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 24, 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 24, 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 24, 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 24, 2019

Exhibit 99.1

Avadel Pharmaceuticals Announces Pharmacokinetic (PK) Data for Once-Nightly FT218 that will be Included in an Oral Presentation at the World Sleep 2019 Congress on September 25th

DUBLIN, Ireland, September 24, 2019 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate, for narcolepsy, today announced pharmacokinetic (PK) data for FT218 from four Phase 1 studies comparing 4.5g and 6g of once-nightly FT218 to 4.5g and 6g of twice-nightly sodium oxybate, evaluating the food effect of FT218, as well as determining the dose proportionality of FT218. The data will be included in an oral presentation by leading sleep expert, Dr. Michael Thorpy, Director of the Sleep-Wake Disorders Center at the Montefiore Medical Center, which is titled, "The Pharmacokinetics of once-nightly controlled-release sodium oxybate (FT218): Overview of results from four Phase 1 Studies," at the World Sleep 2019 Congress on Thursday, September 25th, in Vancouver, Canada.

The key PK data points from these four studies demonstrated:

- Once-nightly FT218 at 4.5g and 6g demonstrated lower overall maximum plasma concentrations (C_{max}) and equivalent exposure (AUC) to twice-nightly sodium oxybate, as well as similar morning plasma levels (C_{8h}) and variability to twice-nightly sodium oxybate.
- The C_{max} of FT218 was dose proportional and AUC was slightly higher than dose proportional, which demonstrates the predictability of FT218 as dosing increases.
- Consistent with the expectations of a sodium oxybate product, FT218 has lower exposure and lower maximum plasma concentration in the Fed versus the Fasted State.
- FT218 up to the 9g dose level was generally well-tolerated. Further, observed Adverse Events for the 4.5 and 6 g doses of FT218 were consistent with those known for sodium oxybate and appeared comparable to the Adverse Effects for corresponding strengths of twice-nightly sodium oxybate in the study.

According to Dr. Thorpy, "The totality of the pharmacokinetic data from these four Phase 1 studies demonstrates that Avadel has developed a formulation of sodium oxybate that exhibits a pharmacokinetic profile desirable for once-nightly dosing."

"Based on the results of these four studies, we are confident that the ongoing Phase 3 REST-ON study of FT218 will demonstrate efficacy in the treatment of both excessive daytime sleepiness and cataplexy in patients with narcolepsy. We currently expect to complete enrollment of the Phase 3 trial by the end of this year, with top line data estimated to be available in the second quarter of 2020," said Jordan Dubow, MD, Chief Medical Officer of Avadel.

In addition to previously published pharmacokinetic data, information on the ongoing Phase 3 REST-ON study of FT218 will be available at Avadel's Booth #113 in the Exhibit Hall during the World SLEEP 2019 Congress.

The four Phase 1 studies include:

A comparative, open-label, randomized, 2-period, 2-sequence, crossover study to assess the bioavailability of FT218 6g compared to twice-nightly sodium oxybate 6g (2 divided doses of 3g) in 28 healthy volunteers. Subjects were randomized to receive either FT218 6g followed by twice-nightly sodium oxybate 6g or twice-nightly sodium oxybate followed by FT218 6g with a minimum of a 3-day washout between doses.

An open-label, randomized, single-dose, two treatment (Fed vs. Fasted), two-period, two-sequence crossover study to assess the effect of food on the pharmacokinetics of FT218 in 16 healthy volunteers. Subjects were randomized to receive either FT218 6g in the Fed (30-minutes after a standardized high-fat breakfast) followed by FT218 in the Fasted (10-hours after an overnight fast) or FT218 6g in the Fasted state followed by FT218 6g in the Fed state with a minimum of a 3-day washout between doses.

A pharmacokinetics and formulation selection pilot study that was designed as a four-way crossover study in 16 healthy volunteers, evaluating three proprietary once-nightly formulations of Micropump™ controlled-release (CR) sodium oxybate (FT218) versus twice-nightly immediate-release (IR) sodium oxybate at a nightly dose of 4.5g (two doses of 2.25g for IR sodium oxybate). Each subject consumed a standard meal two hours prior to dosing. Subjects receiving the twice-nightly sodium oxybate were administered the second dose 4 hours after the first dose.

A dose proportionality study that was an open-label, single ascending dose, three-sequential-period study in 20 healthy volunteers. Subjects received three separate single-dose administrations of FT218 at bedtime, two hours post-evening meal, in a sequential order of 4.5g, 7.5g and 9g with a minimum 7-day washout between doses.

About FT218
FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. The company is currently conducting the REST-ON study, a 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 a 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 branded specialty pharmaceutical company. The Company's primary focus is the development and potential FDA approval of 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.

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.

Contacts:

Michael F. Kanan
Chief Financial Officer
Phone: (636) 449-1844
Email: mkanan@avadel.com

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