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): January 10, 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 1 920 1000

Block 10-1
Blanchardstown Corporate Park, Ballycoolin
Dublin 15, Ireland
(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* Ordinary Shares, nominal value $0.01 per share**	AVDL N/A	The Nasdaq Global Market

*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 January 10, 2020, Avadel Pharmaceuticals plc (the "Company") updated its corporate presentation for use in meetings with investors, analysts and others. A copy of the updated corporate presentation is furnished herewith as Exhibit 99.1 and incorporated herein by reference. The Company undertakes no obligation to update, supplement or amend the materials furnished herewith as Exhibit 99.1.

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 Exchange Act of 1934, 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 of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

On January 7, 2020, Exela Pharma Sciences, LLC ("Exela") filed a complaint against the Company and its subsidiary, Avadel Legacy Pharmaceuticals, LLC ("Avadel Legacy") in the United States District for the District of Delaware. The complaint alleged patent infringement by the Company and Avadel Legacy of a certain Exela patent related to its cysteine hydrochloride product. While Avadel Legacy has not yet been served with notice of this complaint, the Company believes it has defenses to any related cause of action and plans to vigorously pursue these defenses in federal court if necessary.

Item 9.01. Exhibits

(d) Exhibits

99.1 Corporate presentation of Avadel Pharmaceuticals plc, dated January 10, 2020.

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.

January 10, 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 plc

Repositioned: Executing New Strategy

January 2020

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 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 risks that (i) such actions may not result in the amount of cost savings 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 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 could experience delay or failure in completing the Phase 3 REST-ON 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*; (c) risks related to the commercialization of Nouress™, including risks that (i) we delay the commercial launch Nouress or do not commercially launch Nouress at all, (ii) the current patent infringement suit alleging that Nouress infringes the intellectual property of a third party may prevent or delay our commercial launch of Nouress, (iii) we may be required to pay royalties to a third party if we commercially launch Nouress and (iv) third parties may infringe our intellectual property covering Nouress and we may incur substantial costs to defend our intellectual property, and (d) 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 subsequent filings with the U.S. Securities and Exchange Commission. 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.*

AT A GLANCE

The New Avadel: All the Ingredients for Success

FT218
a differentiated product with high potential

100%
enrolled in pivotal Ph3 study REST-ON, single study required for approval; data readout in Q2 2020

ZERO
new chemical entity risk

$72M
cash, funding well into 2021 including completion of REST-ON trial

ZERO
debt due until 2023

18 YEARS
intellectual property protection – until 2037

>$55M
2019 revenues from hospital portfolio of 3 products with a 4th approved pending[1] launch – helps fund FT218

