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**	**Not Applicable**
(Address of Principal Executive Offices)	(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*	AVDL	NASDAQ Stock Market LLC
Ordinary Shares**		(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 7.01 Regulation FD Disclosure.

On September 24, 2019, Avadel Pharmaceuticals plc (the "Company") intends to make a presentation at the Ladenburg Thalmann 2019 Healthcare Conference in New York, New York (the "Conference"). A copy of the Company's complete slide presentation to be used at the Conference is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company's presentation will be webcast live and can be accessed by visiting the Investor section of the Company's website at http://www.avadel.com. A replay of the presentation, together with the complete slide presentation, will also be available and archived for 90 days on the website following the event.

The information responsive to Item 7.01 of this Form 8-K, including Exhibit 99.1, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Slide Presentation of Avadel Pharmaceuticals plc as of September 24, 2019

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™

The Power of Medicine. Reinvented.

Avadel Pharmaceuticals plc
Nasdaq: AVDL

Company Overview - September 2019

Safe Harbor

This presentation 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. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. Although we believe that our forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and as a result there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from the results contemplated in such forward-looking statements. These risks include: *(a) risks relating to our recent cost-saving actions, including the risks that (i) such actions may not result in the amount of cost savings that we anticipate; and (ii) such cost-saving actions may cause us to incur one-time costs in amounts greater than we anticipate; (b) risks relating to the development of our investigational "FT218" sodium oxybate product, including the risks that (i) we may not have adequate capital to complete the development of FT218, we may need to obtain additional capital for such purpose, and such additional capital may not be available on attractive terms or at all; (ii) we may be unsuccessful in accelerating the pace of our clinical trial enrollment for the Phase 3 REST-ON clinical trial, or we could experience delay or failure in completing that clinical trial;* iii) we may encounter challenges in the remaining development efforts for FT218; iv) the FDA may determine there are deficiencies in the NDA for FT218 or may never approve the NDA for FT218; v) FT218 may not have the therapeutic benefits we anticipate; vi) the commercial launch of FT218 could be delayed; vii) FT218 may not achieve commercial acceptance; and viii) other companies may develop competing products that may receive FDA approval before FT218*; and (c) the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2018, and our quarterly reports on Form 10-Q for the periods ended March 31, 2019 and June 30, 2019, in particular disclosures that may be set forth under the captions "Forward-Looking Statements" and "Risk Factors," including without limitation: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz®, Vazculep® and Akovaz® products, which are not patent protected, could continue to face substantial and increased competition resulting in a further loss of market share and/or forcing us to further reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for products we are evaluating for potential application to the FDA pursuant to our "unapproved-to-approved" strategy, or that competitors could complete the development of such products and apply for FDA approval of such products before us; the possibility that our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do; and our dependence on key personnel to execute our business plan. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made and are not guarantees of future performance. We do not undertake any obligation to publicly update or revise these forward-looking statements.*

Avadel™

THE NEW **AVADEL**

We are an **emerging bio-pharmaceutical** company. Our primary focus is on the development and potential FDA approval for our Phase III orphan designated once-nightly sodium oxybate, **FT218,** for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients suffering from narcolepsy. In addition, we market three FDA approved sterile injectable drugs used in the hospital setting which were developed under our "unapproved marketed drug" (UMD) program.

CNS/SLEEP

HOSPITAL

The New AVADEL
2019 YTD – Transformational Change… Building Momentum

Refocused

- Strategically refocused on FT218, a significant late stage opportunity
- Orphan designated Phase III investigational asset
- REST-ON clinical trial 94% enrolled and expected to complete enrollment by end of 2019
- Targeting $1.6B market opportunity

Restructured

- Operationally restructured company resulting in >$80M in annualized cost reductions
- Exited Noctiva™ and winding down Avadel Specialty Pharmaceuticals, LLC entity
- >85% FTE reduction by 12/31/19
- Consolidating geographic locations
- Optimizing hospital cash flow generation

