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

Date of Report (Date of earliest event reported) June 22, 2023

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 D04 E5W7
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Ordinary shares, nominal value $0.0001 per share	JAZZ	The Nasdaq Stock Market LLC

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 7.01. Regulation FD Disclosure.

On June 22, 2023, Jazz Pharmaceuticals, Inc. ("Jazz Inc."), a subsidiary of Jazz Pharmaceuticals plc (together with Jazz Inc., the "Company" or "Jazz"), filed a complaint in the United States District Court for the District of Columbia (the "Court") seeking a declaration that the U.S. Food and Drug Administration's ("FDA") approval on May 1, 2023 of the New Drug Application ("NDA") for Lumryz™, an extended-release reformulation of Jazz's high sodium oxybate product Xyrem®, for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adult patients with narcolepsy, was unlawful.

In the complaint filed by Jazz Inc., Jazz alleges that FDA acted outside its authority under the Orphan Drug Act when, despite the orphan drug exclusivity ("ODE") protecting Jazz's low-sodium oxybate product Xywav®, FDA approved the Lumryz NDA and granted Lumryz ODE based on FDA's finding that Lumryz makes a major contribution to patient care and is therefore clinically superior to Xywav and Xyrem. In addition, Jazz believes that, in doing so, FDA failed to follow its own regulations, failed to follow established agency policy without providing a reasoned explanation for the departure, reversed prior decisions by its own staff and experts without a reasoned explanation, and disregarded the relevant scientific literature and data. Specifically, Jazz alleges in the complaint that:

- FDA's approval and grant of ODE to Lumryz was unlawful under the Orphan Drug Act given the unexpired seven-year orphan exclusivity period that FDA granted to Jazz's low-sodium oxybate product, Xywav, in 2021;
- FDA acted without lawful basis when it determined that the once-nightly dosing regimen for Lumryz makes a major contribution to patient care by providing convenience and an additional medical benefit for narcolepsy patients by allowing them to achieve normal sleep architecture;
- FDA's determination is inconsistent with FDA regulations requiring claims of greater efficacy to be supported by substantial evidence since there has been no head-to-head comparative trial conducted to assess the efficacy or safety of Lumryz as compared to Xywav;
- Because FDA acknowledged Xywav's greater safety due to reduced sodium, FDA's determination is inconsistent with longstanding FDA policy that requires a sponsor seeking a determination that the proposed new drug will make a major contribution to patient care to demonstrate that the proposed new drug is comparably as safe and effective as a previously approved same orphan drug;
- Based on documents obtained by Jazz to date, FDA reversed prior determinations by its own staff and experts, including decisions that Lumryz does not make a major contribution to patient care based on convenience associated with once-nightly dosing; and
- FDA's decisions are not consistent with the scientific literature or its own findings regarding the impact of oxybate therapy on disrupted nighttime sleep or sleep architecture.

Jazz believes that FDA's decision to approve the Lumryz NDA could compromise patient safety and undermine appropriate patient care. Jazz further believes that the proper functioning of the Orphan Drug Act is critical to ensuring the ongoing development of products to treat rare diseases by providing meaningful incentives for companies to continue to develop innovative treatments for patients with rare diseases. Patient safety is a key tenet of Jazz's mission and protecting innovation is important to the ongoing research and development of therapies for people living with rare, serious, debilitating conditions.

Jazz is committed to protecting the work it has done to bring life-changing medicines to patients, which makes it possible for Jazz to research, develop, and provide therapies for patients living with serious, debilitating disorders. The Orphan Drug Act is critical to ensuring the ongoing development of products to treat rare diseases, and the Company believes undercutting the statutory intent of the Orphan Drug Act, as the Company alleges FDA has done in this case, has a direct impact on patients' needs and compromises patient safety. As FDA itself recognizes, Xywav, the only approved low-sodium oxybate product is safer compared to all high sodium oxybate products including Lumryz. Jazz alleges Lumryz has not demonstrated greater efficacy or safety compared to Xywav in clinical studies or otherwise. Jazz believes that statements and claims that mislead prescribers and patients about the risks and benefits of oxybate therapy can put patients at risk. Jazz is committed to the development of safe and differentiated treatments, and what Jazz believes is opaque, inconsistent and arbitrary decision-making by FDA in this case and others like it will ultimately discourage the kind of investment in treatments for rare diseases that the Orphan Drug Act seeks to encourage.

Jazz Inc.'s complaint, filed pursuant to the Administrative Procedure Act, seeks to have the Court vacate and set aside FDA's approval of the Lumryz NDA and seeks a declaration that FDA's approval of the Lumryz NDA was arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law; and that approval of the Lumryz NDA was in excess of FDA's statutory authority and was made without observance of procedure required by law.

Jazz cannot predict the timing or ultimate outcome of this litigation or the impact of this litigation on its oxybate business. In addition, Jazz made the allegations described above based only on information currently known to it. These allegations have not been fully litigated and the information and assumptions underlying these allegations may change after the date of this Current Report on Form 8-K. Unless required by applicable law, Jazz undertakes no obligation to update such information. Moreover, notwithstanding the Company's allegations and its views on the merits of this litigation, litigation is inherently uncertain and there can be no guarantee that the Court will agree with the Company's interpretation of applicable laws and regulations or will otherwise agree with any or all of the allegations described above, or that the Company will otherwise prevail in this litigation. Accordingly, the allegations described above are not intended to be statements of fact to be relied upon by Jazz's shareholders or potential investors.

The information disclosed under this Item 7.01 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 and shall not be deemed incorporated by reference into any filing made under the Securities Act of 1933, except as expressly set forth by specific reference in such filing. The furnishing of information pursuant to this Item 7.01 will not be deemed an admission that any information in this report is material or required to be disclosed by Regulation FD.

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/ Neena Patil
Name: Neena Patil
Title: Executive Vice President and Chief Legal Officer

Date: June 22, 2023