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 8, 2023

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 1 901-5201**

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 8, 2023, Avadel Pharmaceuticals plc announced its financial results for the quarter ended September 30, 2023. 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 8, 2023, 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 8, 2023

Exhibit 99.1

Avadel Pharmaceuticals Provides Corporate Update and Reports Third Quarter 2023 Financial Results

-- $7.0 million in third quarter LUMRYZ™ net revenue from U.S. commercial launch --

-- Generated robust demand for LUMRYZ with greater than 1,000 patients enrolled in RYZUP™ and more than 400 patients initiating therapy as of September 30 --

-- LUMRYZ to be added to preferred position for CVS commercial formularies effective January 1, 2024 --

-- Submitted sNDA for LUMRYZ in pediatric narcolepsy population on November 7th --

-- Management to host a conference call today at 8:30 a.m. ET --

DUBLIN, Ireland, November 8, 2023 - 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, 2023.

"We are very pleased with the significant progress we made during the first full quarter of the launch of LUMRYZ, underscored by the early patient demand and the overwhelmingly positive feedback received from across the narcolepsy community. Our team continues to execute on our launch plan, actively engaging with all stakeholders, driving patient enrollments, converting RYZUP enrollments to patients on therapy, and securing key coverage policy decisions with payers, such as the recent CVS decision to move LUMRYZ to preferred status effective January 1, 2024," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "We are building on the momentum we saw during the quarter, as we continue our mission to transform the lives of those living with narcolepsy. This includes the recently completed submission of our supplemental NDA for LUMRYZ in the pediatric population, which, if approved, will allow us to bring LUMRYZ to eligible children living with narcolepsy and expand the reach of LUMRYZ."

Third Quarter and Recent Company Highlights

LUMRYZ Commercial Updates:

- Launch progress through September 30, 2023:
  - Generated $7 million of LUMRYZ net revenue in the first full quarter of launch.
  - Greater than 1,000 patients enrolled in Avadel's RYZUP patient support services:
    - More than 400 patients initiated therapy with LUMRYZ during Q3.
    - Approximately 600 patients remained in the RYZUP process, going through the benefits investigation or pending their first shipment.
    - RYZUP enrollments and patients currently being treated with LUMRYZ includes majority switch patients from first generation oxybates, followed by patients who previously tried and discontinued a first generation oxybate, and patients who are new to oxybates.
  - Secured LUMRYZ coverage policies for over 100 million commercial lives representing approximately 60% of the total commercially insured lives across the country.
    - Announced that LUMRYZ is moving to preferred status within the CVS commercial formularies effective January 1, 2024.

- Nearly 1,400 health care providers have completed the LUMRYZ REMS certification process, including both experienced oxybate prescribers as well as providers who have never previously prescribed an oxybate.

Pipeline Updates:

- Submitted Supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) for LUMRYZ for treatment of cataplexy or EDS in the pediatric narcolepsy population on November 7, 2023. An approval decision is expected in the second half of 2024.
  - LUMRYZ has the potential to significantly alleviate the burden placed on families and caregivers of children with narcolepsy who are responsible for waking up in the middle of the night to administer a second dose.
  - Pediatric patients currently represent approximately 5% of all oxybate treated narcolepsy patients.

Clinical Updates:

- In October, announced new and encore data supporting the clinical profile for LUMRYZ and patient preference for a once-nightly oxybate in 15 poster presentations and two oral presentations, at World Sleep 2023.
  - New post-hoc analyses demonstrated the robust clinical efficacy of LUMRYZ and provided further insight into the improvements on measures of excessive daytime sleepiness (EDS) and cataplexy compared with placebo in different demographic and clinical subgroups.
  - Post-hoc analyses reinforced data from the completed pivotal Phase 3 REST-ON trial, demonstrating that treatment with LUMRYZ resulted in statistically significant and clinically meaningful improvement in EDS.
  - RESTORE study poster demonstrated long-term tolerability and clinically significant improvement in symptoms.

Overview of Third Quarter Results

Recognized $7.0 million in net product revenue for the quarter ended September 30, 2023. Net product revenue consists of LUMRYZ product sales, which was launched in the U.S. on June 5, 2023.

R&D expenses were $2.8 million in the quarter ended September 30, 2023, compared to $2.9 million for the same period in 2022.

SG&A expenses were $39.2 million in the quarter ended September 30, 2023, compared to $14.1 million for the same period in 2022. This increase was driven by higher compensation costs due to increased headcount, higher selling and marketing and launch-related activities and higher legal fees.

Net loss for the quarter ended September 30, 2023, was $36.3 million, or ($0.41) per diluted share, compared to net loss of $20.1 million, or ($0.33) per diluted share, for the same period in 2022.

Cash, cash equivalents and marketable securities were $153.2 million as of September 30, 2023. The Company drew the first $30.0 million tranche from a $75.0 million royalty financing arrangement on August 1, 2023. Subsequent to September 30, 2023, the Company paid off the remaining $21.2 million of convertible notes.