Recruited

- Strengthened management, clinical and medical teams through recruitment of seasoned industry professionals
- ***New*** Chief Medical Officer, Clinical Operations Lead and Medical Director
- Making significant impact on timing and resources for the REST-ON clinical trial

Positioning the new AVADEL to capitalize on the potential promise of FT218 with adequate liquidity to complete the REST-ON clinical trial

The New AVADEL
Investment Highlights

FT218

- FT218 is a once-nightly dose of sodium oxybate that may offer a substantial improvement compared to standard of care
- Orphan drug designation that targets a growing $1.6B[1] market
- Intellectual property protection through at least June 2037 with additional pending patent filings

Phase 3 Study Near Completion

- The FT218 Phase 3 study, REST-ON, is 94% enrolled
- Enrollment to be completed by end of 2019 (target); data readout in Q2 2020
- No new chemical entity (NCE) risk as a formulation of a well understood molecule being filed under a 505(b)(2) pathway
- Single Phase 3 study required for approval for both excessive daytime sleepiness and cataplexy indications

REST-ON

Hospital Portfolio Funds Operations

- Cash flowing hospital business to help fund FT218 and strengthen balance sheet
- Pending portfolio expansion with December 15, 2019 NDA PDUFA date for AV001
- Sufficient liquidity to fund operations into 2021 including completion of the REST-ON clinical trial

References: 1. Annualized Xyrem revenues from Jazz Pharmaceuticals Q2 2019 earnings press release, August 6, 2019

Narcolepsy Overview

A sleep disorder, involving irregular patterns in Rapid Eye Movement (REM) sleep and significant disruptions of normal sleep/wake cycle that result in excessive daytime sleepiness (EDS) and cataplexy

- Large orphan patient population; an estimated **~ 200K Americans** suffer from Narcolepsy[1]
- **Prevalent symptoms include:** Excessive Daytime Sleepiness (EDS) and Cataplexy[1]

Narcolepsy is **difficult to diagnose**, requiring a complex series of tests

Only **25% of people** with narcolepsy have been diagnosed and are receiving treatment[1]

- **~14,700** diagnosed patients are **treated with sodium oxybate**[2]
- Current SOC - Sodium oxybate dosed twice-night totaling between 6g - 9g[2]

References: 1. Narcolepsy Network foundation http://narcolepsynetwork.org/about-narcolepsy/ **2.** Xyrem 2Q19 Financial Results slide presentation, published August 6, 2019

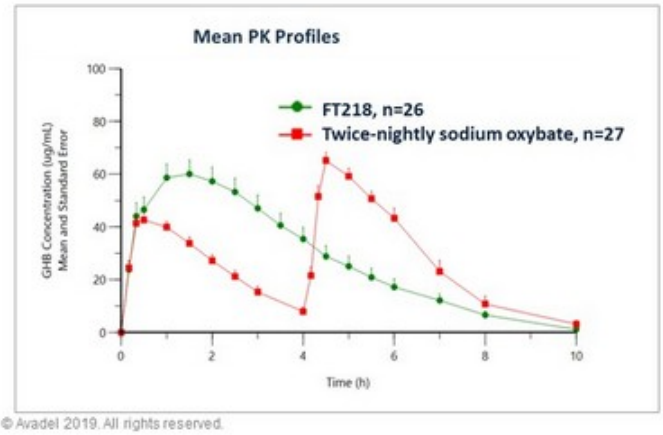
Transforming the way we treat patients

Current treatment paradigm

Sodium Oxybate 2x-nightly is the only FDA-approved treatment for cataplexy and EDS in narcolepsy

Avadel's FT218

The **Micropump™** delivery **technology** is designed to **deliver one single dose at bedtime** and prevent the need for waking up in the middle of the night for a second dose



- Overall exposure (AUC) of FT218 meets bioequivalence criteria compared to AUC of twice-nightly sodium oxybate IR[1]
- Overall Cmax of FT218 is lower than that of twice-nightly sodium oxybate IR[1]
- Morning blood levels (C8h) of FT218 are similar to twice-nightly sodium oxybate IR[1]

[1]4.5 and 6g doses

*"That would be life changing. **To not have to get up in the middle of the night, EVERY SINGLE NIGHT."***

