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): **June 4, 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. ☐

Item 7.01 Regulation FD Disclosure.

On June 9, 2019, Avadel Pharmaceuticals plc (the "Company") intends to present two posters at the 33rd Annual Meeting of the Associated Professional Sleep Societies in San Antonio, Texas. A copy of the Company's posters to be used at the conference is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference.

On June 4, 2019, the Company issued a press release, a copy of which is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information responsive to Item 7.01 of this Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 of 1933 or the Exchange Act, except as may be expressly set forth by specific reference in such a filing.

Cautionary Note Regarding Forward-Looking Statements:

This Current Report on Form 8-K – including Exhibit 99.1 attached hereto – may include "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 or phrases such as "could" 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 of our research, development and commercialization activities and the results of our business and operations will not differ materially from the results contemplated in such forward-looking statements. Please see also the other 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, 2018 which we filed with the Securities and Exchange Commission on March 15, 2019.

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 press release.

Please also see the "Cautionary Note Regarding Forward-Looking Statements" set forth in Exhibit 99.2 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Presentation materials dated June 9, 2019*
99.2	Press release dated June 4, 2019, issued by Avadel Pharmaceuticals plc*

* This information shall be deemed to be "furnished" and not filed herewith.

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: June 7, 2019

Exhibit Index

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99.2	Press release dated June 4, 2019, issued by Avadel Pharmaceuticals plc*

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Pharmacokinetics and dose proportionality of FT218 an investigational controlled-release sodium oxybate formulation designed for once-nightly dosing

D. Monteith [1], J. Grassot [1], C. Castellan [1], J. Dubow [1], T. Roth [2]

[1] Avadel Ireland, Dublin, Ireland, [2] Sleep Disorders Centre, Henry Ford Hospital, Detroit, United States.

Introduction

Sodium oxybate is indicated for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients with narcolepsy. The currently marketed product, an immediate release (IR) sodium oxybate is required to be taken twice nightly: at bedtime and 2.5 to 4 hours later, thus requiring patients to awaken in the middle of the night.

FT218 is an investigational controlled-release (CR) formulation of sodium oxybate intended for once-nightly dosing, using Avadel's proprietary Micropump™ technology. Following the PK pilot PKFT218-1301 study which evaluated the pharmacokinetics (PK) of three prototypes of FT218, the PK and dose proportionality of the optimized formulation of FT218 were evaluated in a Phase I study (PKFT218-1601).

Objectives

Primary objective: to assess the PK of FT218 given as a single dose of 4.5g, 7.5g and 9g.

Secondary objectives:

- To assess the safety and tolerability of FT218.
- To compare PK parameters at the 3 doses and estimate the dose proportionality.

Methods

The study was an open-label, single-dose, 3-sequential period study in 20 healthy volunteers. Subjects received 3 separate single-dose (without titration) 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. Dose proportionality between the three doses was assessed using the power method. Sensitivity analyses were performed using ANOVA.

Variability of concentrations of FT218 and twice-nightly sodium oxybate IR at 8h and 10h post-dose (when patients typically awaken) in the PK pilot and the present study were compared in terms of standard deviation.

Subject disposition

The study was conducted in 20 healthy volunteers (12 males and 8 females). All subjects completed periods 1 (4.5g) and 2 (7.5g), while 12 subjects completed period 3 (9g).

Pharmacokinetics

For the 3 doses, mean pharmacokinetics exhibited similar overall profiles with median T_{max} between 1.5 and 2 hours (Figure 1). Mean C_{max} increased from 42.9 to 84.5 µg/mL across the increasing doses. Following C_{max}, blood levels gradually decreased overnight. Mean AUC_{inf} was 191, 358 and 443 µg.h/mL for the 4.5, 7.5 and 9g doses respectively. Mean concentrations at 8 hours were 4.8, 19.7 and 25.5 µg/mL for the 4.5, 7.5 and 9g doses respectively.

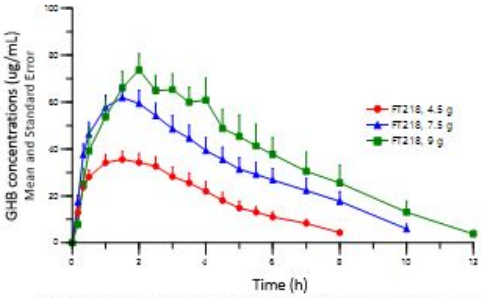

Figure 1. FT218 plasma concentration time curves for rising doses from 4.5g to 9g per night

Table 1. Variability of concentrations at 8h and 10h post-dose for twice-nightly sodium oxybate and FT218 in the PK pilot and dose proportionality studies.