About LUMRYZ™ (sodium oxybate) for extended-release oral suspension

LUMRYZ, is an extended-release sodium oxybate medication approved by the FDA on May 1, 2023, as the first and only once-at-bedtime treatment for cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

The FDA approval of LUMRYZ was supported by results from REST-ON, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial in adults with narcolepsy. LUMRYZ demonstrated statistically significant and clinically meaningful improvements in the three co-primary endpoints: EDS, clinicians' overall assessment of patients' functioning (CGI-I) and cataplexy attacks, for all three evaluated doses when compared to placebo.

With its approval, the FDA also granted seven years of Orphan Drug Exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy due to a finding of clinical superiority of LUMRYZ relative to currently available oxybate treatments. In particular, the FDA found that LUMRYZ makes a major contribution to patient care over currently available, twice-nightly oxybate products by providing a once-nightly dosing regimen that avoids nocturnal arousal to take a second dose.

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. Avadel's commercial product, LUMRYZ, was approved by the U.S. Food & Drug Administration (FDA) as the first and only once-at-bedtime oxybate for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. For more information, please visit www.avadel.com.

IMPORTANT SAFETY INFORMATION

WARNING: Taking LUMRYZ™ (sodium oxybate) with other central nervous system (CNS) depressants, such as medicines used to make you fall asleep, including opioid analgesics, benzodiazepines, sedating antidepressants, antipsychotics, sedating anti-epileptic medicines, general anesthetics, muscle relaxants, alcohol or street drugs, may cause serious medical problems, including trouble breathing (respiratory depression), low blood pressure (hypotension), changes in alertness (drowsiness), fainting (syncope) and death.

The active ingredient of LUMRYZ (sodium oxybate) is a form of gamma hydroxybutyrate (GHB), a controlled substance. Abuse or misuse of illegal GHB alone or with other CNS depressants (drugs that cause changes in alertness or consciousness) have caused serious side effects. These effects include seizures, trouble breathing (respiratory depression), changes in alertness (drowsiness), coma and death. Call your doctor right away if you have any of these serious side effects.

Because of these risks, LUMRYZ is available only by prescription and filled through certified pharmacies in the LUMRYZ REMS. You must be enrolled in the LUMRYZ REMS to receive LUMRYZ. Further information is available at www.LUMRYZREMS.com or by calling 1-877-453-1029.

INDICATIONS

LUMRYZ (sodium oxybate) for extended-release oral suspension is a prescription medicine used to treat the following symptoms in adults with narcolepsy:

- sudden onset of weak or paralyzed muscles (cataplexy)
- excessive daytime sleepiness (EDS)

It is not known if LUMRYZ is safe and effective in people less than 18 years of age.

Do not take LUMRYZ if you take other sleep medicines or sedatives (medicines that cause sleepiness), drink alcohol or have a rare problem called succinic semialdehyde dehydrogenase deficiency.

Keep LUMRYZ in a safe place to prevent abuse and misuse. Selling or giving away LUMRYZ may harm others and is against the law. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

Anyone who takes LUMRYZ should not do anything that requires them to be fully awake or is dangerous, including driving a car, using heavy machinery or flying an airplane, for at least six (6) hours after taking LUMRYZ. Those activities should not be done until you know how LUMRYZ affects you.

Falling asleep quickly, including while standing or while getting up from the bed, has led to falls with injuries that have required some people to be hospitalized.

LUMRYZ can cause serious side effects, including the following:

- **Breathing problems, including** slower breathing, trouble breathing and/or short periods of not breathing while sleeping (e.g., sleep apnea). People who already have breathing or lung problems have a higher chance of having breathing problems when they take LUMRYZ.
- **Mental health problems**, including confusion, seeing or hearing things that are not real (hallucinations), unusual or disturbing thoughts (abnormal thinking), feeling anxious or upset, depression, thoughts of killing yourself or trying to kill yourself, increased tiredness, feelings of guilt or worthlessness and difficulty concentrating. Tell your doctor if you have or had depression or have tried to harm yourself. **Call your doctor right away if you have symptoms of mental health problems or a change in weight or appetite.**
- **Sleepwalking.** Sleepwalking can cause injuries. Call your doctor if you start sleepwalking.

Tell your doctor if you are on a salt-restricted diet or if you have high blood pressure, heart failure or kidney problems. LUMRYZ contains a lot of sodium (salt) and may not be right for you.

The most common side effects of LUMRYZ in adults include nausea, dizziness, bedwetting, headache and vomiting. Your side effects may increase when you take higher doses of LUMRYZ. LUMRYZ can cause physical dependence and craving for the medicine when it is not taken as directed. These are not all the possible side effects of LUMRYZ.

For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full Prescribing Information, including BOXED Warning.

