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): November 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, Ireland, D02 T380** (Address of principal executive offices)	**Not Applicable** (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 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))

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 2.02 Results of Operations and Financial Condition

On November 9, 2022, Avadel Pharmaceuticals plc announced its financial results for the quarter ended September 30, 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 November 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.

AVADEL PHARMACEUTICALS PLC

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

Date: November 9, 2022

Exhibit 99.1

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

- *LUMRYZ™ granted tentative approval on July 18, confirming its safety profile and clinical efficacy*

- *Final approval decision of LUMRYZ expected by June 2023; advancing strategy to potentially accelerate final approval*

- *Commercial launch planned for no later than Q3 2023; launch preparations underway*

- *Updated RESTORE data demonstrates 94% of switch patients prefer once-at-bedtime LUMRYZ dosing regimen; presented new real-world data describing demographic characteristics and comorbidities of patients with narcolepsy*

- *Management to host a conference call today at 8:00 a.m. ET*

DUBLIN, Ireland, November 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 third quarter ended September 30, 2022.

"With tentative approval in hand and approximately seven months or less from a final approval decision, we are in launch preparation mode to make LUMRYZ available to people living with narcolepsy as soon as possible following a final approval decision. In this regard, we continue to execute our strategy to potentially accelerate the timeline to a final approval decision and shorten the timeline to a subsequent launch of LUMRYZ," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "We are fully committed to serving this important patient community and providing a much-needed and highly anticipated treatment option in the $3 billion plus once-at-bedtime oxybate market."

Third Quarter and Recent Company Highlights

- LUMRYZ (previously known as FT218), Avadel's once-at-bedtime investigational formulation of extended-release sodium oxybate for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy, received tentative approval from the U.S. Food and Drug Administration (FDA) in July of 2022.
    - Tentative approval validates the safety profile and clinical efficacy of LUMRYZ and allows the company to continue launch preparations to reduce the time between a potential final approval and commercial availability.
    - Confirms that the latest date of a potential final approval decision is expected after expiry or other disposition of U.S. Patent No. 8,731,963 (the "REMS Patent"), which expires on June 17, 2023.

- Continuing launch preparation activities for LUMRYZ to expedite the time between a final approval decision and product availability.
    - Full commercial launch planned for no later than Q3 2023
    - Building commercial inventory in preparation for potential launch
    - Completing the build out of the LUMRYZ REMS, continuing the patient services center build, finalizing the specialty pharmacy network contracts and advancing payer GPO and PBM discussions

- Advancing the following action to potentially accelerate FDA's final approval decision for LUMRYZ:
    - Renewed Avadel's request for expedited consideration of our motion to delist the REMS Patent from FDA's Orange Book. Oral arguments on the motion are scheduled to occur in the U.S. District Court for the District of Delaware on November 15, 2022.
- Presented posters at the American College of Chest Physicians (CHEST) meeting in October featuring updated interim analyses from the ongoing RESTORE open-label extension/switch study of LUMRYZ, including:
    - Patient preference questionnaires showed that 93.6% of patients who switched from twice-nightly oxybates preferred the once-at-bedtime dosing regimen of LUMRYZ
    - Safety data affirming that LUMRYZ has been generally well tolerated with low discontinuation rates and no new safety signals
    - Data related to dosing and titration demonstrating that most RESTORE participants, whether switching from twice-nightly, immediate-release oxybate or not currently taking oxybate, have successfully had their LUMRYZ dose titrated to a tolerable therapeutic dose.
    - Nocturnal adverse event questionnaires, continuing to reaffirm challenges related to the middle-of-the-night dosing required by twice-nightly oxybates, including missing the middle-of-the-night dose, or taking it too late, both of which cause next day negative effects for patients
- Presented data at the American Neurological Association (ANA) annual meeting in October, including:
    - Encore posters reinforcing positive data from completed Phase 3 REST-ON trial, demonstrating improvements for disrupted nighttime sleep in both NT1 and NT2; and patient and clinician preference for once-nightly over twice-nightly dosing as demonstrated in a discrete choice experiment.
    - New real-world data describing demographic characteristics and comorbidities of patients with narcolepsy treated at the Mayo Clinic, confirming increased psychiatric and sleep co-morbidities, as well as pain-related disorders. Cardiovascular disease was not among the top 20 comorbidities of the matched cohort of more than 2,000 patients.
- Publication of two new peer-reviewed papers: a Plain Language Summary in *Future Neurology*, describing the results of the pivotal REST-ON trial data, to make accessible for patients and the relative bioavailability comparison of LUMRYZ to twice-nightly sodium oxybate in *Sleep Medicine*

Overview of Third Quarter Results

R&D expenses were $2.9 million in the quarter ended September 30, 2022, compared to $4.4 million for the same period in 2021. The period-over-period decrease was primarily attributed to lower costs related to the manufacture of LUMRYZ and lower compensation costs.

SG&A expenses were $14.1 million in the quarter ended September 30, 2022, compared to $21.3 million for the same period in 2021. The period-over-period decrease is the result of a number of factors including lower costs in marketing, compensation, medical affairs and consulting fees. These decreases were partially offset by higher legal costs.

Income tax expense was $0.1 million in the quarter ended September 30, 2022, compared to income tax benefit of $5.1 million for the same period in 2021.

Net loss for the quarter ended September 30, 2022 was $20.1 million, or ($0.33) per diluted share, compared to net loss of $22.0 million, or ($0.38) per diluted share, for the same period in 2021.

Cash, cash equivalents and marketable securities were $106.5 million as of September 30, 2022. Also, as of September 30, 2022, the Company had $26.4 million of convertible debt that matures in February 2023 and $117.4 million that matures in October 2023.

