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): March 1, 2021 (March 1, 2021)

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 1 485 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 March 1, 2021, Avadel Pharmaceuticals plc (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has accepted the Company's New Drug Application ("NDA") for its product candidate, FT218, an investigational, once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. The FDA set a Prescription Drug User Fee Act goal date of October 15, 2021 for the completion of its review of the NDA. 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 March 1, 2021.
104	Cover Page Interactive Data File (embedded with 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: March 1, 2021

By: /s/ Jerad G. Seurer
Name: Jerad G. Seurer
Title: Vice President, Legal Affairs & Corporate Secretary

Exhibit 99.1

Avadel Pharmaceuticals Announces FDA Acceptance of New Drug Application for FT218 in Adults with Narcolepsy for the Treatment of Excessive Daytime Sleepiness and Cataplexy

- - -

FT218 assigned PDUFA target action date of October 15, 2021

DUBLIN, Ireland, March 1, 2021 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's New Drug Application (NDA) for FT218, an investigational, once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy. The FDA assigned the NDA a Prescription Drug User Fee Act (PDUFA) target action date of October 15, 2021.

"The FDA's acceptance of our NDA for once-nightly FT218 and assignment of a PDUFA target action date of October 15th represents another important milestone on the path towards receiving approval. We are confident in our regulatory filing strategy and we look forward to working with the Agency in our pursuit of bringing this important treatment to patients," said Greg Divis, Chief Executive Officer of Avadel. "If approved, FT218 will be the first and only once-nightly oxybate medication, a significant advancement to the twice-nightly regimen that has been required for nearly 20 years."

"It's important to remember that FT218 was granted Orphan Drug Designation by the FDA based on the plausible hypothesis that it may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the Agency for the same indication. If the FDA approves FT218 and grants Orphan Drug Exclusivity, then we would be awarded a seven-year period of market exclusivity in the U.S.," concluded Mr. Divis.

The NDA submission is supported by positive data from the pivotal Phase 3 REST-ON study, which was completed under a Special Protocol Assessment (SPA) agreement with the FDA. The Company plans on presenting data from the study for the three primary endpoints, as well as a number of secondary endpoints and post-hoc analyses at upcoming conferences in the first half of 2021.

About FT218

FT218 is an investigational, once-nightly formulation of sodium oxybate that includes Avadel's MicroPump™ controlled-release (CR) technology. In December 2020, the Company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for FT218 to treat excessive daytime sleepiness and cataplexy in adults with 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 a biopharmaceutical company primarily focused on 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, the benefits of Orphan Drug Exclusivity for FT218, if granted by the FDA, commercial launch of FT218, if approved, and market acceptance 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 approve the NDA for FT218 or such approval is delayed, the risk that FT218 (if approved) may not receive a 7-year Orphan Drug Exclusivity, 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.

Contacts:
Investor Contacts
Tom McHugh
Chief Financial Officer
Phone: (636) 449-1843
Email: tmchugh@avadel.com

Tim McCarthy
LifeSci Advisors, LLC
Phone: (212) 915.2564
Email: tim@lifesciadvisors.com

Media Contact
Patrick Bursey
LifeSci Communications, LLC
Phone: (646) 970-4688
Email: pbursey@lifescicomms.com