	Twice-nightly sodium oxybate IR	FT218		
	PK pilot study	PK pilot study		Dose proportionality study
		Part 1-Step 1	Part 2	
PK parameter	2*2.25g n=15	4.5g n=14	4.5g n=12	4.5g n=20
C_{8h} mean ± SD (µg/mL)				
BQL set to missing	9.24 ± 11.77 (n=14)	7.40 ± 5.88 (n=13)	6.27 ± 5.81	4.76 ± 5.01
BQL set to zero	8.62 ± 11.59	6.87 ± 5.98	6.27 ± 5.81	4.76 ± 5.01
C_{10h} mean ± SD (µg/mL)				
BQL set to missing	2.64 ± 3.84 (n=8)	1.21 ± 1.86 (n=8)	0.94 ± 0.55 (n=7)	0.73 ± 0.41 (n= 9)
BQL set to zero	1.41 ± 3.04	0.69 ± 1.50	0.55 ± 0.63	0.33 ± 0.46

BQL: concentration below quantitation limit.

Variability of C_{8h} and C_{10h}

Mean concentrations at 8h and 10h post-dose for FT218 are at least as low as twice-nightly sodium oxybate IR, regardless of the rule used to address concentrations below quantitation limit (Table 1). Moreover, the variability of the concentrations was similar.

Dose proportionality

Applying the power method, the slope estimate for C_{max} was 1.02 and the confidence interval centered on 1.00 (90% CI: 0.76-1.28). For AUC_{inf}, the estimate was 1.34 (90% CI: 1.19-1.48), indicating that the increase in the AUC is slightly more than proportional. These results were consistent with ANOVA sensitivity analysis results.

Safety profile

Thirteen subjects (65%) reported a total of 31 treatment emergent adverse events:

- 8 TEAEs (mainly headache 5/8) experienced by 7/20 (35%) subjects during the 4.5g period;
- 7 TEAEs (mainly gastrointestinal disorders 4/7) experienced by 4/20 (20%) subjects during the 7.5g period;
- 16 TEAEs (mainly gastrointestinal disorders 8/16) experienced by 6/12 (50%) subjects during the 9g period. One of these, a nervous system disorder (sedation) was a SAE.

The intensity of TEAEs was judged severe for 2/31 TEAEs (both in 9g period), moderate for 10/31 (4 in 4.5g period, 3 in 7.5g period and 3 in 9g period) and mild for 19/31.

All the TEAEs were resolved before the end of the study.

Conclusion

FT218 achieved predictable blood-level profiles, when given at bedtime, consistent with a once-nightly dosing regimen. Dose proportionality was maintained for C_{max} across the dosage range. The safety profile was consistent with what is known for sodium oxybate and most AEs were mild to moderate in severity even without titration.

If approved, FT218 could offer a new option for the treatment of EDS and cataplexy in narcolepsy with a once-nightly formulation of sodium oxybate.

The safety and efficacy of FT218 is currently being evaluated in the pivotal, randomized, double-blind, placebo-controlled Phase 3 REST-ON study.

Pharmacokinetics and formulation selection of FT218 an investigational controlled-release sodium oxybate formulation designed for once-nightly dosing

D. Monteith [1], J. Grassot [1], C. Castellan [1], J. Dubow [1], T. Roth [2]

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FT218 is an investigational controlled-release (CR) formulation of sodium oxybate intended for once-nightly dosing, using Avadel's proprietary Micropump™ technology.

The efficacy and safety of FT218 is currently being evaluated in the pivotal, randomized, double-blind, placebo-controlled Phase 3 REST-ON study.

The pharmacokinetic (PK) performance of three prototypes of FT218 was evaluated in a PK pilot study (PKFT218-1301).

Objectives

Primary objective: to assess the pharmacokinetic profiles of three CR formulations of FT218.

Secondary objectives: to explore the pharmacodynamic effects of sodium oxybate CR (FT218) versus twice-nightly sodium oxybate IR, and investigate safety and tolerability.