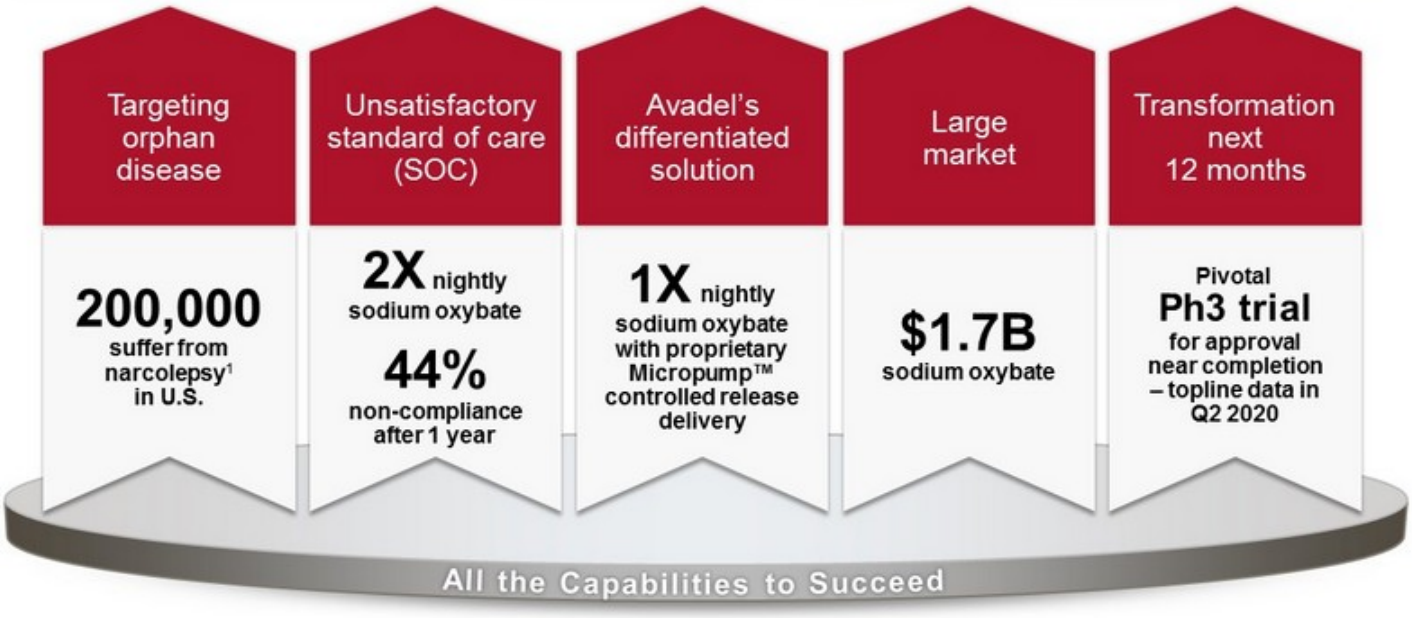
The **RIGHT TEAM** in place

Avadel™

[1]Commercial launch pending resolution of IP matter

THE AVADEL STORY

Repositioned, Executing New Strategy. Transformative Next 12 Months



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Note: 1. Narcolepsy sufferers exhibit excessive daytime sleepiness (EDS) and cataplexy

Characteristics of Narcolepsy – Serious Disease with Large Unmet Need

- An under-researched and under-diagnosed disease; pathogenesis poorly understood
- Unmet medical need despite current treatment options
- Market expected to grow significantly over period to 2027[1]
- Twice-nightly sodium oxybate is currently the only FDA approved treatment for the symptoms of narcolepsy – excessive daytime sleepiness (EDS) and cataplexy

[1]Source: GlobalData, June 2018

A New Paradigm of Treatment is Welcomed by Physicians

There is high unmet need in patients treated with Xyrem

"… I don't know of another medication where the patient has to wake up in the middle of the night to take it again, this is a serious problem for patients that already have a sleep disorder …"

Sleep Specialist KOL, Major Academic Hospital Sleep Center in PA

"… The dosing schedule makes it complicated. It's hard for them to wake up, so they may miss their second dose or take it at the wrong time. It's also a burden on their spouse or parents or roommates …"

Primary Care Physician, Private Clinic in NJ

FT218 target product profile strongly resonates with physicians

"… [FT218] is what we have been expecting, this is what we want. Patients wouldn't be so confused about starting therapy… we would almost only use [FT218] over Xyrem …"

Sleep Specialist, Academic Hospital Sleep Center in WV

"… I would very much prefer [FT218], patients need quality sleep and that's what [FT218] offers. I would welcome it …"

Neurologist, Private Clinic in SC

81%[1] of physicians would prescribe FT218

Avadel™

Note: **1.** Data on file - proprietary market research

… And Could be Life Changing for Patients…

1X nightly

Our Micropump™ delivers one single dose at bedtime

Life Changing

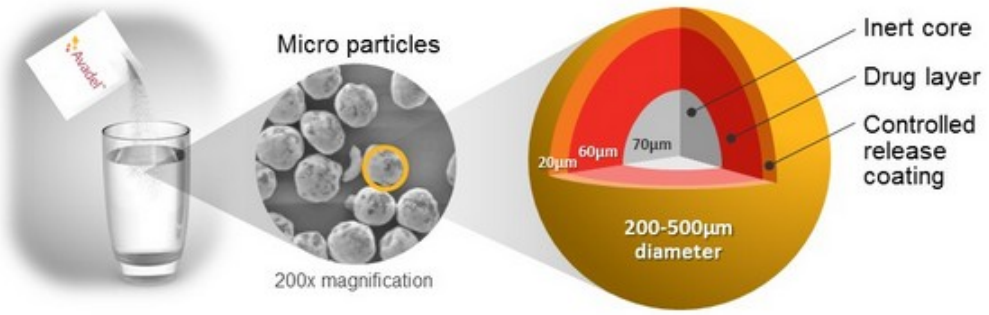
"That would be life changing. ***To not have to get up in the middle of the night, EVERY SINGLE NIGHT."***

