Avadel Pharmaceuticals Provides Corporate Update and Reports Fourth Quarter and Full Year 2023 Financial Results

March 4, 2024 at 6:30 AM EST

-- Generated $19.5 million in fourth quarter and $28.0 million of full year 2023 net revenue from sales of LUMRYZ™ --

-- As of January 31st, greater than 2,200 patients enrolled in RYZUP™ and more than 1,200 patients initiated therapy --

-- Payer coverage now in place for greater than 80% of commercially covered lives for LUMRYZ through new listings including United Healthcare and Anthem --

-- FDA target action date of September 7, 2024, issued for the Supplemental New Drug Application (sNDA) for LUMRYZ in pediatric narcolepsy--

-- Management to host a conference call today at 7:30 a.m. ET --

DUBLIN, Ireland, March 04, 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 fourth quarter ended December 31, 2023.

“We are carrying significant momentum into 2024 following the successful launch of LUMRYZ and are pleased with the strong early launch results we have seen. We have established a strong foundation with patients, prescribers and payers to build on and advance our mission of transforming the lives of people living with narcolepsy,” said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. “While the launch is still in the early stages, we believe the meaningful increase in patients initiating therapy with LUMRYZ underscores the significant unmet need for a once-at-bedtime therapy. We look forward to expanding the LUMRYZ indication for the pediatric narcolepsy population with the anticipated approval decision in September, initiating our Phase 3 pivotal trial program in idiopathic hypersomnia and continuing our robust commercial execution throughout 2024.”

Fourth Quarter and Recent Company Highlights

LUMRYZ Commercial Updates Through the End of January 2024:

- Greater than 2,200 patients enrolled in Avadel’s RYZUP patient support services:
  - More than 1,200 patients initiated therapy.
  - The majority of RYZUP enrollments and patients currently being treated with LUMRYZ are patients who switched from first generation oxybates, with the balance made up of patients who previously tried and discontinued a first generation oxybate and patients who are new to oxybate treatment.
- Secured payor coverage policies for greater than 80% of commercially covered lives with the inclusion of Anthem and the United Healthcare national formulary.
  - Contracts now established with all 3 PBM-owned GPOs (Ascent/ESI, Zinc/CVS and Emisar/Optum).
- Approximately 1,900 health care providers have completed the LUMRYZ REMS certification process, including both experienced oxybate prescribers as well as providers who have never previously prescribed an oxybate.

Pipeline Updates:

- U.S. Food and Drug Administration (FDA) accepted the Supplemental New Drug Application (sNDA) for LUMRYZ for treatment of cataplexy or EDS in the pediatric narcolepsy population. The FDA has assigned a target action date of September 7, 2024, for its approval decision.
- With potential approval in the pediatric population, LUMRYZ could alleviate the burden placed on families and caregivers of children with narcolepsy who are responsible for waking up in the middle of the night to administer a second dose.
- Pediatric patients currently represent approximately 3-5% of all oxybate treated narcolepsy patients.
- Planning to enroll the first patient in a clinical study for the use of LUMRYZ to treat idiopathic hypersomnia in the second half of 2024.

Overview of Fourth Quarter and Full Year Results

Recognized $19.5 million and $28.0 million in net product revenue for the quarter and year ended December 31, 2023, respectively. Net product revenue consists of LUMRYZ product sales, which was launched in the U.S. on June 5, 2023.

R&D expenses for the quarter and year ended December 31, 2023, were $2.4 million and $13.3 million, respectively, compared to $6.2 million and $20.7 for the same periods in 2022. The decreases were driven primarily by lower pre-commercial LUMRYZ related costs that were capitalized into inventory beginning in May 2023 upon FDA approval of LUMRYZ.

SG&A expenses for the quarter and year ended December 31, 2023, were $41.3 million and $151.7 million, compared to $17.0 million and $74.5

million for the same periods in 2022. These increases were driven primarily by higher costs associated with the commercial launch of LUMRYZ, higher compensation costs due to increased headcount, higher marketing and market research activities, and higher legal fees.

Net losses for the quarter and year ended December 31, 2023, were $28.8 million, or ($0.32) per diluted share and $160.3 million, or ($2.00) per diluted share, respectively, compared to net losses of $27.5 million, or ($0.44) per diluted share, and $137.5 million, or ($2.29) per diluted share, for the same periods in 2022.

Cash, cash equivalents and marketable securities were $105.1 million as of December 31, 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. 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. 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.

