

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): June 5, 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 June 5, 2023, Avadel Pharmaceuticals plc (the “Company”) announced that LUMRYZ™ (sodium oxybate) is commercially available in the U.S. for the treatment of cataplexy or excessive daytime sleepiness in adults living with narcolepsy. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

Item 9.01 Exhibits.

(d) Exhibits

[99.1](#) [Press release issued by Avadel Pharmaceuticals plc on June 5, 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: June 5, 2023

AVADEL PHARMACEUTICALS PLC

By: /s/ Jerad G. Seurer

Name: Jerad G. Seurer

Title: General Counsel & Corporate Secretary



Avadel Pharmaceuticals Announces U.S. Commercial Launch of LUMRYZ™ (sodium oxybate) for the Treatment of Cataplexy or Excessive Daytime Sleepiness in Adults Living with Narcolepsy

-LUMRYZ is the first and only once-at-bedtime oxybate for people living with narcolepsy

-Once-nightly dosing regimen of LUMRYZ has been found by FDA to provide a major contribution to patient care over all twice-nightly oxybates

DUBLIN, June 5, 2023 – Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, announced today that LUMRYZ is now commercially available. LUMRYZ is 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.

“We are proud to announce that LUMRYZ is commercially available through both our RYZUP™ patient support program and our specialty pharmacy network for patients living with narcolepsy who have been waiting for over two decades for a single dose treatment option that provides the opportunity for an uninterrupted night sleep,” said Greg Divis, Chief Executive Officer of Avadel. “LUMRYZ represents a new generation of oxybate treatment the FDA deemed clinically superior to all twice nightly oxybate treatments. The Avadel team is fully prepared to execute our commercial strategy and deliver LUMRYZ to the \$3 billion plus once-at-bedtime oxybate market.”

LUMRYZ is the first and only U.S. Food & Drug Administration (FDA) approved once-at-bedtime oxybate for people living with narcolepsy. The commercial strategy for LUMRYZ includes an extensive patient support program, RYZUP, which is designed to provide support and education to patients who have been prescribed LUMRYZ and to assist them in gaining access to their medication. More information about the RYZUP patient support program can be accessed at ryzupsupport.com.

LUMRYZ was granted FDA approval 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.

LUMRYZ was approved by the FDA on May 1 and was granted a seven year period of Orphan Drug Exclusivity as a result of the FDA finding LUMRYZ to be clinically superior to all first generation oxybate products. 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.



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 (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, and Medication Guide.

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; expectations regarding the commercial availability of LUMRYZ; expectations regarding the potential benefits of the RYZUP patient support program; and expectations regarding the potential market opportunity and market impact 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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