Avadel Pharmaceuticals Provides Corporate Update and Reports Third Quarter 2024 Financial Results

November 12, 2024 at 7:00 AM EST

-- Generated $50.0 million in net revenue from sales of LUMRYZ™ --

--2,300 patients on LUMRYZ as of September 30th, including 700 patients that initiated therapy in the quarter --

-- Received FDA approval for LUMRYZ for the treatment of cataplexy or EDS in patients 7 years and older with narcolepsy, granted ODE through October 16, 2031 --

-- LUMRYZ approval upheld by court in suit brought by Jazz regarding FDA's determination that LUMRYZ is clinically superior to twice-nightly oxybate products --

-- Progressed Phase 3 REVITALYZ™ study evaluating efficacy and safety of LUMRYZ in IH --

-- Management to host a conference call today at 8:30 a.m. ET --

DUBLIN, Ireland, Nov. 12, 2024 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a biopharmaceutical company focused on transforming medicines to transform lives, today provided a corporate update and announced its financial results for the quarter ended September 30, 2024.

"Over a year ago, we set out on our mission to transform the lives of those living with narcolepsy, including expanding the oxybate market through the introduction of LUMRYZ. This quarter, we are proud to see that expansion come to fruition and continue to be encouraged by patient uptake and quarter-over-quarter growth of LUMRYZ. In parallel to our launch in adults with narcolepsy, we are expanding into additional patient populations, starting with the recent FDA approval of LUMRYZ for the treatment of cataplexy or EDS in patients 7 years and older with narcolepsy, significantly alleviating the burden on patients and their caregivers of waking up in the middle of the night to administer treatment," stated Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "We are also pleased with the recent court ruling affirming FDA's determination that LUMRYZ, dosed once at bedtime, demonstrates clinical superiority to twice-nightly oxybates, which mitigates an important legal and business risk for the company. With our Phase 3 pivotal trial in IH ongoing, our continued execution of the LUMRYZ launch including our expansion of LUMRYZ into pediatric narcolepsy, we are closing in our business objectives of being a leader in the sleep field and fulfilling the promise of LUMRYZ for all stakeholders."

Third Quarter and Recent Company Highlights

LUMRYZ Commercial Updates:

- Generated $50.0 million of net product revenue from sales of LUMRYZ in the third quarter of 2024.
- As of September 30, there were 2,300 patients on LUMRYZ compared to 1,900 patients on LUMRYZ at June 30.
  - In the third quarter, generated consistent patient demand for LUMRYZ with 700 patients initiating therapy.
  - Observed continuing growth in demand from patients who are new to oxybate – these patients represent the fastest growing patient segment for LUMRYZ.

Corporate and Pipeline Updates:

- On October 30, 2024, the U.S. District Court for the District of Columbia ruled in favor of the U.S. Food and Drug Administration (FDA) in a suit brought by Jazz Pharmaceuticals Inc. under the Administrative Procedure Act regarding the FDA's approval of LUMRYZ.
  - With this ruling, the approval of LUMRYZ is upheld based on the FDA's determination that LUMRYZ is clinically superior to Jazz's twice-nightly oxybate products.
- On October 16, 2024, the FDA approved LUMRYZ for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years or older with narcolepsy.
  - LUMRYZ was granted Orphan Drug Exclusivity (ODE) for this patient population through October 16, 2031.
- 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 idiopathic hypersomnia (IH).
- During the quarter ended September 30, 2024, announced publication of results of:
  - A post-hoc analysis showing consistent efficacy in participants currently taking alerting agents, highlighting the benefit of LUMRYZ to augment response, as well as the 37% who responded positively based upon LUMRYZ monotherapy.
  - Data from the RESTORE open-label study, based upon the largest cohort of switch patients, in which 94% preferred the once-nightly dosing regimen and 93% who would recommend LUMRYZ to a friend or family member with narcolepsy.

- A post-hoc analysis demonstrating weight loss associated with LUMRYZ compared to placebo, and shifting from obese category into overweight and overweight into normal BMI categories.

Overview of Third Quarter Financial Results

Recognized $50.0 million in net product revenue for the third quarter 2024 compared to $7.0 million in the same period in 2023. Net product revenue consists of LUMRYZ product sales, which was launched in the U.S. on June 5, 2023.

Gross profit for the third quarter 2024 was $43.9 million compared to $6.9 million in the same period in 2023.

Total operating expenses were $44.2 million in the quarter ended September 30, 2024 compared to $42.0 million in the same period in 2023. The current quarter operating expenses incudes $6.4 million of non-cash charges comprised of $5.4 million of stock based compensation expense and $1.0 million of depreciation and amortization.

Selling, general and administrative (SG&A) expenses were $40.4 million in the quarter ended September 30, 2024, compared to $39.2 million for the same period in 2023.

Research and development (R&D) expenses were $3.8 million in the quarter ended September 30, 2024, compared to $2.8 million for the same period in 2023. R&D expenses in the current period include clinical study costs related to the Phase 3 pivotal trial in IH.

Operating loss was $0.3 million for the quarter ended September 30, 2024 compared to $35.1 million in the same period in 2023.

Net loss for the quarter ended September 30, 2024, was $2.6 million, or ($0.03) per diluted share, compared to a net loss of $36.3 million, or ($0.41) per diluted share, for the same period in 2023.

