

**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): June 9, 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 8.01 Other Events.

On June 9, 2021, Avadel Pharmaceuticals plc (the “Company”) issued a press release announcing new post hoc analyses of data from the completed pivotal Phase 3 REST-ON clinical trial of FT218. 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 June 9, 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.

Date: June 9, 2021

AVADEL PHARMACEUTICALS PLC

By: /s/ Jerad G. Seurer

Name: Jerad G. Seurer

Title: Vice President, Legal Affairs & Corporate Secretary



Avadel Presents New Clinical Data from Pivotal Phase 3 REST-ON Trial Supporting Clinical Benefit of FT218 in Patients with Narcolepsy at SLEEP 2021

- *Data show improvement in excessive daytime sleepiness for both narcolepsy subtypes and with and without stimulant use; demonstrate decreases in weight and body mass index*
- *Post hoc analyses further support positive primary and secondary endpoint data for all evaluated doses of FT218*
- *Company hosting virtual medical booth to provide detailed information about ongoing research and publications*

DUBLIN, June 9, 2021 – Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for treating excessive daytime sleepiness and cataplexy in adults with narcolepsy, today announced new post hoc analyses of data from the completed pivotal Phase 3 REST-ON clinical trial of FT218. The data were presented in three separate posters at SLEEP 2021, the 35th Annual Meeting of the Associated Professional Sleep Societies (APSS), a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society.

FT218 is currently under review at the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) target date of October 15, 2021.

“For the past 20 years, the standard of care for narcolepsy has been a twice-nightly medication, a challenging dosing regimen that disrupts nighttime sleep. The new data from the REST-ON trial demonstrate that the once-nightly formulation of sodium oxybate taken at bedtime was effective in addressing the symptoms of narcolepsy without requiring the patient to wake up in the middle of the night,” said Asim Roy, M.D., trial investigator and medical director of the Ohio Sleep Medicine Institute. “The new data analyses showing that FT218 improved excessive daytime sleepiness in patients with narcolepsy, both with and without cataplexy, regardless of stimulant use, are important for this patient population. Moreover, the data demonstrating a reduction in weight is an added benefit for narcolepsy patients, who tend to be overweight. I am encouraged by these and other data and believe FT218, if FDA approved, will be an important once-nightly treatment option for people who struggle with managing narcolepsy.”

Highlights from the poster presentations are outlined below.

Efficacy of FT218, a Once-Nightly Sodium Oxybate Formulation, by Narcolepsy Subtype: A Post Hoc Analysis from the REST-ON Study

- FT218 demonstrated statistically significant improvement in excessive daytime sleepiness (EDS) at all evaluated doses in patients with narcolepsy subtypes 1 (NT1, with cataplexy) and 2 (NT2, without cataplexy), with greater improvement in measures of EDS, including mean sleep latency on maintenance of wakefulness test (MWT) and Clinical Global Impression-Improvement (CGI-I) in overall condition, compared to placebo.
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- The least squares (LS) mean difference in mean sleep latency (in minutes) on MWT between FT218 and placebo was 6.0 for 9 g (week 13), 7.0 for 7.5 g (week 8), and 4.9 for 6 g (week 3) in NT1 patients (all $p < 0.001$), and 6.3 for 9 g ($P < 0.05$), 4.0 for 7.5 g ($P = \text{NS}$), and 5.3 for 6 g ($P < 0.05$) in NT2 patients.
- A significantly greater percentage of patients with NT1 receiving FT218 were rated as much or very much improved on the CGI-I compared to placebo: 75.5% vs. 35.9% at 9 g, 66.9% vs. 27.9% at 7.5 g, and 39.9% vs. 7.8% at 6 g (all $P < 0.001$). A greater percentage of NT2 patients receiving FT218 were rated as much/very much improved at all three doses vs. placebo

Efficacy of FT218, a Once-Nightly Sodium Oxybate Formulation, by Stimulant Use: A Post Hoc Analysis from the REST-ON Study