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; the anticipated market availability, demand and sales opportunity of LUMRYZ; the potential expansion of LUMRYZ into the pediatric narcolepsy population including FDA’s review of the sNDA for such population and timing related thereto; the Company’s plans and timing to initiate the idiopathic hypersomnia clinical study; 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 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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AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF LOSS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Net product revenue	$ 19,453	$ —	$ 27,963	$ —
Cost of products sold	693	—	846	—

Gross profit	18,760	—	27,117	—
Operating expenses:				
Research and development expenses	2,359	6,235	13,261	20,700
Selling, general and administrative expenses	41,301	16,981	151,705	74,516
Restructuring (income) expense	—	(178)	—	3,345
Total operating expenses	43,660	23,038	164,966	98,561
Operating loss	(24,900)	(23,038)	(137,849)	(98,561)
Investment and other (expense) income, net	(1,632)	(1,072)	87	(536)
Interest expense	(2,354)	(3,255)	(9,886)	(12,342)
Loss on extinguishment of debt	—	—	(13,129)	—
Loss before income taxes	(28,886)	(27,365)	(160,777)	(111,439)
Income tax (benefit) provision	(100)	85	(501)	26,025
Net loss	$ (28,786)	$ (27,450)	$ (160,276)	$ (137,464)
Net loss per share - basic	$ (0.32)	$ (0.44)	$ (2.00)	$ (2.29)
Net loss per share - diluted	(0.32)	(0.44)	(2.00)	(2.29)
Weighted average number of shares outstanding - basic	89,798	62,276	80,174	60,094
Weighted average number of shares outstanding - diluted	89,798	62,276	80,174	60,094

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

	December 31, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,167	$ 73,981
Marketable securities	73,944	22,518
Accounts receivable, net	12,103	—
Inventories	10,380	—
Research and development tax credit receivable	1,322	2,248
Prepaid expenses and other current assets	5,286	2,096
Total current assets	134,202	100,843
Property and equipment, net	585	839
Operating lease right-of-use assets	2,591	1,713
Goodwill	16,836	16,836
Research and development tax credit receivable	332	1,232
Other non-current assets	10,152	11,322
Total assets	$ 164,698	$ 132,785
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term debt	$ —	$ 37,668
Current portion of operating lease liability	934	960
Accounts payable	11,433	7,890
Accrued expenses	24,227	7,334
Other current liabilities	261	1,941
Total current liabilities	36,855	55,793
Long-term debt	—	91,614
Long-term operating lease liability	1,690	780
Royalty financing obligation	32,760	—
Other non-current liabilities	5,654	5,743
Total liabilities	76,959	153,930
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 5,194 issued and outstanding at December 31, 2023 and 488 issued and outstanding at December 31, 2022	52	5

Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 89,825 issued and outstanding at December 31, 2023 and 62,878 issued and outstanding at December 31, 2022	898	628
Additional paid-in capital	855,452	589,783
Accumulated deficit	(745,496)	(585,220)
Accumulated other comprehensive loss	(23,167)	(26,341)
Total shareholders' equity (deficit)	87,739	(21,145)
Total liabilities and shareholders' equity (deficit)	$ 164,698	$ 132,785

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

	Twelve Months Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (160,276)	$ (137,464)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,766	1,493
Amortization of debt discount and debt issuance costs	2,796	6,052
Changes in deferred taxes	—	26,025
Share-based compensation expense	15,811	7,013
Loss on extinguishment of debt	13,129	—
Other adjustments	1,262	2,042
Net changes in assets and liabilities		
Accounts receivable	(12,103)	—
Inventories	(9,532)	—
Prepaid expenses and other current assets	(3,127)	30,815
Research and development tax credit receivable	1,884	30
Accounts payable & other current liabilities	1,545	(3,108)
Accrued expenses	16,892	227
Other assets and liabilities	1,442	(3,429)
Net cash used in operating activities	(128,511)	(70,304)
Cash flows from investing activities:		
Purchases of property and equipment	—	(716)
Proceeds from sales of marketable securities	187,136	83,828
Purchases of marketable securities	(237,229)	(3,414)
Net cash (used in) provided by investing activities	(50,093)	79,698
Cash flows from financing activities:		
Proceeds from April 2023 public offering, net of issuance costs	134,151	—
Payments for February 2023 Notes	(17,500)	(8,653)
Payments for October 2023 Notes	(21,165)	—
Payments for debt issuance costs	(4,357)	(4,804)
Proceeds from royalty purchase agreement	30,000	—
Proceeds from issuance of shares off the at-the-market offering program	11,913	25,318
Proceeds from stock option exercises and employee share purchase plan	2,293	2,682
Net cash provided by financing activities	135,335	14,543
Effect of foreign currency exchange rate changes on cash and cash equivalents	455	(664)
Net change in cash and cash equivalents	(42,814)	23,273
Cash and cash equivalents at January 1	73,981	50,708
Cash and cash equivalents at December 31	$ 31,167	$ 73,981

Source: Avadel Pharmaceuticals plc