– A twice-nightly sodium oxybate patient

Avadel's View of the FT218 Opportunity

	FT218
A Better Solution Despite being the standard of care, only 9% of patients are prescribed 2x-nightly sodium oxybate as 1st line therapy[1]	✓
Improved compliance Approximately 44% of newly treated patients discontinue twice-nightly sodium oxybate within 12 months and data suggests ~27% of patients are non-compliant with 2nd dose[1,2]	✓
Improved Dosing Market research shows physicians prefer 1x-nightly over 2x-low sodium and generics[1]	✓
Large Market 2x-nightly sodium oxybate (Xyrem®) revenues exceeded $1.6 billion[4] in 2018 branded sales	✓

References: 1. Data on file. **2.** Mayer G, et al. *Sleep*, 2018; 41(9). **3.** Data on file, **4.** Annualized Xyrem revenues from Jazz Pharmaceuticals Q2 2019 earnings press release, August 6, 2019, **5** according to Drugs.com https://www.drugs.com/price-guide/xyrem

An Overview of the Phase 3 Trial, REST-ON

94% enrolled as of September 2019

Study Design

- Randomized, double-blind, parallel-group placebo-controlled study with 1:1 randomization to FT218 or placebo in patients with Narcolepsy, either NT1 or NT2
- Primary objective is to evaluate the efficacy of FT218
- Secondary objective is to evaluate the safety and tolerability of FT218
- Primary endpoints: Maintenance of Wakefulness Test (MWT), Clinical Global Impression (CGI) and number of Cataplexy attacks
- Starting dose of 4.5g and titrating up to 9g
- 13-week duration
- **N = 205**
- Special Protocol Assessment in place with FDA

FDA Special Protocol Assessment Updates
(announced 9/23/19)

- Reduce # of randomized patients to 205
- Complete enrollment by end of 2019 (target)
- Announce topline data in Q2 2020 (target)

REST-ON
remains one of the largest studies ever conducted in these indications

REST-ON Statistical Analysis Plan (SAP) and Protocol Amendment

FDA Special Protocol Assessment (SPA) Amendment
(announced 9/23/19)

- Modified the statistical analysis of the primary endpoint from two doses in parallel (7.5 or 9 g) to each dose sequentially (9 g followed by 7.5 g)
  - If 9g analysis is positive, repeat these analyses for 7.5g, followed by analyses for 6.0g
- As a result, p-value requirement increases from 0.025 to 0.05
- Sample size decreases from 264 to a target of 205

Study Impact

- No modifications were made to the fundamental design of the study including:
  - Primary and secondary endpoints
  - Dosing scheme or doses tested
  - Duration of treatment for randomized patients
- Maintains a robustness of overall study power needed to demonstrate statistical significance for both excessive daytime sleepiness and cataplexy
- The SPA remains intact per previous agreement

The Hospital Franchise

H1 2019 revenues of **~$34M**; strategic objective is to optimize these cash flows to invest in the development of FT218

3 commercial sterile injectable products used in the hospital setting

VAZCULEP™ AKOVAZ™ BLOXIVERZ™

4th sterile injectable NDA accepted in May 2019; PDUFA date of December 15, 2019; estimated market of $30M+

Performance and Financial Highlights

YTD Accomplishments

- **Refocused** on **FT218**, a Phase 3 opportunity
- Operationally restructured company resulting in **>$80M in annualized cost reductions**
- **Strengthened** management, clinical and medical **teams**
- Secured **FT218 protocol amendment**

Guidance

- **Complete enrollment** of FT218 REST-ON Phase 3 study by end of **December 2019**
- Announce **topline FT218 data in Q2 2020**
- **Hospital** product **revenues +$45.0 million** for 2019
- **December 15**, 2019 **PDUFA date** for AV001

Cash, Marketable Securities

- Totaled **$79.3 million** as of June 30, 2019 which is expected to fund operations into 2021

The New AVADEL
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Avadel™

The Power of Medicine. Reinvented.

Thank you

September 2019