- FT218 demonstrated statistically significant improvement in EDS at all evaluated doses in narcolepsy patients with or without stimulant use, with improvement over placebo on MWT and CGI-I.
- The LS mean difference in mean sleep latency (in minutes) on MWT between FT218 and placebo was 6.0 for 9 g (week 13), 5.5 for 7.5 g (week 8), and 5.4 for 6 g (week 3) for patients with concomitant stimulant use (all $P \leq 0.001$). For patients not taking stimulants, the LS mean difference was 6.3 for 9 g ($P = 0.001$), 7.1 for 7.5 g ($P < 0.001$), and 4.2 for 6 g ($P < 0.01$).
- More patients receiving FT218 were rated much/very much improved on CGI-I compared to placebo: 80.5% vs. 35.3% at 9 g, 66.3% vs. 26.5% at 7.5 g, and 39.8% vs. 4.4% at 6 g for patients with stimulant use (all $P < 0.001$); 55.1% vs. 27.2% at 9 g ($P < 0.05$), 54.5% vs. 17.5% at 7.5 g ($P = 0.006$), and 40.0% vs. 7.7% at 6 g ($P < 0.01$) for patients without stimulant use.

Weight Loss with FT218, a Once-Nightly Sodium Oxybate Formulation for the Treatment of Narcolepsy: Post Hoc Analysis from REST-ON

- Patients receiving FT218 experienced a significantly greater decrease in weight and body mass index (BMI) from baseline to study end (week 13) compared to placebo.
 - At study end, the mean (SD) change in weight from baseline was -1.3 (3.6) kg for patients receiving FT218 compared to 0.2 (2.6) kg for patients receiving placebo. Overall, 17.8% of patients receiving FT218 compared to 3.8% of patients receiving placebo experienced $\geq 5\%$ weight loss.
 - At study end, the LS mean (SE) change in BMI from baseline was -0.5 (0.13) kg/m^2 for patients receiving FT218 and 0.1 (0.13) kg/m^2 for patients receiving placebo ($P = 0.001$).
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“Avadel is focused on providing a meaningful solution for people with narcolepsy and we are pleased to share further evidence of the clinical benefit of FT218, taken once at bedtime,” said Jennifer Gudeman, PharmD, Vice President of Medical and Clinical Affairs at Avadel. “We leveraged our unique scientific capabilities to develop a proprietary formulation of sodium oxybate to address the limitations of currently available treatments that require twice-nightly dosing. We believe these new analyses, along with previously presented REST-ON positive Phase 3 data, strengthen the body of evidence demonstrating that FT218, if approved, has the potential to be a transformative treatment for people living with narcolepsy.”

Previously released results from the REST-ON trial demonstrated highly statistically significant ($p < 0.001$ compared to placebo) and clinically meaningful improvement across all three co-primary endpoints (MWT, CGI-I and mean weekly cataplexy attacks) with FT218 at 6, 7.5 and 9 g. Secondary endpoint data for FT218 taken once at bedtime demonstrated clinically meaningful results at all tested doses, for reducing disturbed nocturnal sleep; additional post hoc analyses further demonstrated significant increase in time in deep sleep, and significant decrease in light sleep compared to placebo for doses evaluated beginning by week 3 with only a 6-g-dose. As reported at the American Academy of Neurology 2021 meeting, FT218 also demonstrated a significant improvement in the Epworth Sleepiness Scale, a patient reported outcome, and significantly improved patient perceptions of the quality and refreshing nature of sleep at all doses tested beginning by week 3. FT218 taken once at bedtime at 9 g was generally well tolerated with commonly known sodium oxybate adverse reactions occurring at low rates. These findings will also be presented by Avadel at SLEEP 2021 in an oral and poster session (abstract # 488) and two additional posters (abstract # 489 and 490).

The Company is also hosting a virtual medical booth that houses the posters, an on-demand symposium titled “How Narcolepsy Management Is Evolving: Expert Panel Discussion,” and detailed information about its ongoing research and publications. The virtual medical booth can be accessed at <http://www.sleep2021.avadelmedicalbooth.com/> until November 30, 2021.

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.



About Avadel Pharmaceuticals plc

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a biopharmaceutical company primarily focused on the development and U.S. Food and Drug Administration (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.

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 the Company’s future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects, or other events. Such forward-looking statements include, but are not limited to, expectations regarding the tolerability or therapeutic benefits of FT218, the timing of the FDA’s review of the NDA for FT218, the sufficiency of data supporting the 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).

The Company’s 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, the Company’s business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of the Company’s 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 the Company’s 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 the Company’s 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 the Company’s Annual Report on Form 10-K for the year ended December 31, 2020, which was 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. The Company does not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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