Cash, cash equivalents and marketable securities were $65.8 million as of September 30, 2024. Cash used in the quarter ended September 30, 2024 included the payment of a $2.0 million commitment fee due to the decision to not draw the second financing tranche that was available under the royalty financing agreement entered into in March 2023.

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. To access the conference call, investors are invited to dial (800) 579-2543 (U.S. and International) and reference the conference ID AVADEL.

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 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 and in October 2024, the FDA also granted 7 years of Orphan Drug Exclusivity to LUMRYZ for the treatment of cataplexy or EDS in adults with narcolepsy and pediatric patients 7 years and older with narcolepsy (respectively) 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 patients 7 years and older 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 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 http://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 and expansion into additional patient populations; the anticipated market demand and sales opportunity of LUMRYZ; the potential for the Company to be a leader in the market; the Company’s idiopathic hypersomnia clinical study for LUMRYZ, including enrollment and timing related thereto; the Company’s anticipated financial condition, expenses, uses of capital and other future financial results. In some cases, forward-looking statements can be identified by 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 most recent Annual Report on Form 10-K and subsequent filings with the Securities and Exchange Commission.

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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AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF LOSS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net product revenue	$ 50,025	$ 7,014	$ 118,707	$ 8,510
Cost of products sold	6,155	117	10,465	153
Gross profit	43,870	6,897	108,242	8,357
Operating expenses:				
Research and development expenses	3,803	2,849	10,922	10,902
Selling, general and administrative expenses	40,394	39,158	136,422	110,404
Total operating expense	44,197	42,007	147,344	121,306
Operating loss	(327)	(35,110)	(39,102)	(112,949)
Investment and other income, net	610	903	3,114	1,719
Interest expense	(2,820)	(1,978)	(8,128)	(7,532)
Loss on extinguishment of debt	—	—	—	(13,129)
Loss before income taxes	(2,537)	(36,185)	(44,116)	(131,891)
Income tax provision (benefit)	88	89	(327)	(401)
Net loss	$ (2,625)	$ (36,274)	$ (43,789)	$ (131,490)
Net loss per share - basic	$ (0.03)	$ (0.41)	$ (0.46)	$ (1.71)
Net loss per share - diluted	$ (0.03)	$ (0.41)	$ (0.46)	$ (1.71)
Weighted average number of shares outstanding - basic	96,300	89,380	94,720	76,931
Weighted average number of shares outstanding - diluted	96,300	89,380	94,720	76,931

AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	September 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,582	$ 31,167
Marketable securities	37,225	73,944
Accounts receivable, net	37,102	12,103
Inventories	16,097	10,380
Prepaid expenses and other current assets	8,252	6,608
Total current assets	127,258	134,202
Property and equipment, net	469	585
Operating lease right-of-use assets	1,930	2,591
Goodwill	16,836	16,836
Other non-current assets	11,760	10,484

Total assets	$ 158,253	$ 164,698
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of operating lease liability	$ 725	$ 934
Accounts payable	7,917	11,433
Accrued expenses	33,907	24,227
Other current liabilities	234	261
Total current liabilities	42,783	36,855
Long-term operating lease liability	1,216	1,690
Royalty financing obligation	34,437	32,760
Other non-current liabilities	5,154	5,654
Total liabilities	83,590	76,959
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; zero issued and outstanding at September 30, 2024 and 5,194 issued and outstanding at December 31, 2023	—	52
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 96,338 issued and outstanding at September 30, 2024 and 89,825 issued and outstanding at December 31, 2023	963	898
Additional paid-in capital	886,787	855,452
Accumulated deficit	(789,285)	(745,496)
Accumulated other comprehensive loss	(23,802)	(23,167)
Total shareholders' equity	74,663	87,739
Total liabilities and shareholders' equity	$ 158,253	$ 164,698

AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (43,789)	$ (131,490)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,013	1,784
Amortization of debt discount and debt issuance costs	—	2,796
Share-based compensation expense	16,261	12,293
Loss on extinguishment of debt	—	13,129
Other adjustments	(1,052)	(349)
Net changes in assets and liabilities		
Accounts receivable	(24,999)	(6,239)
Inventories	(5,255)	(5,286)
Prepaid expenses and other current assets	(1,615)	(3,203)
Accounts payable & other current liabilities	(3,516)	3,837
Accrued expenses	9,680	10,621
Other assets and liabilities	(2,508)	1,625
Net cash used in operating activities	(54,780)	(100,482)
Cash flows from investing activities:		
Proceeds from sales of marketable securities	298,829	125,498
Purchases of marketable securities	(261,962)	(203,519)
Net cash provided by (used in) investing activities	36,867	(78,021)
Cash flows from financing activities:		
Proceeds from April 2023 public offering, net of issuance costs	—	134,149
Payments for February 2023 Notes	—	(17,500)

Payments for debt issuance costs	—	(4,357)
Proceeds from royalty purchase agreement	—	30,000
Proceeds from issuance of shares off the at-the-market offering program	9,250	11,913
Proceeds from stock option exercises and employee share purchase plan	5,840	2,241
Net cash provided by financing activities	15,090	156,446
Effect of foreign currency exchange rate changes on cash and cash equivalents	238	(113)
Net change in cash and cash equivalents	(2,585)	(22,170)
Cash and cash equivalents at January 1,	31,167	73,981
Cash and cash equivalents at September 30,	$ 28,582	$ 51,811

Source: Avadel Pharmaceuticals plc