Conference Call

Avadel will host a conference all and live audio webcast to discuss third quarter 2022 financial results and provide a corporate update today at 8:00 a.m. ET. To access the live conference call, please register here. A live audio webcast of the call and accompanying slide presentation will also be available in 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 LUMRYZ

LUMRYZ 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 cataplexy or excessive daytime sleepiness (EDS) 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 LUMRYZ in patients with narcolepsy. Among the three co-primary endpoints, LUMRYZ 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 LUMRYZ Orphan Drug Designation for the treatment of narcolepsy based on the plausible hypothesis that LUMRYZ 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.

On July 18, 2022, the FDA tentatively approved the LUMRYZ NDA for the treatment of cataplexy or EDS in adults with narcolepsy. Final approval of LUMRYZ cannot be granted until the expiration or other disposition of U.S. Patent No. 8,731,963, which expires on June 17, 2023.

Avadel is currently evaluating the long-term safety and tolerability of LUMRYZ in the open-label RESTORE clinical study. For more information, visit: www.restore-narcolepsy-study.com.

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, LUMRYZ, 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 cataplexy or EDS 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 timing of FDA's final approval decision for LUMRYZ, ongoing efforts of the Company to accelerate the FDA's final approval decision; the Company's preparations to accelerate the timing between a potential final approval of LUMRYZ and commercial launch as well as the expected results thereof; the estimated once-at-bedtime oxybate market and anticipated market acceptance of LUMRYZ (if approved); the continued advancement of the RESTORE study to generate long-term safety, tolerability, and efficacy data for LUMRYZ; the Company's cash runway and anticipated uses of capital; and the expected maturity of the Company's convertible debt. 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development expenses	$ 2,933	$ 4,380	$ 14,465	$ 14,994
Selling, general and administrative expenses	14,096	21,283	57,535	47,469
Restructuring (income) expense	(69)	—	3,523	(53)
Total operating expense	16,960	25,663	75,523	62,410
Operating loss	(16,960)	(25,663)	(75,523)	(62,410)
Investment and other income, net	448	489	503	1,531
Interest expense	(3,564)	(1,929)	(9,087)	(5,788)
Gain from release of certain liabilities	—	—	33	166
Loss before income taxes	(20,076)	(27,103)	(84,074)	(66,501)
Income tax provision (benefit)	70	(5,101)	25,940	(11,473)
Net loss	$ (20,146)	$ (22,002)	$ (110,014)	$ (55,028)
Net loss per share – basic	$ (0.33)	$ (0.38)	$ (1.85)	$ (0.94)
Net loss per share – diluted	(0.33)	(0.38)	(1.85)	(0.94)
Weighted average number of shares outstanding - basic	60,201	58,585	59,359	58,506
Weighted average number of shares outstanding - diluted	60,201	58,585	59,359	58,506

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

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 60,715	$ 50,708
Marketable securities	45,760	106,513
Research and development tax credit receivable	2,077	2,443
Prepaid expenses and other current assets	4,670	32,826
Total current assets	113,222	192,490
Property and equipment, net	896	285
Operating lease right-of-use assets	1,947	2,652
Goodwill	16,836	16,836
Research and development tax credit receivable	1,137	1,225
Other non-current assets	11,720	33,777
Total assets	$ 145,758	$ 247,265
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 26,299	$ —
Current portion of operating lease liability	1,011	900
Accounts payable	2,479	7,679
Accrued expenses	7,965	7,151
Other current liabilities	3,757	5,270
Total current liabilities	41,511	21,000
Long-term debt	109,934	142,397
Long-term operating lease liability	1,026	1,707
Other non-current liabilities	5,727	3,917
Total liabilities	158,198	169,021
Shareholders' (deficit) equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at September 30, 2022 and 488 issued and outstanding at December 31, 2021	5	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 60,885 issued and outstanding at September 30, 2022 and 58,620 issued and outstanding at December 31, 2021	608	586
Additional paid-in capital	572,626	549,349
Accumulated deficit	(557,770)	(447,756)
Accumulated other comprehensive loss	(27,909)	(23,940)
Total shareholders' (deficit) equity	(12,440)	78,244
Total liabilities and shareholders' (deficit) equity	$ 145,758	$ 247,265

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (110,014)	$ (55,028)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	907	614
Amortization of debt discount and debt issuance costs	4,147	937
Change in deferred taxes	25,916	(11,322)
Share-based compensation expense	5,086	6,088
Gain from release of certain liabilities	(33)	(166)
Other adjustments	1,539	1,056
Net changes in assets and liabilities		
Prepaid expenses and other current assets	27,948	(54)
Research and development tax credit receivable	27	3,079
Accounts payable & other current liabilities	(11,629)	(201)
Accrued expenses	4,277	2,421
Other assets and liabilities	(3,109)	(2,228)
Net cash used in operating activities	(54,938)	(54,804)
Cash flows from investing activities:		
Purchases of property and equipment	(716)	(26)
Proceeds from the disposition of the hospital products	—	16,500
Proceeds from sales of marketable securities	59,873	83,726
Purchases of marketable securities	(2,334)	(58,591)
Net cash provided by investing activities	56,823	41,609
Cash flows from financing activities:		
Payments for debt issuance costs	(4,803)	—
Proceeds from issuance of shares off the at-the-market offering program	10,532	—
Proceeds from stock option exercises and employee share purchase plan	2,192	263
Net cash provided by financing activities	7,921	263
Effect of foreign currency exchange rate changes on cash and cash equivalents	201	(621)
Net change in cash and cash equivalents	10,007	(13,553)
Cash and cash equivalents at January 1,	50,708	71,722
Cash and cash equivalents at September 30,	$ 60,715	$ 58,169