

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): December 16, 2020 (December 15, 2020)

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 1 485 1200

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

*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.

On December 16, 2020, Avadel Pharmaceuticals plc (the “Company”) issued a press release announcing the submission of its New Drug Application to the U.S. Food and Drug Administration for its product candidate FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01. Exhibits

(d) Exhibits

[99.1](#) [Press release issued by the Company on December 16, 2020.](#)

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.

AVADEL PHARMACEUTICALS PLC

Date: December 16, 2020

By: /s/ Jerad G. Seurer

Name: Jerad G. Seurer

Title: Vice President, Legal Affairs & Corporate Secretary

Avadel Pharmaceuticals Announces Submission of New Drug Application for FT218 to the FDA

DUBLIN, Ireland, December 16, 2020 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL) today announced the submission of its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy.

“The submission of our NDA represents a significant milestone for the Company. We look forward to working with the FDA during the NDA review process in order to get once-nightly FT218 approved and commercially available to patients with narcolepsy who suffer from excessive daytime sleepiness and cataplexy,” said Greg Divis, Chief Executive Officer of Avadel. “If approved, we believe once-nightly FT218 has the potential to provide a valuable treatment option for sodium oxybate eligible narcolepsy patients, including those who are not satisfied with the current twice-nightly treatment, which requires waking up in the middle of the night to take a second dose.”

About FT218

FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. In March of 2020, the Company completed the REST-ON study, a pivotal, double-blind, randomized, placebo-controlled Phase 3 trial, to assess the efficacy and safety of FT218 in the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. FT218 has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of narcolepsy. The designation was granted on the plausible hypothesis that FT218 may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the FDA for the same indication. In particular, FT218 may be safer due to ramifications associated with the dosing regimen of the previously approved product.

About Avadel Pharmaceuticals plc:

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is an emerging biopharmaceutical company. The Company’s primary focus is the development and FDA approval of FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy 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, the FDA’s review of the NDA for FT218 and commercial launch of FT218, 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).

Our 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, our business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of our 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 our forward-looking statements include the risk that the FDA does not accept the NDA submission for FT218, the risk that such NDA is not approved by the FDA or such approval is delayed, the risk that commercial launch of FT218 (if approved) is delayed, the risk that the potential market performance for FT218 (if approved) may differ materially from projections, and the risk that the impact of the current COVID-19 pandemic on our financial results and results of operations could be greater than we anticipate and the risks and uncertainties described in the “Risk Factors” section of Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2019, which we filed with the Securities and Exchange Commission (SEC) on March 16, 2020 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. We do not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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