– A twice-nightly sodium oxybate patient

Avadel™

Leveraging Our Proprietary Micropump™ Technology – Delivering Sodium Oxybate Once Nightly

The Technology



- **Technology contains thousands of 'micro particles' per capsules**
  - each is a miniature delivery system
- **Microparticulate design can be adapted to each drug's specific challenges**
  - modify coatings / thickness

The Advantages

- Delayed delivery of small molecule drugs taken orally
- Potential to: improve efficacy, reduce toxicity, improve compliance

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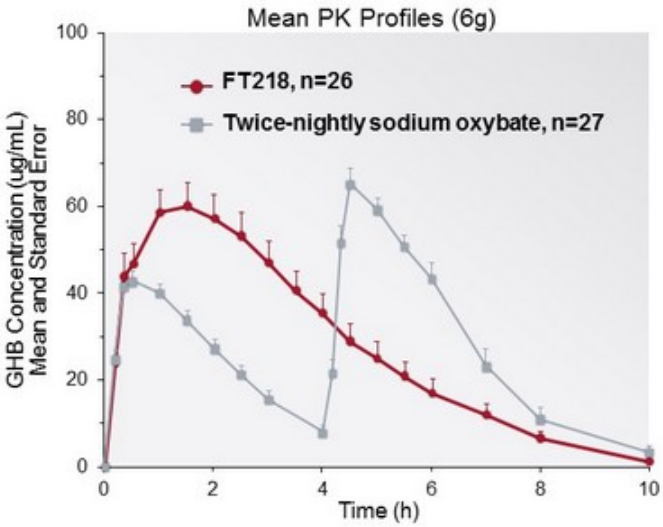
Source: 10-k pg 89, data on file

Investigational Study Clearly Indicated Powerful Potential Advantages of FT218

The Results



The Comparison vs. 2X Nightly

Single dose	**Advantage**
No disruption of sleep	**Advantage**
Overall Peak concentration (Cmax) - lower	**Advantage**
Overall exposure (AUC) - bioequivalent to SOC	**Similar**
Onset time	**Similar**
Morning blood levels (C8H)	**Similar**

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Overview of the Phase 3 Trial, REST-ON

Regulatory Pathway / Study Design

Pathway

- Abbreviated 505(b)(2) approval process; study conducted under SPA agreement with FDA, requires only 1 pivotal study for approval

Study Type

- Randomized, double-blind, parallel-group placebo-controlled study with 1:1 randomization to FT218 or placebo in patients with Narcolepsy, either NT1 or NT2

Objectives

- 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

Dosage / Duration / Participants

- Starting dose of 4.5g and titrating up to 9g
- 13-week duration
- N = 205 (**completed**)

Advantage of Legacy Portfolio of Cash Flow Positive Hospital Products

3

Commercial sterile injectable products used in the hospital setting

VAZCULEP™ AKOVAZ™ BLOXIVERZ™

2019 annual revenues of $55M+ supporting development of FT218

+

A new 4TH

Nouress™ (cysteine hydrochloride) sterile injectable **approved by FDA** on Dec 15, 2019; **IP granted** with additional IP expected; launch pending[1]

Estimated Market value of >$50M

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*Commercial launch pending resolution of IP matter

Priorities Going Forward

1. Laser focus on successful completion of pivotal FT218 Ph3 trial
2. Continue to ensure strong liquidity to support FT218 program
   - includes maximizing cash flow from Hospital products
3. Scale up FT218 manufacturing and complete NDA requirements
4. Advance FT218 “go to market” planning
5. Build strong credibility with investors by delivering on our commitments

