settlement Agreement relates to subpoenas that Jazz received from the DOJ in 2016 and 2017 requesting documents related to Jazz support of charitable organizations that provide financial assistance to Medicare patients. Jazz previously announced an agreement in principle to resolve this matter.

In accordance with the Settlement Agreement, the Company will pay the U.S. Government the sum of \$57.0 million plus interest at a rate of 2.75% commencing from April 10, 2018 through the day before full payment is made, within ten business days. During 2018, the Company recorded \$58.2 million related to this matter, including related interest, within accrued liabilities on its consolidated balance sheet with the related expense included in selling, general and administrative expenses on its consolidated statement of income. The U.S. Government will release the Company from any civil or administrative monetary claim the U.S. Government has arising from allegations described in the Settlement Agreement relating to Jazz s conduct between 2011 and May 2014 in supporting a charitable foundation that provided financial assistance to Medicare patients. The Settlement Agreement is not an admission of any wrongdoing or liability by Jazz but a settlement of the U.S. Government s claims.

In connection with the civil settlement, the Company also entered into a Corporate Integrity Agreement (the Corporate Integrity Agreement) with the OIG, which requires the Company to maintain its ongoing corporate compliance program and obligates the Company to implement or continue, as applicable, a set of defined corporate integrity activities for a period of five years from the effective date of the Corporate Integrity Agreement. Among other things, the Corporate Integrity Agreement requires the Company to impose certain oversight obligations on the nominating and corporate governance committee of the Company s board of directors; provide certain management certifications; continue or implement, as applicable, certain compliance training and education; implement a risk assessment and mitigation process; maintain certain policies, procedures and practices for cash donations to independent charity patient assistance programs and for Jazz-sponsored patient assistance programs; and engage an independent review organization to perform certain auditing and reviews. The Corporate Integrity Agreement also includes certain reporting, certification, record retention, and notification requirements. In the event of a breach of the Corporate Integrity Agreement, Jazz could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs.

The foregoing description of the Settlement Agreement and Corporate Integrity Agreement is not intended to be complete and is qualified in its entirety by reference to the full text of such agreements, which will be filed as exhibits to Jazz s quarterly report on Form 10-Q for the quarter ended March 31, 2019.

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: Executive Vice President and Chief Financial Officer

Date: April 4, 2019