

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 3, 2022

AVADEL PHARMACEUTICALS PLC
(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction
of incorporation)

001-37977
(Commission
File Number)

98-1341933
(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 to 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 8.01 Other Events.

As previously disclosed, on June 23, 2022, Avadel CNS Pharmaceuticals, LLC (“Avadel CNS”), a subsidiary of Avadel Pharmaceuticals plc (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 and seeking to have the motion resolved concurrent with the parties’ *Markman* hearing, which was held on October 25, 2022. At the *Markman* hearing, the Company reiterated its request for an expedited hearing on the Renewed Motion for Judgment on the Pleadings for the de-listing of the REMS Patent. The United States District Court for the District of Delaware (the “Delaware Court”) recently granted the Company’s request and scheduled the hearing for November 15, 2022.

As previously disclosed, on July 21, 2022, Avadel CNS filed an Administrative Procedure Act (“APA”) suit against the FDA, the U.S. Department of Health and Human Services, the Secretary of Health and Human Services and the Commissioner of Food and Drugs in the United States District Court for the District of Columbia (the “DC Court”) related to the New Drug Application (“NDA”) for LUMRYZ (sodium oxybate), alleging that the FDA’s decision requiring Avadel CNS to file a patent certification concerning the REMS Patent was arbitrary, capricious and contrary to law and asked the DC Court to vacate the FDA’s decision and order the FDA to take final action on the LUMRYZ NDA. On November 3, 2022, the DC Court issued a written opinion and determined that Avadel CNS is not entitled to seek relief under the APA because of the availability of adequate alternative relief in the Delaware Court, as described in the preceding paragraph for delisting of the REMS Patent.

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 4, 2022

AVADEL PHARMACEUTICALS PLC

By: /s/ Jerad G. Seurer

Name: Jerad G. Seurer

Title: General Counsel & Corporate Secretary
