

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): May 1, 2023

AVADEL PHARMACEUTICALS PLC
(Exact name of registrant as specified in its charter)

Ireland
(State or other jurisdiction
of incorporation)

001-37977
(Commission
File Number)

98-1341933
(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 to 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 7.01 Regulation FD Disclosure.

On May 1, 2023, Avadel Pharmaceuticals plc (the “Company”) announced that the U.S. Food and Drug Administration (the “FDA”) has approved LUMRYZ, an extended-release formulation of sodium oxybate indicated to be taken once at bedtime for the treatment of cataplexy or excessive daytime sleepiness (“EDS”) in adults with narcolepsy. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

Item 8.01 Other Events.

On May 1, 2023, the FDA approved LUMRYZ, an extended-release formulation of sodium oxybate indicated to be taken once at bedtime for the treatment of cataplexy or EDS in adults with narcolepsy. The FDA has also granted Orphan Drug Exclusivity to LUMRYZ for a period of seven years through May 2030.

Item 9.01 Exhibits.

(d) Exhibits

[99.1](#) [Press release issued by Avadel Pharmaceuticals plc on May 1, 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.

Date: May 1, 2023

AVADEL PHARMACEUTICALS PLC

By: /s/ Jerad G. Seurer

Name: Jerad G. Seurer

Title: General Counsel & Corporate Secretary



Avadel Pharmaceuticals Announces Final FDA Approval of LUMRYZ™ (sodium oxybate) for Extended-Release Oral Suspension as the First and Only Once-at-Bedtime Oxybate for Cataplexy or Excessive Daytime Sleepiness in Adults with Narcolepsy

- Granted Orphan Drug Exclusivity through May 1, 2030 -

-Advanced commercial preparations on track; LUMRYZ product availability expected in early June -

- Final approval supported by robust efficacy and safety data from pivotal Phase 3 REST-ON clinical trial -

- Management to host conference call today, May 1, 2023 at 4:00 p.m. ET -

DUBLIN, May 1, 2023 – Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, announced today that the U.S. Food & Drug Administration (FDA) has granted final approval to LUMRYZ, an extended-release formulation of sodium oxybate indicated to be taken once at bedtime for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. With final approval, LUMRYZ becomes the first and only FDA approved once-at-bedtime oxybate for people living with narcolepsy. LUMRYZ was additionally granted Orphan Drug Exclusivity by the FDA.

“Today’s landmark approval and receipt of Orphan Drug Exclusivity represents a major milestone for both Avadel and people living with narcolepsy. As we have heard from key stakeholders, previously approved narcolepsy therapies have the potential to disrupt sleep by either causing insomnia or through forced awakening during the middle of the night for their crucial second dose. LUMRYZ can now offer people with narcolepsy the opportunity for an uninterrupted night sleep while receiving the full benefit of their prescribed treatment in one single bedtime dose that addresses their symptoms of narcolepsy,” said Greg Divis, Chief Executive Officer of Avadel. “We would like to thank the patients, caregivers, clinical trial investigators, healthcare providers, and advocates who have tirelessly partnered with us throughout the drug development process and look forward to providing the narcolepsy community access to now approved LUMRYZ.”

Narcolepsy is a chronic neurological condition that impairs the brain's ability to regulate the sleep-wake cycle. The condition affects approximately one in 2,000 people in the United States with the cardinal symptom of EDS. Additional symptoms can vary by person but may include disrupted nighttime sleep, a sudden loss of muscle tone usually triggered by strong emotion (cataplexy), sleep paralysis and hallucinations.



“This long-awaited therapy for people living with narcolepsy fills a critical unmet need by avoiding the burden of a second middle-of-the-night dose that immediate-release oxybate products require. The once-at-bedtime dosing regimen of LUMRYZ may help restore a more natural sleep-wake cycle,” said Michael J. Thorpy, M.D., an investigator from the REST-ON Phase 3 trial and Director at the Sleep-Wake Disorders Center at Montefiore Medical Center and Professor of Neurology at the Albert Einstein College of Medicine.

The FDA’s final approval of LUMRYZ was based on positive results from the pivotal Phase 3 REST-ON clinical study completed in March 2020. In the REST-ON Phase 3 trial, once-at-bedtime LUMRYZ demonstrated highly statistically significant ($p < 0.001$) and clinically meaningful improvement compared to placebo across all three co-primary endpoints (Maintenance of Wakefulness Test, Clinical Global Impression-Improvement and mean weekly cataplexy attacks) for all three doses evaluated, 6, 7.5 and 9 grams.

With this approval, the FDA has also found LUMRYZ to be clinically superior to currently marketed twice-nightly oxybate products and granted LUMRYZ seven years of Orphan Drug Exclusivity. In particular, 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. The FDA’s Orphan Drug program is designed to support the development of drugs that treat a condition affecting less than 200,000 U.S. patients. The seven-year market exclusivity for LUMRYZ began on the date of FDA approval, May 1, 2023.

“For people living with narcolepsy, and for all of us who advocate for this community, the approval of LUMRYZ is an important step forward,” said Julie Flygare, JD, President and CEO of Project Sleep. “People living with narcolepsy will finally have a new treatment option to manage EDS and cataplexy, and the fact that this new oxybate option allows for reduced dosing frequency is a game-changing advancement that shows Avadel’s commitment to understanding the patient experience. We look forward to continued collaboration with Avadel as part of a shared mission to positively impact the lives of people with narcolepsy.”

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 were nausea, dizziness, enuresis, headache, and vomiting.

Conference Call

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 program. 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 (eg, 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](tel: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 Orphan Drug Exclusivity for LUMRYZ and potential benefits resulting from such designation; the preparation and timing of commercial launch and the success of such commercialization for LUMRYZ; expectations regarding the potential market impact of LUMRYZ; and the anticipated market availability of LUMRYZ. 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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