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): May 9, 2022

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 D02 T380** **Ireland**	**Not Applicable**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **+353 1 920 1000**

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 2.02 Results of Operations and Financial Condition

On May 9, 2022, Avadel Pharmaceuticals plc announced its financial results for the quarter ended March 31, 2022. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current 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, 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, as amended, 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 May 9, 2022, furnished herewith.
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 caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 9, 2022

AVADEL PHARMACEUTICALS PLC

By: /s/ Jerad G. Seurer
Name: Jerad G. Seurer
Title: General Counsel & Corporate Secretary

Exhibit 99.1

Avadel Pharmaceuticals Provides Corporate Update and Reports First Quarter 2022 Financial Results

- *FDA review of NDA for FT218 continues; launch readiness preparations on-track to support potential commercial launch*
- *Presented interim results from ongoing RESTORE open-label extension / switch study of FT218 highlighting overwhelming patient preference for the once-at-bedtime dosing regimen and characterizing the burden associated with the second dose currently required for twice-nightly oxybates*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, May 9, 2022 - Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, today provided a corporate update, and announced its financial results for the first quarter ended March 31, 2022.

"As our NDA for FT218 continues in late-stage review, we stand at a pivotal moment for the company and our stakeholders, ready and excited to bring this important medicine to people living with narcolepsy. As we have communicated in the past, based on our interactions with the FDA to date, we continue to believe in the full approvability of FT218, and are devoted to continuing to work with the FDA to complete the review of our NDA," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "I am pleased with the resilience of our team, and with our presentation of important interim results from the ongoing open-label RESTORE study of FT218, which continue to add to the totality of evidence demonstrating the great unmet need that exists for a once-at-bedtime oxybate therapy for people living with narcolepsy. The expertise of our team, strong body of clinical evidence supporting the overall value proposition of FT218, and our financial stability, well-position us as the review of our NDA continues and we move closer to potentially launching FT218."

First Quarter and Recent Company Highlights

- Avadel continues to have interactions with the U.S. Food and Drug Administration (FDA) as it relates to the review of the New Drug Application (NDA) for FT218, which Avadel believes is ready for final Agency action. The FDA has maintained they have no outstanding questions or information requests and do not currently need any additional data.
- Launch readiness activities progress on-track to support the potential commercialization of FT218, which, if approved, would be the first and only once-at-bedtime option for managing excessive daytime sleepiness (EDS) and cataplexy in narcolepsy.
- Presented interim data from the open-label RESTORE study at the 2022 American Academy of Neurology (AAN) Annual Meeting highlighting results from questionnaires on patient preference and experience with oxybates.
    - At an interim data cutoff date of September 7, 2021, 35 participants who switched from twice-nightly oxybates to once-at-bedtime FT218 completed patient preference questionnaires three months after switching, with responses indicating that 94.3% (33/35 participants) preferred the once-at-bedtime versus twice-nightly dosing regimen.

- As of the data cutoff, 60 participants who switched from twice-nightly oxybates to once-at-bedtime FT218 also completed a nocturnal adverse event questionnaire prior to switching to assess their experiences with the second nightly sodium oxybate dose. Results included:
    - 38 (63%) participants unintentionally missed their second twice-nightly oxybate dose within the preceding three months. Of these participants, 84% indicated that their narcolepsy symptoms were worse the next day.
    - 24 (40%) participants reported that they had taken their second dose more than four hours after the first dose. Of these participants, 42% (10/24) reported feeling somewhat, quite a bit or extremely groggy or unsteady the next morning.
    - For 73% (44/60) of participants, taking a second nighttime dose was characterized as somewhat, quite a bit or extremely inconvenient, with 54 (90%) reporting that they arose from bed after the second dose, three reporting associated falls and two reporting injuries. In addition, anxiety or concern related to taking the second dose and the need for someone else to wake them were reported by 20% and 23% of participants, respectively.

- Presented multiple posters at World Sleep 2022, including new data that contributes to the growing body of evidence to support the potential benefit of FT218 for people living with narcolepsy.
- Published positive secondary endpoint data from the REST-ON trial of FT218 in *CNS Drugs*.
    - At all doses evaluated (6g, 7.5g and 9g), FT218 demonstrated a statistically significant decrease in the number of transitions from stages N1, N2, N3, and rapid eye movement (REM) sleep to wake. Sleep quality and refreshing nature of sleep were significantly improved with all evaluated doses compared to placebo.
- Completed the exchange and an eight-month maturity extension on $117.4 million of the $143.8 million of senior unsecured convertible notes due 2023.
    - $117.4 million of convertible notes that were exchanged mature on October 2, 2023.
    - $26.4 million remaining from the 2023 convertible notes mature on February 1, 2023.

Overview of First Quarter Results

R&D expenses were $7.0 million in the quarter ended March 31, 2022, compared to $3.9 million for the same period in 2021. The period-over-period increase was primarily attributed to the purchase of active pharmaceutical ingredients used in the production and research and development of FT218 during the current period.

SG&A expenses were $21.6 million in the quarter ended March 31, 2022, compared to $11.0 million for the same period in 2021. The period-over-period increase is the result of a number of factors including commercial launch planning costs related to FT218, higher professional fees, and higher compensation costs associated with higher headcount, primarily in the areas of commercial and medical affairs.

Income tax benefit was $4.3 million in the quarter ended March 31, 2022, compared to income tax benefit of $2.6 million for the same period in 2021.

Net loss for the quarter ended March 31, 2022, was $26.4 million, or ($0.45) per diluted share, compared to net loss of $13.4 million, or ($0.23) per diluted share, for the same period in 2021.

