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): October 17, 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 7.01 Regulation FD Disclosure.

On October 17, 2024, Avadel Pharmaceuticals plc (the "Company") issued a press release titled "Avadel Pharmaceuticals Announces FDA Approval of LUMRYZ™ (sodium oxybate) Extended-Release Oral Suspension (CIII) for the Treatment of Cataplexy or Excessive Daytime Sleepiness in Patients 7 Years of Age and Older with Narcolepsy." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information under this Item 7.01, including Exhibit 99.1 hereto, is being furnished herewith and shall not be deemed "filed" for the 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 such information be deemed incorporated by reference into 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 8.01 Other Events.

On October 17, 2024, the Company announced that the U.S. Food and Drug Administration ("FDA") approved its supplemental new drug application for LUMRYZ for the treatment of cataplexy or excessive daytime sleepiness in pediatric patients 7 years of age or older with narcolepsy. The FDA also granted Orphan Drug Exclusivity to LUMRYZ in pediatric narcolepsy patients 7 years and older for a seven-year period until October 16, 2031.

Item 9.01 Exhibits.

(d) Exhibits

99.1	Press release issued by Avadel Pharmaceuticals plc on October 17, 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: October 17, 2024

Exhibit 99.1

Avadel Pharmaceuticals Announces FDA Approval of LUMRYZ™ (sodium oxybate) Extended-Release Oral Suspension (CIII) for the Treatment of Cataplexy or Excessive Daytime Sleepiness in Patients 7 Years of Age and Older with Narcolepsy

-- LUMRYZ is the only FDA-approved once-at-bedtime oxybate treatment for cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy—

- Granted Orphan Drug Exclusivity in pediatric narcolepsy patients 7 years and older through October 16, 2031 -

DUBLIN, October 17, 2024 – Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, announced today that the U.S. Food and Drug Administration (FDA) has approved its supplemental new drug application (sNDA) for LUMRYZ for the treatment of cataplexy or EDS in patients 7 years of age and older with narcolepsy.

“This approval represents an important milestone for the narcolepsy community, specifically for younger narcolepsy patients and their caregivers who face significant challenges associated with waking up in the middle of the night to complete treatment regimens. With this label expansion, pediatric patients 7 years and older living with narcolepsy now have the same option that adult patients with narcolepsy have – to choose a once-nightly treatment option that does not disrupt sleep for a middle of the night dose,” said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. “In less than two years, Avadel has made great strides in establishing our commitment to the development of transformative medicines for sleep disorders. This includes successfully launching LUMRYZ for the adult narcolepsy population, initiating a Phase 3 pivotal trial evaluating LUMRYZ for the treatment of idiopathic hypersomnia, and now the expansion of LUMRYZ into the pediatric narcolepsy population.”

"I have been prescribing sodium oxybate for children and adolescents with narcolepsy for years as I have seen how effective this medication is and can safely be used," said Anne Marie Morse, DO, a board-certified and fellowship-trained pediatric neurologist and sleep medicine specialist at Geisinger Health System. “And before this, although numerous families have also witnessed the transformation in their children's lives, I have also had many families turn down the medication, or discontinue after starting, because of the challenge experienced or feared to experience with a forced awakening causing a purposeful nightly disruption, many times met with an exhausting fight, to take the second dose of first-generation oxybates. The expanded FDA approval for LUMRYZ allows me to now share with my patients and their families that there is an FDA-approved treatment that offers a single bedtime dose of medication, provided in a pre-filled packet. I can now offer more options to more patients which allows me to continue my role as a partner in my patients' journeys."

Narcolepsy is a chronic neurological condition that impairs the brain's ability to regulate the sleep-wake cycle. The condition affects approximately 1 in 2,000 people in the United States, where roughly 5% of patients are under the age of 18. Symptoms of narcolepsy are EDS and may also include a sudden loss of muscle tone usually triggered by strong emotion (cataplexy), disrupted nighttime sleep, sleep paralysis and hallucinations when falling asleep or waking up.

LUMRYZ is a once-at-bedtime formulation extended-release sodium oxybate and was first approved by the FDA on May 1, 2023, for the treatment of cataplexy or EDS in adult patients with narcolepsy.

LUMRYZ was approved by the FDA for use in the treatment of cataplexy or EDS in the pediatric narcolepsy population 7 years and older on October 16, 2024, and was granted Orphan Drug Exclusivity through October 16, 2031.

LUMRYZ has a boxed warning as a central nervous system depressant, and for its potential for abuse and misuse. LUMRYZ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy called the LUMRYZ REMS. Most common adverse reactions (incidence ≥ 5% and greater than placebo) reported for all doses of LUMRYZ combined in a trial of adults with narcolepsy were nausea, dizziness, enuresis, headache, and vomiting. Similarly, in a trial of pediatric narcolepsy patients receiving immediate-release sodium oxybate, the most commonly observed adverse reactions (incidence ≥5%) were nausea, enuresis, vomiting, headache, decreased weight, decreased appetite, dizziness, and sleepwalking.

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. On October 16, 2024, LUMRYZ was additionally approved as a once-at-bedtime treatment for cataplexy or EDS in patients 7 years of age and older 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 (MWT), clinicians' overall assessment of patients' functioning (CGI-I), and cataplexy attacks, for all three evaluated doses when compared to placebo.

With its approval in May 2023, the FDA also granted 7 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 EDS in both adults and pediatrics with narcolepsy. For more information, please visit www.avadel.com.

INDICATIONS

LUMRYZ (sodium oxybate) for extended-release oral suspension is a prescription medicine used to treat the following symptoms in patients 7 years of age and older with narcolepsy:

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

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.

Do not take LUMRYZ if you take or your child takes 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 or your child 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 or your child have or had depression or have tried to harm yourself. **Call your doctor right away if you or your child have symptoms of mental health problems or a change in weight or appetite.**
- **Sleepwalking.** Sleepwalking can cause injuries. Call your doctor if you or your child start sleepwalking.

Tell your doctor if you or your child are on a salt-restricted diet or 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. The most common side effects in children include nausea, bedwetting, vomiting, headache, decreased weight, decreased appetite, dizziness, and sleepwalking. 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 safety and potential therapeutic benefit of, and market and prescriber preference for, LUMRYZ in treating cataplexy and EDS in patients 7 years of age and older with narcolepsy; and the pediatric Orphan Drug Exclusivity for LUMRYZ and potential benefits resulting from such exclusivity. 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, 2023, which was filed with the Securities and Exchange Commission (SEC) on February 29, 2024, 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 Mogerley
Precision AQ
Courtney.Mogerley@precisionaq.com
(212) 698-8687

Media Contact:

Lesley Stanley
Real Chemistry
lestanley@realchemistry.com
(609) 273-3162