Methods

The study was an exploratory open label, randomized, crossover study in 16 healthy male and female volunteers. Each volunteer received 4 different formulations of sodium oxybate in 4 randomized study periods with a 3 day washout between periods: a single 4.5g dose of one of the three test formulations of FT218 or 2 x 2.25g doses of twice-nightly sodium oxybate IR given 4-hours apart. Pharmacodynamic effects were explored using the Leeds Sleep Evaluation Questionnaire (LSEQ) and actigraphy.

Pharmacokinetics

Each of the three FT218 prototypes exhibited a sustained release profile with C_{max} below the global C_{max} of twice-nightly sodium oxybate IR and a C_{8h} similar to twice-nightly sodium oxybate IR (Fig. 1).

Prototype 2 was selected for further optimization, as it exhibited PK characteristics closest to the desired target profile. This formulation exhibited a higher C_{max} compared to the other prototypes, and the AUC_{inf} was the closest to the AUC_{inf} of the twice-nightly sodium oxybate IR (Table 1).

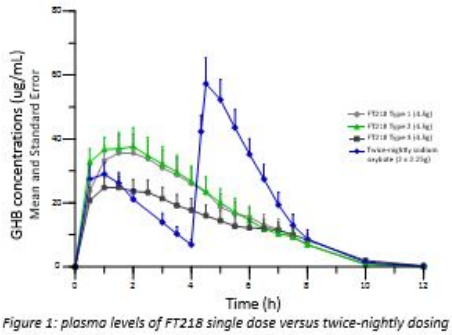

Figure 1: plasma levels of FT218 single dose versus twice-nightly dosing

Table 1: PK parameters (mean ± Standard Error)

	FT218 Type 1	FT218 Type 2	FT218 Type 3	Twice-nightly sodium oxybate IR
C_{max} (µg/mL)	43 ± 6	46 ± 5	30 ± 4	66 ± 7
AUC_{inf} (h.µg/mL)	189 ± 28	210 ± 28	153 ± 22	214 ± 27
C_{8h} (µg/mL)	6.85 ± 2.09	7.40 ± 1.63	8.33 ± 1.93	9.24 ± 3.15

Sleep quality and alertness on awakening

For each LSEQ domain, there were no clinically meaningful differences between groups.

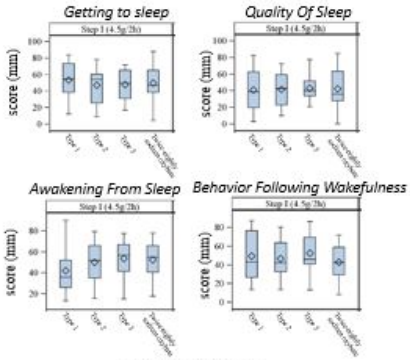

Figure 2: LSEQ results

Actigraphy

Sleep time over 8 hours after administration was similar between the treatments.

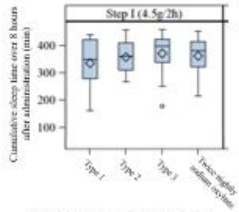

Figure 3: Actigraphy results

Safety profile

Four subjects (25%) reported a total of 5 treatment emergent adverse events (Table 2). All were of mild or moderate intensity. There were no serious adverse events or adverse events leading to discontinuation.

Table 2: Incidence of adverse events

	Type 1 N=15 n(%)	Type 2 N=14 n(%)	Type 3 N=15 n(%)	Twice-nightly sodium oxybate IR N=15. n(%)	Overall N=16 n(%)
Pharyngitis	1 (6.7%)	0	0	0	1 (6.3%)
Flu-like syndrome	1 (6.7%)	0	0	0	1 (6.3%)
Gastroenteritis	0	0	1 (6.7%)	0	1 (6.3%)
Nausea	0	0	0	1 (6.7%)	1 (6.3%)
Headache	0	0	0	1 (6.7%)	1 (6.3%)
Overall	**2 (13.3%)**	**0**	**1 (6.7%)**	**1 (6.7%)**	**4 (25%)**

Conclusion

The three FT218 prototypes exhibited CR profiles covering the entire night (8 hours) with once-nightly dosing. Prototype 2, compared to twice-nightly sodium oxybate IR, exhibited a lower overall C_{max} and, importantly, a comparable C_{8h}, while the AUC was maintained. Between-subject variability of FT218 and twice-nightly sodium oxybate IR was comparable. Safety and tolerability was similar between groups. If approved, FT218 could offer a new option for the treatment of EDS and cataplexy in narcolepsy with a once-nightly formulation of sodium oxybate.

