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): March 12, 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*	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 2.02 Results of Operations and Financial Condition

On March 12, 2020, Avadel Pharmaceuticals plc announced its financial results for the quarter and full year ended December 31, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and 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 expressly set forth by specific reference in such filing.

Item 9.01. Exhibits

(d) Exhibits

99.1 Press release issued by Avadel Pharmaceuticals plc on March 12, 2020, furnished herewith.

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.

March 12, 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 Reports Fourth Quarter and Full Year 2019 Financial Results

- *Completed enrollment for the pivotal REST-ON Phase 3 study in Q4 2019; data readout expected in Q2 2020*
- *Raised $65 million in gross proceeds from private placement with leading biotech investment funds in February 2020*
- *Realized over $80 million in cost savings from restructuring and other cost reduction actions*
- *Reported revenue at the high end of the annual guidance at $59.2 million for full year 2019*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, March 12, 2020 -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy, today announced its financial results for the fourth quarter and year ended December 31, 2019, and provided a company update.

“Throughout the past year we have successfully executed on our focused development strategy for FT218 and completed a corporate restructuring program that resulted in $82 million of cost savings year-over-year. We believe these activities have changed the course of the company and created a significant opportunity to drive long-term shareholder value,” said Greg Divis, Chief Executive Officer of Avadel. “The opportunity presented by the development of FT218 is increasingly being recognized by the investment community, as we completed in February 2020 a $65 million private placement priced at-the-market with leading biotech investors, Vivo Capital, Avoro Capital Advisors, RTW Investments, Venrock Healthcare Capital Partners, Acuta Capital, and KVP Capital.”

“Looking ahead, we have several near-term clinical milestones, including the last patient last visit for the pivotal Phase 3 REST-ON trial for FT218 scheduled to occur in the next two weeks, which will be followed by topline data from the study in the second quarter of 2020. In addition, we’ve announced plans to enhance the FT218 program by including an open-label extension study for REST-ON, and a switch study to evaluate patients switching from twice-nightly sodium oxybate to once-nightly FT218, which we plan to start by the end of the first quarter of 2020. This is an exciting time in Avadel’s history, as we believe that FT218, if approved by the FDA, has the potential to take a significant share of the twice-nightly sodium oxybate market, which we estimated to be approximately $1.7 billion[1] in 2019,” concluded Mr. Divis.

Fourth quarter and recent company highlights

- Completed enrollment for the REST-ON Phase 3 pivotal trial of FT218 for excessive daytime sleepiness and cataplexy in patients with narcolepsy for a total Phase 3 trial size of 212 patients, which exceeded the trial’s enrollment target of 205 patients;
    - Last patient last visit for the REST-ON Phase 3 trial is expected to occur in the next two weeks, with topline data expected in the second quarter of 2020;
- Completed a $65 million private placement with leading biotech investment funds in February 2020;

- Strengthened the management team's financial and operational capabilities with the appointments of Thomas McHugh as Chief Financial Officer and Dr. Jason Vaughn to the newly created role of Senior Vice President of Technical Operations
- Appointed Dr. Mark McCamish, an internationally recognized expert in drug development and manufacturing, to the Board of Directors
- Achieved approximately $82 million of lower operating expenses for the full year 2019 compared to 2018 due to cost reductions and restructuring actions;
- Received U.S. FDA approval for Nouress™, a cysteine hydrochloride injection for treating neonate patients requiring total parental nutrition, and the USPTO issued an Orange Book-listed patent for Nouress; and
- Reported revenues of $11.0 million for the fourth quarter of 2019.

Overview of fourth quarter 2019 financial results

Revenues for the fourth quarter of 2019 were $11.0 million, compared to $20.9 million in the fourth quarter of 2018. The decline on a year-over-year basis was primarily attributed to lower overall sales volume across the Company's hospital products as a result of increased market competition.

R&D expenses were $7.8 million in the fourth quarter of 2019, compared to $6.1 million in the fourth quarter of 2018. The increase on a year-over-year basis was primarily attributed to the Company's investment in R&D spend in its FT218 development program.

SG&A expenses were $7.7 million in the fourth quarter of 2019, compared to $23.2 million in the fourth quarter of 2018. The year-over-year decline is primarily the result of realized cost reductions resulting from the exit of Noctiva™ and the Company's cost reduction and restructuring actions.

Net loss for the fourth quarter of 2019 was $2.7 million, or $0.07 per share, compared to a net loss of $63.9 million or $1.72 per share for the same period in 2018.