Cash, cash equivalents and marketable securities were $123.5 million as of March 31, 2022. The Company has $26.4 million of convertible debt that matures in February 2023 and $117.4 million that matures in October 2023.

Conference Call

To access the conference call, investors are invited to dial (844) 388-0559 (U.S. and Canada) or (216) 562-0393 (International). The conference ID number is 8183841. 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.

About FT218

FT218 is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once-at-bedtime for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adults with narcolepsy.

In March 2020, Avadel completed the REST-ON study, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial, to assess the efficacy and safety of FT218 in patients with narcolepsy. Among the three co-primary endpoints, FT218 demonstrated statistically significant and clinically meaningful results in EDS, the clinician's overall assessment of the patient's functioning, and reduction in cataplexy attacks, for all three evaluated does when compared to placebo.

In January 2018, the U.S. Food and Drug Administration (FDA) granted FT218 Orphan Drug Designation for the treatment of narcolepsy based on the plausible hypothesis that FT218 may be safer than the twice-nightly formulation of sodium oxybate already approved by the FDA due to the ramifications associated with dosing regimen of that product. FT218 is currently under review by the FDA.

About Avadel Pharmaceuticals plc

Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a biopharmaceutical company focused on transforming medicines to transform lives. Our approach includes applying innovative solutions to the development of medications that address the challenges patients face with current treatment options. Our current lead drug candidate, FT218, is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once at bedtime for the treatment of EDS 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 our 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 FDA's review of the NDA for FT218, the commercial launch of FT218 (if approved), the market acceptance of FT218 (if approved), the potential therapeutic benefit of FT218, the continued advancement of the RESTORE study to generate long-term safety, tolerability, and efficacy data for FT218, and the expected maturity of the Company's notes. 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 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, 2021, which was filed with the Securities and Exchange Commission (SEC) on March 16, 2022, 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.

Investor Contact:
Courtney Turiano
Stern Investor Relations, Inc.
Courtney.Turiano@sternir.com
(212) 698-8687

Media Contact:
Nicole Raisch Goelz
Real Chemistry
ngoelz@realchemistry.com
(408) 568-4292

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

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development expenses	$ 6,991	$ 3,852
Selling, general and administrative expenses	21,635	11,012
Restructuring income	—	(53)
Total operating expense	28,626	14,811
Operating loss	(28,626)	(14,811)
Investment and other (expense) income, net	(137)	610
Interest expense	(2,017)	(1,929)
Gain from release of certain liabilities	33	78
Loss before income taxes	(30,747)	(16,052)
Income tax benefit	(4,323)	(2,607)
Net loss	$ (26,424)	$ (13,445)
Net loss per share - basic	$ (0.45)	$ (0.23)
Net loss per share - diluted	(0.45)	(0.23)
Weighted average number of shares outstanding - basic	58,824	58,443
Weighted average number of shares outstanding - diluted	58,824	58,443

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

	March 31, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,873	$ 50,708
Marketable securities	62,608	106,513
Research and development tax credit receivable	2,387	2,443
Prepaid expenses and other current assets	34,873	32,826
Total current assets	160,741	192,490
Property and equipment, net	268	285
Operating lease right-of-use assets	2,410	2,652
Goodwill	16,836	16,836
Research and development tax credit receivable	1,237	1,225
Other non-current assets	39,635	33,777
Total assets	$ 221,127	$ 247,265
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 26,184	$ —
Current portion of operating lease liability	917	900
Accounts payable	6,048	7,679
Accrued expenses	9,432	7,151
Other current liabilities	1,442	5,270
Total current liabilities	44,023	21,000
Long-term debt	116,525	142,397
Long-term operating lease liability	1,500	1,707
Other non-current liabilities	3,847	3,917
Total liabilities	165,895	169,021
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at March 31, 2022 and 488 issued and outstanding at December 31, 2021, respectively	5	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 59,032 issued and outstanding at March 31, 2022 and 58,620 issued and outstanding at December 31, 2021	590	586
Additional paid-in capital	553,859	549,349
Accumulated deficit	(474,180)	(447,756)
Accumulated other comprehensive loss	(25,042)	(23,940)
Total shareholders' equity	55,232	78,244
Total liabilities and shareholders' equity	$ 221,127	$ 247,265

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

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (26,424)	$ (13,445)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	259	218
Amortization of debt discount and debt issuance costs	312	312
Change in deferred taxes	(4,323)	(2,534)
Stock-based compensation expense	2,505	1,728
Gain from release of certain liabilities	(33)	(78)
Other adjustments	702	561
Net changes in assets and liabilities		
Prepaid expenses and other current assets	(2,058)	(3,736)
Research and development tax credit receivable	(19)	80
Accounts payable & other current liabilities	(5,613)	(3,789)
Accrued expenses	2,314	(2,112)
Other assets and liabilities	(1,667)	(618)
Net cash used in operating activities	(34,045)	(23,413)
Cash flows from investing activities:		
Purchases of property and equipment	—	(26)
Proceeds from the disposition of the hospital products	—	8,250
Proceeds from sales of marketable securities	44,341	40,736
Purchases of marketable securities	(2,090)	(37,769)
Net cash provided by investing activities	42,251	11,191
Cash flows from financing activities:		
Proceeds from stock option exercises and employee share purchase plan	2,009	149
Net cash provided by financing activities	2,009	149
Effect of foreign currency exchange rate changes on cash and cash equivalents	(50)	(477)
Net change in cash and cash equivalents	10,165	(12,550)
Cash and cash equivalents at January 1,	50,708	71,722
Cash and cash equivalents at March 31,	$ 60,873	$ 59,172