The REST-ON pivotal phase 3 study is currently enrolling patients with narcolepsy to evaluate the efficacy and safety of FT218. Enrollment is expected to be completed in 2020.

Avadel to Present New Data on Once-Nightly Sodium Oxybate at SLEEP 2019 Conference

DUBLIN, Ireland, June 4th, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218 for narcolepsy, today announced it will present two posters at the 33rd Annual Meeting of the Associated Professional Sleep Societies being held in San Antonio, Texas, from June 8-12, 2019. The posters highlight pharmacokinetic (PK) data for its investigational, once-nightly controlled-release sodium oxybate (FT218), including a head-to-head PK comparison to twice-nightly sodium oxybate and dose proportionality across three doses.

“Our once-nightly controlled-release sodium oxybate demonstrated lower overall peak plasma concentrations (C_{max}) and similar total exposures (AUC), compared to twice-nightly sodium oxybate in a head-to-head study,” said Jordan Dubow, MD, Chief Medical Officer of Avadel Pharmaceuticals. “Furthermore, results from our dose proportionality study showed that FT218 exhibits predictable increases in plasma levels with increasing doses, consistent with the PK profile desired for a once-nightly sodium oxybate formulation. We are excited about the potential benefits of our once-nightly formulation and look forward to completion of the Phase 3 REST-ON trial, which is nearly two-thirds complete.”

Poster Presentations:

Poster 0609, presented Sunday, June 9, 5:15- 7:15 p.m. CDT
“Pharmacokinetics and Formulation Selection of FT218, an Investigational Controlled-Release Sodium Oxybate Formulation Designed for Once-Nightly Dosing”

Poster 0610, presented Sunday, June 9, 5:15 – 7:15 p.m. CDT
“Pharmacokinetics and Dose Proportionality of FT218, an Investigational Controlled-Release Sodium Oxybate Formulation Designed for Once-Nightly Dosing”

The pharmacokinetics and formulation selection pilot study 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 IR sodium oxybate, were administered the second dose 4 hours after the first dose. Two subjects dropped out of the study prior to the completion. The key data for the 14 evaluable subjects demonstrates:

- FT218 exhibited rapid initial absorption comparable to twice-nightly IR sodium oxybate
- FT218 demonstrated a lower overall C_{max} than twice-nightly IR sodium oxybate
- FT218 mean blood concentrations (ug/ml) at 8 hours were similar to that of twice-nightly IR sodium oxybate
- Safety and tolerability were similar across administrations

The dose proportionality study was an open-label, single-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. PK profiles were assessed for dose proportionality across the three doses and the results demonstrated:

- FT218, at each dose, exhibited PK profiles consistent with those desired for once-nightly dosing
- Dose proportionality was maintained for C_{max} across the dosage range
- Safety profile was consistent with what is known for sodium oxybate

The safety and efficacy of FT218 for the once-nightly treatment of excessive daytime sleepiness (EDS) and cataplexy in patients with narcolepsy is currently being evaluated in the Phase 3, multi-centered, double-blind, placebo-controlled REST-ON trial, which is expected to complete enrollment in 2020. Poster reprints and REST-ON information will be available at Avadel's Booth #1027 in the Exhibit Hall during the SLEEP 2019 conference.

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. Avadel is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com.

Cautionary Disclosure Regarding Forward-Looking Statements

This press release may include "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 or phrases such as "will," "as we continue," "objective," "future success," "potential, "opportunity" 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 of our research, development and commercialization activities 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 (i) the risk that we could experience failure or delay in completing the Phase 3 "REST-ON" clinical trial for our FT218 product, or that if the FDA ultimately approves such product, the approval may not include any period of market exclusivity; (ii) the risk that, even if we successfully complete the development of FT218 and begin its commercialization, it may not receive market acceptance, or new, announced alternative products in development may be approved and may be viewed as more effective than FT218 or otherwise receive greater market acceptance; (iii) the risk that servicing our $143.75 million Exchangeable Senior Notes due 2023 may require a significant amount of cash, and we may not have sufficient cash or the ability to raise the funds necessary to settle exchanges of such 2023 Notes in cash, repay the 2023 Notes at maturity, or repurchase the 2023 Notes as required following a "fundamental change" event described in the indenture governing the 2023 Notes; and (iv) the other 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, 2018 which we filed with the Securities and Exchange Commission on March 15, 2019.

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 press release.

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Source: Avadel Pharmaceuticals plc