Cash, cash equivalents and marketable securities were $64.2 million as of December 31, 2019. In February 2020, the Company completed a private placement with leading biotech investment funds receiving net proceeds of approximately $61.1 million. The Company has convertible debt of $143.8 million due in February 2023.

Based on recent hospital products sales performance, increased competition from additional products launched in 2019, and recent market price actions, revenue for the first quarter of 2020 is expected to be at or above $10 million.

Conference Call:
A conference call to discuss these results has been scheduled for Tuesday, March 12, 2020 at 8:30 a.m. EST. To access the conference call, investors are invited to dial (877) 407-9716 (U.S. and Canada) or (201) 493-6779 (International). The conference ID number is 13699575. A live audio webcast can be accessed by visiting the investor relations section of the Company's website, www.avadel.com. A replay of the webcast will be archived on Avadel's website for 90 days following the event.

Footnote:
1. Annualized Xyrem revenues from the Jazz Pharmaceuticals Full Year and Fourth Quarter 2019 Financial Results press release, February 25, 2020

About FT218
FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. The company is currently conducting the REST-ON study, a 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. 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 an emerging biopharmaceutical company. The Company's primary focus is the development and potential FDA approval of FT218, which is in a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness and cataplexy. In addition, Avadel develops and markets a portfolio of sterile injectable drugs used in the hospital setting. 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 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 such as "will," "may," "believe," "expect," "look forward," "on track," "could," "guidance," "anticipate," "estimate," "project" 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. Actual results (including, without limitation, the timely completion and success of our Phase 3 REST-ON study and our ability to achieve FDA approval for FT218, our ability to achieve sales of our current marketed hospital products consistent with our current expectations, our ability to launch and commercialize Nouress, our ability to continue to service our Exchangeable Senior Notes due in 2023 and our ability to achieve continued cost savings from our restructuring plan) may differ materially from those set forth or implied in the forward-looking statements. These forward-looking statements involved certain risks and uncertainties that are subject to change based on various factors (many of which are beyond our control) including those set forth in our 2018 Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission and subsequent 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 the forward-looking statements contained in this Annual Report.

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AVADEL PHARMACEUTICALS PLC
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Product sales	$ 10,995	$ 19,320	$ 59,215	$ 101,423
License revenue	—	1,600	—	1,846
Total revenues	10,995	20,920	59,215	103,269
Operating expenses:				
Cost of products	2,414	4,292	12,125	17,516
Research and development expenses	7,757	6,086	32,917	39,329
Selling, general and administrative expenses	7,663	23,200	30,183	100,359
Intangible asset amortization	206	1,623	816	6,619
Changes in fair value of related party contingent consideration	(1,539)	(5,695)	845	(22,731)
Impairment of intangible asset	—	66,087	—	66,087
Restructuring costs	1,841	748	6,441	1,016
Total operating expenses	18,342	96,341	83,327	208,195
Operating loss	(7,347)	(75,421)	(24,112)	(104,926)
Investment and other income, net	(1,479)	(393)	1,069	452
Interest expense	(3,190)	(3,045)	(12,483)	(10,622)
Gain (loss) on deconsolidation of subsidiary	162	—	(2,678)	—
Other income (expense) - changes in fair value of related party payable	118	467	(378)	1,899
Loss before income taxes	(11,736)	(78,392)	(38,582)	(113,197)
Income tax benefit	(8,997)	(14,533)	(5,356)	(17,893)
Net loss	$ (2,739)	$ (63,859)	$ (33,226)	$ (95,304)
Net loss per share - basic	$ (0.07)	$ (1.72)	$ (0.89)	$ (2.55)
Net loss per share - diluted	(0.07)	(1.72)	(0.89)	(2.55)
Weighted average number of shares outstanding - basic	37,465	37,073	37,403	37,325
Weighted average number of shares outstanding - diluted	37,465	37,073	37,403	37,325

