UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or Section 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 18, 2022

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland	**001-37977**	**98-1341933**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10 Earlsfort Terrace **Dublin 2, Ireland, D02 T380** (Address of principal executive offices)	**Not Applicable** (Zip Code)

Registrant's telephone number, including area code: **+353 1 920 1000**

Not applicable
(Former name or former address, if changed since last report)

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
American Depositary Shares* Ordinary Shares, nominal value $0.01 per share**	AVDL N/A	The Nasdaq Global Market

*American Depositary Shares may be evidenced by American Depositary Receipts. Each American Depositary Share represents one (1) Ordinary Share.

** Not for trading, but only in connection with the listing of American Depositary Shares on The Nasdaq Global Market.

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 November 18, 2022, Avadel Pharmaceuticals plc (the "Company") issued a press release titled "Avadel Pharmaceuticals Announces Favorable Ruling on Motion to Delist REMS Patent from FDA's Orange Book." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

As previously disclosed, on June 23, 2022, Avadel CNS Pharmaceuticals, LLC ("Avadel CNS"), a subsidiary of the Company, filed a Renewed Motion for Judgment on the Pleadings, with respect to its counterclaim against Jazz Pharmaceuticals, Inc. ("Jazz"), seeking to have U.S. Patent No. 8731963 (the "REMS Patent") de-listed from the U.S. Food and Drug Administration's ("FDA") Orange Book. On November 15, 2022, the United States District Court for the District of Delaware (the "Delaware Court") held a hearing on that motion. On November 18, 2022, the Delaware Court issued its written opinion ordering Jazz to request delisting of the REMS Patent. With the issuance of this ruling, the Company intends to seek final FDA approval for LUMRYZ upon removal of the REMS Patent from the FDA's Orange Book.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Avadel Pharmaceuticals plc on November 18, 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 18, 2022

AVADEL PHARMACEUTICALS PLC

By: /s/ Jerad G. Seurer
Name: Jerad G. Seurer
Title: General Counsel & Corporate Secretary

Exhibit 99.1

Avadel Pharmaceuticals Announces Favorable Ruling on Motion to Delist REMS Patent from FDA's Orange Book

- *Delisting of REMS Patent sets path to potentially accelerate final approval by FDA*

DUBLIN, Ireland, November 18, 2022 - Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, announced today that the United States District Court for the District of Delaware (the "Delaware Court") ordered Jazz Pharmaceuticals to delist U.S. Patent No. 8731963 (the "REMS Patent") from the U.S. Food and Drug Administration's ("FDA") Orange Book. With this decision, Avadel seeks to accelerate the FDA's final approval decision for LUMRYZ™, a once-at-bedtime investigational formulation of sodium oxybate for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

"We are pleased with the court's decision in favor of delisting the REMS Patent from the FDA's Orange Book, potentially accelerating a final approval. Upon the delisting of the REMS Patent, we are prepared to work collaboratively with the FDA to move to a final approval decision for LUMRYZ," said Greg Divis, Chief Executive Officer at Avadel Pharmaceuticals. "We are fully committed to bringing LUMRYZ to all eligible people with narcolepsy and look forward to providing updates on our progress."

On July 18, 2022, LUMRYZ received tentative approval from the FDA, with potential final approval pending disposition of the REMS Patent. On October 25, 2022, a Markman hearing was held in which Avadel renewed its request for expedited consideration of its pending motion to have the REMS Patent delisted from FDA's Orange Book. The Delaware Court granted that request on October 28th and held a hearing on that motion on November 15, 2022. Earlier today, the Delaware Court issued its written opinion ordering Jazz to request delisting of the REMS Patent. With the issuance of this ruling, Avadel intends to seek final FDA approval for LUMRYZ upon removal of the REMS Patent from the FDA's Orange Book.

About LUMRYZ

LUMRYZ is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once-at bedtime for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

In March 2020, Avadel completed the REST-ON study, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial, to assess the efficacy and safety of LUMRYZ in patients with narcolepsy. Among the three co-primary endpoints, LUMRYZ demonstrated statistically significant and clinically meaningful results in EDS, the clinician's overall assessment of the patient's functioning, and reduction in cataplexy attacks, for all three evaluated does when compared to placebo.

In January 2018, the U.S. Food and Drug Administration (FDA) granted LUMRYZ Orphan Drug Designation for the treatment of narcolepsy based on the plausible hypothesis that LUMRYZ may be safer than the twice-nightly formulation of sodium oxybate already approved by the FDA due to the ramifications associated with dosing regimen of that product.

On July 18, 2022, the FDA tentatively approved the LUMRYZ NDA for the treatment of cataplexy or EDS in adults with narcolepsy.

Avadel is currently evaluating the long-term safety and tolerability of LUMRYZ in the open-label RESTORE clinical study. For more information, visit: **www.restore-narcolepsy-study.com**.

About Avadel Pharmaceuticals plc

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a biopharmaceutical company focused on transforming medicines to transform lives. Our approach includes applying innovative solutions to the development of medications that address the challenges patients face with current treatment options. Our current lead drug candidate, LUMRYZ™, is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once at bedtime for the treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy. For more information, please visit **www.avadel.com**.

Cautionary Disclosure Regarding Forward-Looking Statements

This press release includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements relate to our future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. Such forward-looking statements include, but are not limited to, expectations regarding the potential therapeutic benefit of LUMRYZ; the timing of FDA’s final approval decision for LUMRYZ; ongoing efforts of the Company to accelerate potential final FDA approval of LUMRYZ; the Company’s efforts to make LUMRYZ commercially available following potential final approval by the FDA; and the anticipated market acceptance of LUMRYZ (if approved). In some cases, forward-looking statements can be identified by the use of words such as “will,” “may,” “could,” “believe,” “expect,” “look forward,” “on track,” “guidance,” “anticipate,” “estimate,” “project,” “next steps” and similar expressions, and the negatives thereof (if applicable).

The Company’s forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. However, the Company’s business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of the company’s business and operations will not differ materially from the results contemplated in such forward-looking statements. Factors that could cause actual results to differ from expectations in the Company’s forward-looking statements include the risks and uncertainties described in the “Risk Factors” section of Part I, Item 1A of the Company’s Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the Securities and Exchange Commission (SEC) on March 16, 2022, and subsequent SEC filings.

Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. The Company does not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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