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): August 8, 2024

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
Ordinary Shares, nominal value $0.01 per share	AVDL	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 August 8, 2024, Avadel Pharmaceuticals plc announced its financial results for the quarter ended June 30, 2024. 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 August 8, 2024, 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: August 8, 2024

Exhibit 99.1

Avadel Pharmaceuticals Provides Corporate Update and Reports Second Quarter 2024 Financial Results

-- Generated $41.5 million in net revenue from sales of LUMRYZ™ --

-- More than 1,900 patients on LUMRYZ as of June 30th --

-- First patient dosed in Phase 3 trial evaluating LUMRYZ in idiopathic hypersomnia --

-- FDA target action date of September 7, 2024 for sNDA for LUMRYZ in pediatric narcolepsy --

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

DUBLIN, Ireland, August 8, 2024 - 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 quarter ended June 30, 2024.

"The continued strong quarter over quarter growth in patient demand is a testimonial to the reception LUMRYZ has received from the narcolepsy community since its launch last year. Alongside our focus on maximizing the launch of LUMRYZ for the treatment of narcolepsy, creating further sustainable value through indication expansion is a priority," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "We are driven by our commitment to provide patients suffering from sleep disorders with transformative treatment options, and we are well positioned to continue executing on our mission to transform the sleep disorder treatment landscape. Last week, we dosed the first patient in the Phase 3 trial in idiopathic hypersomnia, and a potential FDA approval for the pediatric narcolepsy population is expected in September. We look forward to potentially extending LUMRYZ as a treatment option to both of these patient populations."

Second Quarter and Recent Company Highlights

LUMRYZ Commercial Updates:

- Generated $41.5 million of net product revenue from sales of LUMRYZ in the second quarter of 2024.
- As of June 30, there were more than 1,900 patients on LUMRYZ compared to more than 1,400 as of March 31 and more than 900 as of December 31, 2023.
    - From launch through June 30, approximately 3,800 patients had enrolled in Avadel's RYZUP™ patient support services and greater than 2,400 patients had initiated therapy.

Pipeline and Corporate Updates:

- Dosed the first patient in REVITALYZ™, a Phase 3 double-blind, placebo-controlled, randomized withdrawal, multicenter study designed to evaluate the efficacy and safety of LUMRYZ in idiopathic hypersomnia (IH). Enrollment is open to patients who are currently being treated with a twice-nightly oxybate and those not taking oxybates. The study is expected to enroll approximately 150 adults who are diagnosed with IH and includes an open label extension portion.
- Supplemental New Drug Application (sNDA) for LUMRYZ for treatment of cataplexy or EDS in the pediatric narcolepsy population is under review with the U.S. Food and Drug Administration (FDA), with an assigned target action date of September 7, 2024.
    - With potential approval in the pediatric population, LUMRYZ could 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.
- On July 1, joined the Russell 3000® Index.

Overview of Second Quarter Financial Results

Recognized $41.5 million in net product revenue for the second quarter 2024 compared to $1.5 million in the same period in 2023. Net product revenue consists of LUMRYZ product sales, which was launched in the U.S. on June 5, 2023.

Gross profit for the second quarter 2024 was $38.7 million compared to $1.5 million in the same period in 2023.

Selling, general and administrative (SG&A) expenses were $47.4 million in the quarter ended June 30, 2024, compared to $46.8 million for the same period in 2023. SG&A expenses in the current period include $5.0 million of non-recurring costs related to the mandatory exchange of the Company's American Depositary Shares (ADSs) for the underlying ordinary shares and the termination of its American Depository Receipt program (ADR Program).

Research and development (R&D) expenses were $4.1 million in the quarter ended June 30, 2024, compared to $4.2 million for the same period in 2023. R&D expenses in the current period include clinical study costs related to the Phase 3 pivotal trial in IH.

Net loss for the quarter ended June 30, 2024, was $13.8 million, or ($0.14) per diluted share, compared to net loss of $64.4 million, or ($0.83) per diluted share, for the same period in 2023.

Cash, cash equivalents and marketable securities were $71.4 million as of June 30, 2024. Cash used during the quarter ended June 30, 2024, included $5.0 million of non-recurring costs related to the mandatory exchange of the Company's ADSs for the underlying ordinary shares and the termination of its ADR Program.

Conference Call Details:

A live audio webcast of the call 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. Participants may register for the conference call here and are advised to do so at least 10 minutes prior to joining the call.

