

**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) May 4, 2022

**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.)

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 8.01. Other Events.

On May 4, 2022, Jazz Pharmaceuticals plc (the “Company”) issued a press release announcing that it has entered into an exclusive licensing agreement with Sumitomo Pharma Co., Ltd. for the Company to acquire rights in the United States, Europe and other territories for DSP-0187, a potent, highly selective oral orexin-2 receptor agonist. A copy of the press release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release date May 4, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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/ Renée Galá
Name: Renée Galá

Title: Executive Vice President and Chief Financial
Officer

Date: May 4, 2022



Jazz Pharmaceuticals and Sumitomo Pharma Announce Exclusive License Agreement to Develop and Commercialize DSP-0187, a Potent, Highly Selective Oral Orexin-2 Receptor Agonist

Jazz licenses development and commercialization rights in U.S., Europe and other territories; Sumitomo Pharma retains rights in Japan, China and other Asia/Pacific territories

Sumitomo Pharma to receive \$50 million upfront payment

Jazz continues to expand neuroscience pipeline and strengthen leadership in sleep medicine

DUBLIN and OSAKA, Japan – May 4, 2022 – Jazz Pharmaceuticals plc (Nasdaq: JAZZ) and Sumitomo Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President, and CEO: Hiroshi Nomura; Securities Code: 4506, Prime Market of TSE) today announced that the companies have entered into an exclusive licensing agreement under which Jazz has acquired development and commercialization rights in the United States, Europe and other territories for Sumitomo Pharma’s investigational DSP-0187, a potent, highly selective oral orexin-2 receptor agonist with potential application for the treatment of narcolepsy, idiopathic hypersomnia and other sleep disorders. Jazz has designated this molecule JZP441.

Sumitomo Pharma initiated a Phase 1 trial in Japan of DSP-0187 in November 2021 to evaluate safety, tolerability and pharmacokinetics in healthy volunteers. Jazz expects to rapidly advance development of DSP-0187 based on these clinical findings.

“Orexin agonism is an exciting area of sleep disorder research and an approach that may be complementary to oxybate therapy. We believe that DSP-0187 has the potential to advance the treatment of narcolepsy and other sleep disorders based on its profile,” said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. “As a leader in sleep medicine, we are committed to delivering innovative therapies to people who are living with debilitating sleep disorders. We look forward to leveraging our expertise in sleep disorders to rapidly advance this promising therapy into clinical trials in the U.S. and Europe. This agreement exemplifies both our ability to identify promising compounds that have the potential to improve patient care and our corporate objective of making strategic, value-creating investments in our pipeline.”

“DSP-0187 is a potent, highly selective oral orexin-2 receptor agonist, which is a novel small molecule compound originally created by Sumitomo Pharma by utilizing our advanced expertise in drug discovery for central nervous system disorders. We are pleased to partner with Jazz on DSP-0187 given their strong track record of development success and commercial execution in sleep disorders and long-term commitment to advancing therapies to improve the lives of people with sleep disorders,” said Toru Kimura, Representative Director, Executive Vice President of Sumitomo Pharma. “Jazz’s accomplishments in sleep medicine make the company an ideal partner for us as DSP-0187 enters its next phase of development.”

Orexins are neuropeptides that play an important role in the regulation of sleep and wakefulness. DSP-0187 is a potent, highly selective orexin-2 receptor agonist designed to activate orexin signaling. DSP-0187 is initially planned to be evaluated in patients with narcolepsy, a debilitating sleep disorder which can manifest clinically with cataplexy, excessive daytime sleepiness (EDS), disrupted nighttime sleep (DNS), sleep paralysis and other symptoms. There is also potential for DSP-0187 to treat other sleep disorders.

Transaction Terms

Under the terms of the agreement, Jazz will receive an exclusive license to develop and commercialize DSP-0187 throughout the world except for Japan, China and certain other Asia/Pacific countries and regions, where Sumitomo Pharma will retain all development and commercialization rights. Sumitomo Pharma will receive an upfront payment of \$50 million, and is eligible to receive development, regulatory and commercial milestone payments of up to \$1.09 billion. Pending approval, Sumitomo Pharma is eligible to receive a tiered, low double-digit royalty on Jazz's net sales of DSP-0187.

About Jazz Pharmaceuticals plc

Jazz Pharmaceuticals plc (NASDAQ: Jazz) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases – often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. For more information, please visit www.jazzpharmaceuticals.com and follow @JazzPharma on Twitter.

About Sumitomo Pharma Co., Ltd.

Sumitomo Pharma Co., Ltd. is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China, and other Asian countries with more than 7,000 employees worldwide. Sumitomo Pharma defines its corporate mission as “To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide.” One of its research focus areas is psychiatry and neurology and Sumitomo Pharma is promoting competitive drug discovery research based on its proprietary drug discovery platforms established by continuously incorporating cutting-edge technologies. Additional information about Sumitomo Pharma is available through its corporate website at <https://www.sumitomo-pharma.com>.

Jazz Pharmaceuticals plc Caution Concerning Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to DSP-0187's potential application for the treatment of narcolepsy, idiopathic hypersomnia and other sleep disorders; the potential future development, manufacturing, regulatory and commercialization activities; potential future payments by Jazz Pharmaceuticals to Sumitomo Pharma for development, regulatory and commercial milestones as well as tiered royalties based on future net sales; and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals' 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: Jazz Pharmaceuticals' ability

to achieve the expected benefits (commercial or otherwise) from the license agreement; pharmaceutical product development and clinical success thereof; the regulatory approval process; effectively commercializing any product candidates; and other risks and uncertainties affecting Jazz Pharmaceuticals, 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 Jazz Pharmaceuticals’ Annual Report on Form 10-K for the year ended December 31, 2021 and future filings and reports by Jazz Pharmaceuticals. Other risks and uncertainties of which Jazz Pharmaceuticals is not currently aware may also affect Jazz Pharmaceuticals’ 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 Jazz Pharmaceuticals on its website or otherwise. Jazz Pharmaceuticals 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.

Sumitomo Pharma Co., Ltd. Disclaimer Regarding Forward-looking Statements

The statements made in this press release contain forward-looking statements based on management’s assumptions and beliefs in light of information available as of the day of this release, which involve both known and unknown risks and uncertainties. Actual results of those matters covered in the forward-looking statements including financial forecast may differ materially from those contained in this release, due to a number of factors.

Jazz Media Contact:

Kristin Bhavnani
Head of Global Corporate Communications
Jazz Pharmaceuticals plc
CorporateAffairsMediaInfo@jazzpharma.com
Ireland +353 1 637 2141
U.S. +1 215 867 4948

Jazz Investor Contact:

Andrea N. Flynn, Ph.D.
Vice President, Head, Investor Relations
Jazz Pharmaceuticals plc
Investorinfo@jazzpharma.com
Ireland +353 1 634 3211
U.S. +1 650 496 2717

Sumitomo Pharma Contact:

Corporate Communications
Sumitomo Pharma Co., Ltd.
TEL: +81-6-6203-1407 (Osaka); +81-3-5159-3300 (Tokyo)