

**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): April 17, 2021

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 7.01. Regulation FD Disclosure.

On April 17, 2021, Avadel Pharmaceuticals plc (the “Company”) issued a press release to announce the Company’s presentation of positive secondary endpoint data 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, at the American Academy of Neurology Annual (AAN) Meeting held virtually from April 17-22, 2021. 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 April 17, 2021, furnished herewith.](#)
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 caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

April 19, 2021

AVADEL PHARMACEUTICALS PLC

By: /s/ Jerad G. Seurer

Name: Jerad G. Seurer

Title: Vice President, Legal Affairs & Corporate Secretary



Avadel Presents New Data from its Pivotal REST-ON Phase 3 Trial of FT218, once-nightly sodium oxybate, at the 2021 American Academy of Neurology Annual Meeting

- *Secondary endpoint data for once-nightly FT218 further supports previously announced topline data demonstrating clinically meaningful results at 6 g, 7.5 g, and 9 g doses*

DUBLIN, Ireland, April 17, 2021 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate (ON-SXB) for the treatment of excessive daytime sleepiness and cataplexy in adults with narcolepsy, today announced the presentation of positive secondary endpoint data at the 2021 American Academy of Neurology Annual (AAN) Meeting being held virtually from April 17-22, 2021. FT218 is currently under review at the U.S. Food and Drug Administration with a Prescription Drug User Fee Act (PDUFA) target date of October 15, 2021.

“The positive results previously disclosed from the REST-ON trial, regarding the three co-primary endpoints, are further bolstered by the secondary endpoints presented at AAN. The consistency with which FT218, or once-nightly sodium oxybate, improved both subjective and objective symptoms of narcolepsy – including disturbed nocturnal sleep – represent the promise of a potential new treatment strategy for physicians and patients. I am particularly impressed by the consistency of results as early as three weeks, with only a 6 g dose,” said Michael J. Thorpy, M.D., Investigator on the REST-ON Phase 3 trial and Director at the Sleep-Wake Disorders Center at Montefiore Medical Center and Professor of Neurology at the Albert Einstein College of Medicine. “I know that clinicians have been eager to learn more about a once-nightly form of sodium oxybate, and we appreciate this forum to present these data.”

Jennifer Gudeman, PharmD, Vice President of Medical and Clinical Affairs at Avadel, added, “FT218 demonstrated significant ($P < 0.001$) and clinically meaningful results versus placebo at all doses tested for secondary endpoints of the Epworth Sleepiness Scale, sleep quality and refreshing nature of sleep, sleep paralysis, and disturbed nocturnal sleep, representing an improvement on important narcolepsy symptoms. We are pleased that neurologists attending AAN will have the opportunity to learn about a once-nightly form of sodium oxybate. We believe that patient perspective is critical to successful long-term therapy, and we are presenting several positive endpoints supporting symptomatic improvement as determined directly by patients.”

To register for the meeting, visit AAN’s website: www.aan.com/conferences-community/annual-meeting.

Data highlights from the poster presentations are outlined below:

Polysomnographic Measures of Sleep Continuity in Patients with Narcolepsy: Results From the REST-ON Trial, a Pivotal Phase 3 Study of FT218, a Once-Nightly Sodium Oxybate Formulation

- FT218 demonstrated significant consolidation of sleep on polysomnography (randomized, n=212) for the 6 g dose at Week 3, the 7.5 g dose at Week 8, and 9 g dose at Week 13 compared to placebo
- Data from the randomized, double-blind, placebo-controlled, multicenter, parallel-group study showed that the mean difference between FT218 and placebo for disturbed nocturnal sleep (shifts from deeper to lighter stages of sleep and wake) was statistically significant ($P < 0.001$) at all doses tested: -22.63 at 9 g (week 13), -17.70 at 7.5 g (week 8), and -11.00 at 6 g (week 3).
- The mean difference between FT218 and placebo for number of arousals was -23.68 ($P < 0.001$) at 9 g, -19.41 ($P < 0.001$) at 7.5 g and -11.29 ($P < 0.021$) at 6 g.
- FT218 was generally well tolerated, and the most common adverse reactions were well-known and established sodium oxybate adverse reactions.

Daytime Sleepiness, Sleep Quality, Hallucinations, and Sleep Paralysis in Patients with Narcolepsy: Results From the REST-ON Trial, a Pivotal Phase 3 Study of FT218, a Once-Nightly Sodium Oxybate Formulation

- FT218 demonstrated significant ($P < 0.001$) improvement in the Epworth Sleepiness Scale (ESS) versus placebo at all doses tested: LS mean difference -3.86 at 9 g (week 13), -3.16 at 7.5 g (week 8), and -2.06 at 6 g (week 3).
- FT218 showed a statistically significant ($P < 0.001$) improvement compared to placebo at all doses tested for sleep quality and refreshing nature of sleep on a visual analogue scale, and for sleep paralysis on a sleep symptom diary ($P = 0.037, 0.021, 0.039$ at 9, 7.5, 6 g, respectively).
 - FT218 did not demonstrate significant improvement for hypnagogic compared to placebo.
- Adverse events were similar to the known sodium oxybate safety profile.

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, extended-release formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy. For more information, please visit www.avadel.com.

About FT218

FT218 is an investigational, once-nightly formulation of sodium oxybate that includes Avadel's MicroPump™ controlled-release (CR) technology. 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. 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. The NDA for FT218 was accepted by the FDA in February 2021 and assigned a Prescription Drug User Fee Act (PDUFA) target action date of October 15, 2021. 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.

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, our expectations of the therapeutic benefits of FT218, the timing of the FDA’s review of our NDA for FT218, the sufficiency of data supporting our NDA for FT218, the commercial launch of FT218 (if approved), and the 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 positive results from the REST-ON trial may not necessarily be predictive of the results of future or ongoing clinical studies; the risk that the NDA for FT218 is not approved by the FDA 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 or never occurs; 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, 2020, which we filed with the Securities and Exchange Commission (SEC) on March 9, 2021 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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