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): **September 23, 2019**

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)	(I.R.S. Employer Identification No.)

Block 10-1 **Blanchardstown Corporate Park, Ballycoolin** **Dublin 15, Ireland** (Address of Principal Executive Offices)	**Not Applicable** (Zip Code)

Registrant's telephone number, including area code: **+353 1 485 1200**

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))

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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Ticker symbol(s)**	**Name of each exchange on which registered**
American Depositary Shares* Ordinary Shares**	AVDL	NASDAQ Stock Market LLC (NASDAQ Global Market)

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

** Nominal value $0.01 per share. Not for trading, but only in connection with the listing of American Depositary Shares.

Item 8.01 Other Events.

On September 23, 2019, Avadel Pharmaceuticals plc issued a press release, a copy of which is furnished as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1		Press release dated September 23, 2019, issued by Avadel Pharmaceuticals plc

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

By: /s/ Phillandas T. Thompson
Phillandas T. Thompson
Senior Vice President, General Counsel and
Corporate Secretary

Date: September 23, 2019

Exhibit 99.1

Avadel Pharmaceuticals Announces FDA Agreement to Reduce the Sample Size for the Ongoing Pivotal Phase 3 Study for Once-Nightly FT218; Full Enrollment Now Expected by End of 2019

- *FDA agrees with Company's proposed changes to the statistical analysis plan for the REST-ON Phase 3 study for once-nightly sodium oxybate, FT218*
- *Reduces estimated time to completion by up to 12 months; now expected to complete patient enrollment by end of 2019, with pivotal data readout now expected in 2Q 2020*
- *Enrollment currently at 193 patients for the REST-ON Phase 3 study (94% complete)*
- *Management to hold conference call today at 9:00 a.m. ET*

DUBLIN, Ireland, September 23, 2019 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing once-nightly sodium oyxbate, FT218, for narcolepsy, today announced that the U.S. Food and Drug Administration (FDA) has agreed to the Company's proposed amendments to the statistical analysis plan and protocol under its special protocol assessment agreement (SPA), resulting in a lower sample size needed to demonstrate significance for both excessive daytime sleepiness and cataplexy in narcolepsy patients. No modifications were made to the fundamental design of the study, including the primary or secondary endpoints, dosing scheme or duration of the study, and the SPA remains intact.

The REST-ON study will now target enrolling 205 patients. Based on this updated target sample size and enrollment currently at 193 patients, the company now expects to complete enrollment by the end of 2019 and have topline data in the second quarter of 2020. This is up to a year ahead of expectations to complete enrollment for the previous target of 264 patients for the study. Even with this change, the REST-ON clinical trial remains one of the largest studies conducted, to date, for this indication.

"This REST-ON clinical trial update is a direct result of an overall strategic review of the entire FT218 program. The addition of our recently appointed medical and clinical team members was instrumental in this important development and their contributions have put us on track to save significant time, resources and capital in the completion of the REST-ON clinical trial," said Greg Divis, Chief Executive Officer of Avadel.

The REST-ON study is a double-blind, randomized, placebo-controlled Phase 3 trial to assess the efficacy and safety of once-nightly FT218, a formulation of sodium oxybate using Avadel's proprietary Micropump™ technology for extended-release oral suspension, in the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy.

Once-nightly 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 once-nightly FT218 may be clinically superior to a formulation of sodium oxybate that is already approved by the FDA for the same indication. In particular, once-nightly FT218 may be safer due to ramifications associated with the dosing regimen of the previously approved product. The twice-nightly sodium oxybate market is currently valued at an estimated annualized rate of $1.6 billion[1]. Avadel's market research leads it to believe that FT218, if approved by the FDA, has the potential to take a significant share of this market.

Conference Call:
A conference call to discuss these results has been scheduled for Monday, September 23, 2019 at 9:00 a.m. EDT. To access the conference call, investors are invited to dial 877-407-9716 (U.S. and Canada) or 201-493-6779 (International). The conference ID number is 13694841. A live audio webcast can be accessed by visiting the investor relations section of the Company's website, www.avadel.com or clicking http://public.viavid.com/index.php?id=136221. A replay of the webcast will be archived on Avadel's website for 90 days following the event.

About Avadel Pharmaceuticals plc:
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a branded specialty pharmaceutical company. The Company's primary focus is on the development and potential FDA approval for FT218, which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, Avadel develops and markets a portfolio of sterile injectable drugs used in the hospital setting. For more information, please visit www.avadel.com.

Footnote:
1. Annualized Xyrem revenues from Jazz Pharmaceuticals Q2 2019 earnings press release, August 6, 2019

Cautionary Disclosure Regarding Forward-Looking Statements
This press release contains "forward looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements (which may be identified by words such as "will," "look forward," "should," "planned" and "anticipate") are not statements of historical facts regarding FT218, the FDA review process relating thereto including the expected timing of that process, and the possible commercial launch of FT218. All forward-looking statements involve risks and uncertainties, including, without limitation, the risks that i) the Company may encounter challenges in the remaining development efforts for FT218, ii) the FDA may determine there are deficiencies in the NDA for FT218 or may never approve the NDA for FT218, iii) FT218 may not have the therapeutic benefits the Company anticipates, iv) the commercial launch of FT218 could be delayed, v) FT218 may not achieve commercial acceptance, vi) other companies may develop competing products that may receive FDA approval before FT218, and vii) the other risks detailed in Avadel's filings with the SEC, including, without limitation, its Form 10-K, Forms 10-Q and other reports on Forms 8-K, all of which can be obtained on the SEC website at www.sec.gov. Avadel assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

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