Avadel Announces Preliminary 2024 Results and 2025 Commercial Priorities to Accelerate the LUMRYZ Launch

January 8, 2025 at 4:15 PM EST

-- Approximately $50.0 million of net revenue from sales of LUMRYZ™ estimated for the fourth quarter, a greater than 150% increase over $19.5 million for the comparable period in 2023 --

--2,500 patients on LUMRYZ as of December 31, 2024, including 600 patients that initiated therapy in the fourth quarter --

-- LUMRYZ net product revenue of $240 – $260 million in 2025, representing 50% year-over-year growth at the midpoint --

-- Management to host a conference call today at 4:30 p.m. ET --

DUBLIN, Ireland, Jan. 08, 2025 (GLOBE NEWSWIRE) -- 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 2024 net revenue and cash, cash equivalents and marketable securities.

"2024 was a pivotal year for Avadel, marked by consistent patient adoption of LUMRYZ and overwhelmingly positive feedback from both patients and providers about the transformative benefits of once-nightly dosing," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "As we move into 2025, we are building on this momentum with a refined commercial strategy to increase demand for and persistency on, LUMRYZ, with the primary goal of enhancing the overall LUMRYZ experience for both patients and providers. We believe the strategic initiatives we're introducing now will drive uptake among each of the three narcolepsy patient segments – switches, new to oxybates, and previously treated and discontinued – and allow us to further unlock the market potential of LUMRYZ. With the continued execution of our commercial launch in narcolepsy and ongoing progress in our Phase 3 trial in idiopathic hypersomnia (IH), we are well positioned to solidify our leadership in the sleep space and transform care for patients with sleep disorders."

2024 Financial Highlights:

- Generated fourth quarter net product revenue of approximately $50.0 million, a greater than 150% increase compared to $19.5 million in the fourth quarter of 2023.
    - Fourth quarter revenue was impacted by approximately $6.0 million due to an estimated 1.5 fewer weeks of inventory in the channel at December 31, 2024, compared to September 30, 2024.
- Full year net product revenue of approximately $169.0 million compared to $28.0 million in 2023.
- Positive cash flow during the fourth quarter ending with approximately $73.0 million of cash, cash equivalents and marketable securities at December 31, 2024.

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, 2024. The Company expects to announce its full results for the twelve months ended December 31, 2024 on or before March 3, 2025.

Launch Progress through December 31, 2024 and 2025 Commercial Initiatives:

- As of December 31, 2024, there were 2,500 patients on LUMRYZ, a more than 275% increase compared to 900 as of December 31, 2023.
    - In the fourth quarter, generated consistent patient demand for LUMRYZ with 600 patients initiating therapy.
    - Continuing demand from all three patient segments during the fourth quarter, with 38% of patients switching from first generation oxybates, 34% who are new to oxybate and 28% who have previously tried and discontinued oxybates.
    - As of December 31, 2024, approximately 74% of patients on therapy were reimbursed.
- The Company recently made the following commercial investments to accelerate LUMRYZ's reach and improve persistency into 2025:
    - Expanded and upgraded field sales team by nearly 15% to gain broader physician reach and impact into the under-penetrated 75% prescriber universe;
    - Doubled field reimbursement team to align with field sales team to accelerate the time and pace of patient fulfillment;
    - Expanded patient ambassador direct-to-patient initiatives to better educate and activate oxybate patients to seek LUMRYZ; and
    - Progressing field-based patient support services beyond the traditional telephonic and digital interventional tools to a more personal intervention at the patient and physician office level.

Full Year 2025 Guidance:

- Net product revenue in the range of $240 – 260 million, representing a 50% increase at the midpoint of guidance from 2024.
- Cash flow of $20 – $40 million.
- 2,800 – 3,000 patients initiating therapy.
- 3,300 – 3,500 total patients on therapy at December 31, 2025.

Pipeline Updates:

- Patient enrollment is ongoing in the REVITALYZ pivotal study, a Phase 3 double-blind, placebo-controlled, randomized withdrawal, multicenter study designed to evaluate the efficacy and safety of LUMRYZ in IH. Completion of this study is expected during the second half of 2025.
- Preclinical development ongoing for a once-nightly, low-/no-sodium oxybate formulation with a target product profile bioequivalent to LUMRYZ.

The Company's full year 2025 guidance is preliminary and based upon the Company's current view of existing market conditions and assumptions for the year ending December 31, 2025. These statements are forward-looking, and actual results could differ materially depending on market conditions.

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 EDS in both adults and pediatrics with narcolepsy. For more information, please visit www.avadel.com.

Avadel intends to use its Investor Relations website as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor the Company's Investor Relations website, in addition to following the Company's press releases, SEC filings, public conference calls, presentations, and webcast.

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 patients 7 years of age and older with narcolepsy:

- sudden onset of weak or paralyzed muscles (cataplexy)

- excessive daytime sleepiness (EDS)

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; the success of commercialization of LUMRYZ; the anticipated market availability, demand and sales opportunity of LUMRYZ, expectations for the Company to solidify its leadership in the sleep space; expectations regarding the Company’s financial results for the fourth quarter of 2024, including net product revenue and cash as of December 31, 2024; and the Company’s full year 2025 guidance, including net product revenue, cash flow, total patient initiations and total patients as of December 31, 2025. 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 estimate of revenue for the fourth quarter of 2024 and cash as of December 31, 2024 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, 2024, 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, 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.

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