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 potential therapeutic benefit of LUMRYZ; the success of the commercialization of LUMRYZ; the anticipated market availability, demand and sales opportunity of LUMRYZ; the potential expansion of LUMRYZ into the pediatric narcolepsy population including acceptability for filing and FDA’s review of the sNDA for such population; the potential benefits of payor coverage, including CVS preferred status; the Company’s anticipated financial condition, expenses, uses of capital and other future financial results. 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, 2022, which was filed with the Securities and Exchange Commission (SEC) on March 29, 2023, 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,	
	2023	2022	2023	2022
Net product revenue	$ 7,014	$ —	$ 8,510	$ —
Cost of products sold	117	—	153	—
Gross profit	6,897	—	8,357	—
Operating expenses:				
Research and development expenses	2,849	2,933	10,902	14,465
Selling, general and administrative expenses	39,158	14,096	110,404	57,535
Restructuring (income) expense	—	(69)	—	3,523
Total operating expense	42,007	16,960	121,306	75,523
Operating loss	(35,110)	(16,960)	(112,949)	(75,523)
Investment and other income, net	903	448	1,719	536
Interest expense	(1,978)	(3,564)	(7,532)	(9,087)
Loss on extinguishment of debt	—	—	(13,129)	—
Loss before income taxes	(36,185)	(20,076)	(131,891)	(84,074)
Income tax provision (benefit)	89	70	(401)	25,940
Net loss	$ (36,274)	$ (20,146)	$ (131,490)	$ (110,014)
Net loss per share – basic	$ (0.41)	$ (0.33)	$ (1.71)	$ (1.85)
Net loss per share – diluted	(0.41)	(0.33)	(1.71)	(1.85)
Weighted average number of shares outstanding - basic	89,380	60,201	76,931	59,359
Weighted average number of shares outstanding - diluted	89,380	60,201	76,931	59,359

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

	September 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,811	$ 73,981
Marketable securities	101,368	22,518
Accounts receivable, net	6,239	—
Inventories	5,286	—
Research and development tax credit receivable	1,199	2,248
Prepaid expenses and other current assets	6,352	2,096
Total current assets	172,255	100,843
Property and equipment, net	648	839
Operating lease right-of-use assets	2,804	1,713
Goodwill	16,836	16,836
Research and development tax credit receivable	409	1,232
Other non-current assets	10,148	11,322
Total assets	$ 203,100	$ 132,785
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term debt	$ 21,187	$ 37,668
Current portion of operating lease liability	916	960
Accounts payable	13,263	7,890
Accrued expenses	17,957	7,334
Other current liabilities	731	1,941
Total current liabilities	54,054	55,793
Long-term debt	—	91,614
Long-term operating lease liability	1,928	780
Royalty financing obligation	31,151	—
Other non-current liabilities	5,818	5,743
Total liabilities	92,951	153,930
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 5,194 issued and outstanding at September 30, 2023 and 488 issued and outstanding at December 31, 2022	52	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 89,398 issued and outstanding at September 30, 2023 and 62,878 issued and outstanding at December 31, 2022	893	628
Additional paid-in capital	851,865	589,783
Accumulated deficit	(716,710)	(585,220)
Accumulated other comprehensive loss	(25,951)	(26,341)
Total shareholders' equity (deficit)	110,149	(21,145)
Total liabilities and shareholders' equity (deficit)	$ 203,100	$ 132,785

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (131,490)	$ (110,014)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,784	907
Amortization of debt discount and debt issuance costs	2,796	4,147
Changes in deferred taxes	—	25,916
Share-based compensation expense	12,293	5,086
Loss on extinguishment of debt	13,129	—
Other adjustments	(349)	1,506
Net changes in assets and liabilities		
Accounts receivable	(6,239)	—
Inventories	(5,286)	—
Prepaid expenses and other current assets	(4,277)	27,948
Research and development tax credit receivable	1,918	27
Accounts payable & other current liabilities	3,837	(11,629)
Accrued expenses	10,621	4,277
Other assets and liabilities	781	(3,109)
Net cash used in operating activities	(100,482)	(54,938)
Cash flows from investing activities:		
Purchases of property and equipment	—	(716)
Proceeds from sales of marketable securities	125,498	59,873
Purchases of marketable securities	(203,519)	(2,334)
Net cash (used in) provided by investing activities	(78,021)	56,823
Cash flows from financing activities:		
Proceeds from April 2023 public offering, net of issuance costs	134,149	—
Payments for February 2023 Notes	(17,500)	—
Payments for debt issuance costs	(4,357)	(4,803)
Proceeds from royalty purchase agreement	30,000	—
Proceeds from issuance of shares off the at-the-market offering program	11,913	10,532
Proceeds from stock option exercises and employee share purchase plan	2,241	2,192
Net cash provided by financing activities	156,446	7,921
Effect of foreign currency exchange rate changes on cash and cash equivalents	(113)	201
Net change in cash and cash equivalents	(22,170)	10,007
Cash and cash equivalents at January 1,	73,981	50,708
Cash and cash equivalents at September 30,	$ 51,811	$ 60,715