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 25, 2020

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 7.01. Regulation FD Disclosure.

On March 25, 2020, Avadel Pharmaceuticals plc (the "Company") issued a press release to announce the completion of its REST-ON Phase 3 clinical trial for FT218, an investigational, once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01. Exhibits

(d) Exhibits

99.1 Press release issued by the Company on March 25, 2020, furnished herewith.

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.

March 25, 2020

AVADEL PHARMACEUTICALS PLC

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

Exhibit 99.1

Avadel Pharmaceuticals Completes the REST-ON Phase 3 Pivotal Trial of FT218 for Excessive Daytime Sleepiness and Cataplexy in Patients with Narcolepsy

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Topline data from the REST-ON study expected in Q2 2020

DUBLIN, Ireland, March 25, 2020 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy, announced today that it has completed the REST-ON Phase 3 clinical trial for FT218. The REST-ON study enrolled a total of 212 patients, and the last patient last visit occurred earlier this week. The Company currently expects to announce topline data from the study in the second quarter of 2020.

“We’re excited to complete our pivotal Phase 3 REST-ON study of FT218 and look forward to announcing the topline data from the study as we move closer toward potentially bringing this new drug to narcolepsy patients. I want to thank our investigators, study staff and patients for their participation in this study, as well as the Avadel team for their continued dedication,” stated Dr. Jordan Dubow, Chief Medical Officer of Avadel.

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

Based on the Company’s industry research, it believes FT218, if approved by the FDA, has the potential to provide a valuable advancement in the treatment of both excessive daytime sleepiness and cataplexy for patients with narcolepsy. Currently, the twice-nightly sodium oxybate market is valued at an estimated annualized rate of $1.7 billion[1].

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 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 potential FDA approval of FT218, which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness and cataplexy. In addition, Avadel 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 the Jazz Pharmaceuticals Full Year and Fourth Quarter 2019 Financial Results press release, February 25, 2020*

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. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "believe," "expect," "look forward," "on track," "could," "guidance," "anticipate," "estimate," "project" 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. Actual results (including, without limitation, the timely announcement of topline data and success of our Phase 3 REST-ON study and our ability to achieve FDA approval for FT218) may differ materially from those set forth or implied in the forward-looking statements. These forward-looking statements involved certain risks and uncertainties that are subject to change based on various factors (many of which are beyond our control) including those set forth in our 2019 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission and subsequent 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 the forward-looking statements contained in this Annual Report.

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