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 demand and sales opportunity of LUMRYZ; the FDA’s review of the sNDA for LUMRYZ in the pediatric narcolepsy population and timing related thereto; the Company’s idiopathic hypersomnia clinical study for LUMRYZ, including enrollment and timing related thereto; 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 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 most recent Annual Report on Form 10-K and subsequent filings with the Securities and Exchange Commission.

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 June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Net product revenue	$ 41,504	$ 1,496	$ 68,682	$ 1,496
Cost of products sold	2,788	36	4,310	36
Gross profit	38,716	1,460	64,372	1,460
Operating expenses:				
Research and development expenses	4,051	4,223	7,119	8,053
Selling, general and administrative expenses	47,406	46,778	96,029	71,246
Total operating expense	51,457	51,001	103,148	79,299
Operating loss	(12,741)	(49,541)	(38,776)	(77,839)
Investment and other income, net	1,126	623	2,504	816
Interest expense	(2,716)	(2,295)	(5,308)	(5,554)
Loss on extinguishment of debt	—	(13,129)	—	(13,129)
Loss before income taxes	(14,331)	(64,342)	(41,580)	(95,706)
Income tax (benefit) provision	(509)	90	(416)	(490)
Net loss	$ (13,822)	$ (64,432)	$ (41,164)	$ (95,216)
Net loss per share - basic	$ (0.14)	$ (0.83)	$ (0.44)	$ (1.35)
Net loss per share - diluted	$ (0.14)	$ (0.83)	$ (0.44)	$ (1.35)
Weighted average number of shares outstanding - basic	96,151	77,246	93,922	70,603
Weighted average number of shares outstanding - diluted	96,151	77,246	93,922	70,603

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

	June 30, 2024 (Unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,847	$ 31,167
Marketable securities	42,535	73,944
Accounts receivable, net	33,377	12,103
Inventories	13,313	10,380
Research and development tax credit receivable	927	1,322
Prepaid expenses and other current assets	6,781	5,286
Total current assets	125,780	134,202
Property and equipment, net	484	585
Operating lease right-of-use assets	2,154	2,591
Goodwill	16,836	16,836
Research and development tax credit receivable	252	332
Other non-current assets	12,015	10,152
Total assets	$ 157,521	$ 164,698
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of operating lease liability	$ 866	$ 934
Accounts payable	9,794	11,433
Accrued expenses	33,711	24,227
Other current liabilities	242	261
Total current liabilities	44,613	36,855
Long-term operating lease liability	1,308	1,690
Royalty financing obligation	35,493	32,760
Other non-current liabilities	5,819	5,654
Total liabilities	87,233	76,959
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; zero issued and outstanding at June 30, 2024 and 5,194 issued and outstanding at December 31, 2023	—	52
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 96,204 issued and outstanding at June 30, 2024 and 89,825 issued and outstanding at December 31, 2023	961	898
Additional paid-in capital	880,202	855,452
Accumulated deficit	(786,660)	(745,496)
Accumulated other comprehensive loss	(24,215)	(23,167)
Total shareholders' equity	70,288	87,739
Total liabilities and shareholders' equity	$ 157,521	$ 164,698

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

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (41,164)	$ (95,216)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	978	1,189
Amortization of debt discount and debt issuance costs	—	2,460
Share-based compensation expense	10,851	9,166
Loss on extinguishment of debt	—	13,129
Other adjustments	(1,208)	42
Net changes in assets and liabilities		
Accounts receivable	(21,274)	(1,775)
Inventories	(2,264)	(1,439)
Prepaid expenses and other current assets	(1,557)	(4,400)
Research and development tax credit receivable	451	2,127
Accounts payable & other current liabilities	(1,638)	2,470
Accrued expenses	9,484	10,246
Other assets and liabilities	(549)	(255)
Net cash used in operating activities	(47,890)	(62,256)
Cash flows from investing activities:		
Proceeds from sales of marketable securities	207,835	25,618
Purchases of marketable securities	(175,898)	(113,460)
Net cash provided by (used in) investing activities	31,937	(87,842)
Cash flows from financing activities:		
Proceeds from April 2023 public offering, net of issuance costs	—	134,151
Payments for February 2023 Notes	—	(17,500)
Payments for debt issuance costs	—	(4,357)
Proceeds from issuance of shares off the at-the-market offering program	9,250	11,913
Proceeds from stock option exercises and employee share purchase plan	4,663	1,779
Net cash provided by financing activities	13,913	125,986
Effect of foreign currency exchange rate changes on cash and cash equivalents	(280)	116
Net change in cash and cash equivalents	(2,320)	(23,996)
Cash and cash equivalents at January 1,	31,167	73,981
Cash and cash equivalents at June 30,	$ 28,847	$ 49,985