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): January 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
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 Operation and Financial Condition.

Avadel Pharmaceuticals plc (the "Company") expects to report that its net product revenue received from sales of LUMRYZ in the United States equaled approximately $19 million and $28 million for the quarter and year ended December 31, 2023, respectively. Although the Company has not finalized its financial results for the twelve months ended December 31, 2023, the Company currently anticipates that its cash, cash equivalents and marketable securities were approximately $105 million as of December 31, 2023. This information is unaudited and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2023 and its results of operations for the twelve months ended December 31, 2023. The audit of the Company's financial statements for the year ended December 31, 2023, is ongoing and could result in changes to the information set forth above.

Item 8.01 Other Events

On January 8, 2024, the Company issued a press release providing an update on the launch of LUMRYZ and other business highlights.

The full text of the press release regarding the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Exhibits

(d) Exhibits

99.1	Press release issued by Avadel Pharmaceuticals plc on January 8, 2024.
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: January 8, 2024

Exhibit 99.1

Avadel Pharmaceuticals Announces Strong LUMRYZ Launch Performance and Provides Preliminary Fourth Quarter and Full Year 2023 Financial Highlights

-- Approximately $19 million and $28 million of net revenue from sales of LUMRYZ™ estimated for the fourth quarter and full year 2023, respectively --

-- Generated continued robust demand for LUMRYZ with greater than 1,900 patients enrolled in RYZUP™ and more than 1,000 patients initiating therapy through December 31 --

-- Signed Emisar (Optum Rx GPO) contract, all 3 PBM owned GPO contracts now finalized for 2024 --

-- Supplemental New Drug Application (sNDA) for LUMRYZ in the pediatric narcolepsy population accepted by FDA; approval decision expected in September 2024 --

DUBLIN, Ireland, January 8, 2024 – Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, today provided a business update including preliminary estimates of fourth quarter and full year net revenue and cash, cash equivalents and marketable securities.

"2023 was transformational for Avadel defined by significant growth and continued execution of milestones critical to Avadel's success, beginning with the FDA approval and receipt of Orphan Drug Exclusivity for LUMRYZ. The LUMRYZ launch has thus far been marked by robust demand and overwhelmingly positive feedback from the narcolepsy community, health care providers and payers. Our team is proud of the momentum built this year, and looking toward 2024, we are excited to see LUMRYZ's continued impact across the narcolepsy community," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals.

Launch Progress Through December 31, 2023:

- Greater than 1,900 patients enrolled in Avadel's RYZUP patient support services:
  - More than 1,000 patients initiated therapy.
  - The majority of RYZUP enrollments and patients currently being treated with LUMRYZ are patients who switched from first generation oxybates, with the balance made up of patients who previously tried and discontinued a first generation oxybate and patients who are new to oxybate treatment.
- Signed contract with Emisar (Optum Rx GPO)
  - Contracts now in place with all 3 PBM owned GPOs (Ascent/ESI, Zinc/CVS and Emisar/Optum).
  - LUMRYZ moved to preferred status within the CVS commercial formularies and Optum Select as of January 1, 2024.
- Nearly 1,800 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.

Financial Highlights:

- Approximately $19 million and $28 million of net product revenue, respectively, estimated for the quarter and year ended December 31, 2023. Net product revenue consists of LUMRYZ product sales, which was launched in the U.S. on June 5, 2023.
- Approximately $105 million of cash, cash equivalents and marketable securities at December 31, 2023.

Results reported above are preliminary, unaudited and are subject to change, perhaps materially, upon the audit of the Company's financial statements for the year ended December 31, 2023. The Company expects to announce its full results for the twelve months ended December 31, 2023 on or before February 29, 2024.

Pipeline Update:

- Supplemental New Drug Application (sNDA) for LUMRYZ in the pediatric narcolepsy population accepted by FDA:
  - 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 of twice-nightly oxybate.
  - Pediatric patients currently represent approximately 5% of all oxybate treated narcolepsy patients.

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 benefits of payor coverage, including preferred status; and the Company's expectations regarding its financial results for the fourth quarter and full year 2023. 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 final audit adjustments and other developments that may arise that would cause the Company's expectations with respect to the fourth quarter and full year 2023 revenue estimates and cash as of December 31, 2023 to differ, perhaps materially, from the financial results that will be reflected in the Company's audited consolidated financial statements for the fiscal year ended December 31, 2023, and 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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