AVADEL PHARMACEUTICALS PLC
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	December 31, 2019 (unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,774	$ 9,325
Marketable securities	54,384	90,590
Accounts receivable	8,281	11,330
Inventories, net	3,570	4,770
Research and development tax credit receivable	2,107	283
Prepaid expenses and other current assets	4,264	8,553
Total current assets	82,380	124,851
Property and equipment, net	544	1,911
Operating lease right-of-use assets	3,612	—
Goodwill	18,491	18,491
Intangible assets, net	813	1,629
Research and development tax credit receivable	6,322	7,272
Other non-current assets	39,274	36,146
Total assets	$ 151,436	$ 190,300
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Current portion of long-term debt	$ —	$ 106
Current portion of long-term related party payable	5,554	9,439
Current portion of operating lease liability	645	—
Accounts payable	6,100	3,503
Accrued expenses	19,810	21,695
Other current liabilities	3,875	3,640
Total current liabilities	35,984	38,383
Long-term debt, less current portion	121,686	115,734
Long-term related party payable, less current portion	11,773	19,401
Long-term operating lease liability	2,319	—
Other non-current liabilities	8,873	14,002
Total liabilities	180,635	187,520
Shareholders' (deficit) equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; none issued or outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 42,927 issued and 37,520 outstanding at December 31, 2019, and 42,720 issued and 37,313 outstanding at December 31, 2018	429	427
Treasury shares, at cost, 5,407 shares held at December 31, 2019 and December 31, 2018, respectively	(49,998)	(49,998)
Additional paid-in capital	434,391	433,756
Accumulated deficit	(391,215)	(357,989)
Accumulated other comprehensive loss	(22,806)	(23,416)
Total shareholders' (deficit) equity	(29,199)	2,780
Total liabilities and shareholders' (deficit) equity	$ 151,436	$ 190,300

AVADEL PHARMACEUTICALS PLC
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Twelve Months Ended December 31,	
	2019	**2018**
Net loss	$ (33,226)	$ (95,304)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	2,486	7,430
Impairment of intangible asset	—	66,087
Amortization of premiums on marketable securities	41	2,823
Remeasurement of related party acquisition-related contingent consideration	845	(22,731)
Remeasurement of related party financing-related contingent consideration	378	(1,899)
Amortization of debt discount and debt issuance costs	5,995	4,830
Changes in deferred tax	(6,334)	(19,152)
Stock-based compensation expense	519	7,852
Loss on deconsolidation of subsidiary	1,750	—
Other adjustments	(295)	1,365
Net changes in assets and liabilities		
Accounts receivable	2,471	3,452
Inventories, net	1,155	711
Prepaid expenses and other current assets	(1,187)	3,577
Research and development tax credit receivable	(1,014)	(2,545)
Accounts payable & other current liabilities	4,641	(2,032)
Deferred revenue	(114)	(1,892)
Accrued expenses	357	(10,640)
Accrued income taxes	(30)	(341)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(10,988)	(19,468)
Royalty payments for related party payable in excess of original fair value	(1,748)	(2,838)
Other assets and liabilities	(4,027)	(2,001)
Net cash used in operating activities	(38,325)	(82,716)
Cash flows from investing activities:		
Purchases of property and equipment	(29)	(178)
Proceeds from disposal of property and equipment	154	—
Purchase of intangible assets	—	(20,000)
Proceeds from sales of marketable securities	63,246	359,507
Purchases of marketable securities	(24,648)	(376,310)
Net cash provided by (used in) investing activities	38,723	(36,981)
Cash flows from financing activities:		
Proceeds from debt issuance	—	143,750
Payments for debt issuance costs	—	(6,190)
Earn-out payments for related party contingent consideration	—	(645)
Exercise of warrants	—	2,911
Proceeds from issuance of ordinary shares	118	577
Share repurchases	—	(27,637)
Other financing activities, net	(145)	(107)
Net cash (used in) provided by financing activities	(27)	112,659
Effect of foreign currency exchange rate changes on cash and cash equivalents	78	(201)
Net change in cash and cash equivalents	449	(7,239)
Cash and cash equivalents at January 1	9,325	16,564
Cash and cash equivalents at December 31	$ 9,774	$ 9,325

AVADEL PHARMACEUTICALS PLC
UNAUDITED SUPPLEMENTAL INFORMATION
(In thousands, except per share data)
(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
Revenues by Product:	**2019**	**2018**	**2019**	**2018**
Bloxiverz	$ 1,087	$ 4,159	$ 7,479	$ 20,850
Vazculep	5,483	9,819	33,152	42,916
Akovaz	4,696	5,676	18,642	33,759
Other	(271)	(334)	(58)	3,898
Total product sales	10,995	19,320	59,215	101,423
License revenue	—	1,600	—	1,846
Total revenues	$ 10,995	$ 20,920	$ 59,215	$ 103,269