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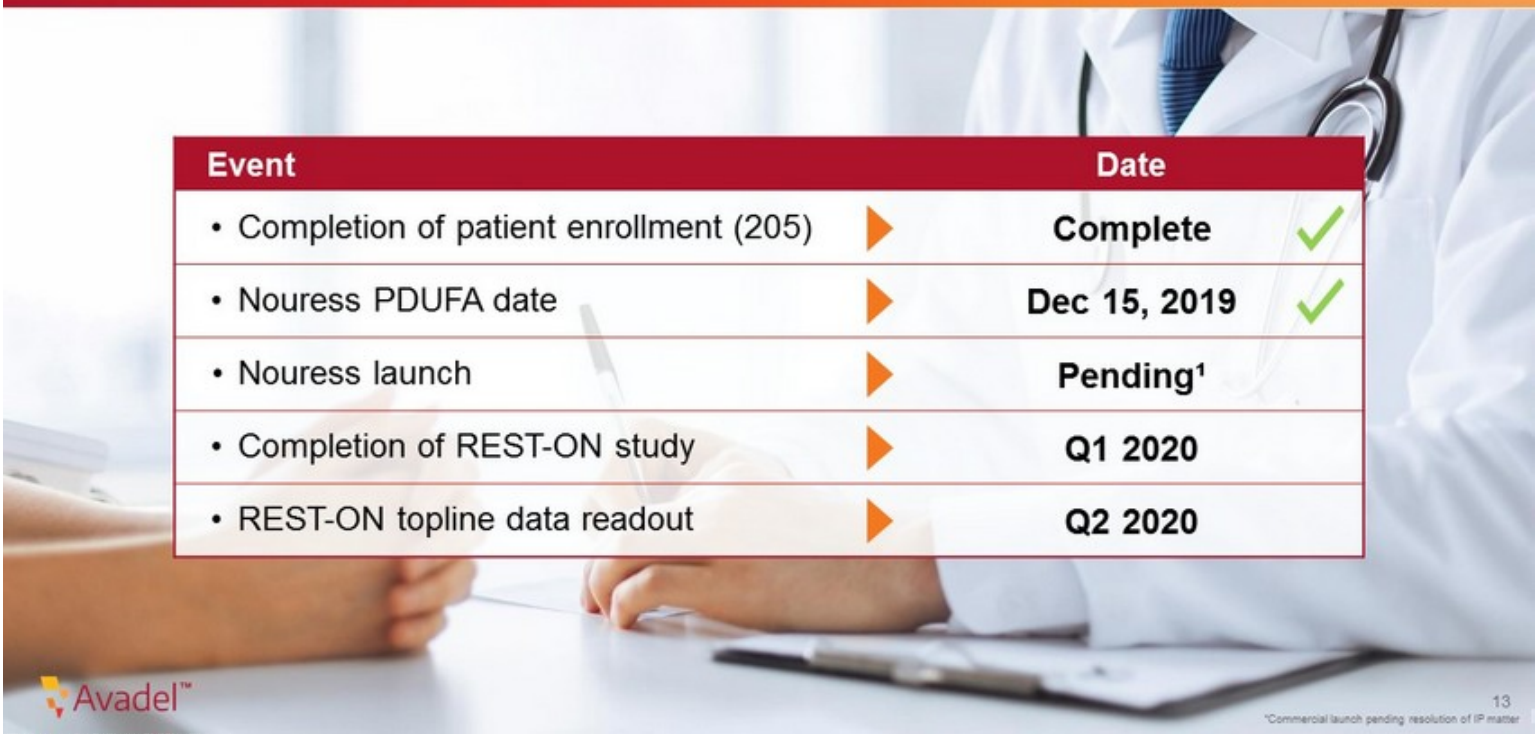
WHAT TO EXPECT:

Near-Term Key Milestones



Event	Date
• Completion of patient enrollment (205)	**Complete** ✓
• Nouress PDUFA date	**Dec 15, 2019** ✓
• Nouress launch	**Pending[1]**
• Completion of REST-ON study	**Q1 2020**
• REST-ON topline data readout	**Q2 2020**

Avadel™

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