Avadel Pharmaceuticals Provides Corporate Update and Reports First Quarter 2023 Financial Results

May 4, 2023

-- Received FDA approval for LUMRYZ™ (sodium oxybate), the first and only once-at-bedtime oxybate for treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy –

-- FDA awarded LUMRYZ Orphan Drug Exclusivity through May 1, 2030 --

-- LUMRYZ product availability on track for early June; robust market research and physician feedback supports potential of LUMRYZ to capture a meaningful share of the $3 billion plus once-nightly oxybate market --

-- Secured over $200 million of capital to support the near-term launch of LUMRYZ --

DUBLIN, Ireland, May 04, 2023 (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 first quarter ended March 31, 2023.

“On May 1, we announced the final FDA approval and receipt of Orphan Drug Exclusivity for LUMRYZ, the first and only once-at-bedtime oxybate therapy for the treatment of cataplexy or EDS in adults with narcolepsy. The receipt of Orphan Drug Exclusivity recognizes the clinically superior benefit of a once at bedtime treatment option over existing twice nightly oxybates,” said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. “With the approval of LUMRYZ, we are poised to positively impact the treatment experience for all eligible patients, increase oxybate utilization and secure a meaningful position in the $3 billion plus once-nightly oxybate market.”

First Quarter and Recent Company Highlights

- On May 1, 2023, Avadel announced final approval and receipt of Orphan Drug Exclusivity for LUMRYZ from the U.S. Food & Drug Administration (FDA), 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.
    - The FDA 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, 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.
- U.S. commercial launch of LUMRYZ expected in early June 2023.
    - Advancing commercial preparations to support launch, including the finalization of specialty pharmacy network and patient services center, RYZUP.
    - Avadel continues to engage with key stakeholders including sleep specialists and payers while expanding medical science liaisons, sales leadership team, territory business managers and field reimbursement specialists.
- Successfully executed multiple strategic financing activities and secured over $200 million of capital to fund the launch of LUMRYZ.
    - Entered into a royalty agreement with RTW Investments (RTW) for up to $75 million to support the commercialization of LUMRYZ.
        - Under the terms of the royalty agreement, RTW will provide up to $75 million non-dilutive synthetic royalty financing commitment to Avadel in return for tiered rate, cash royalty payments based on net sales of LUMRYZ.
    - Completed an equity offering with gross proceeds of $143.8 million, before deducting underwriting discounts, commissions and estimated offering expenses.
    - Exchanged $96.2 million of convertible notes with a new maturity date of April 3, 2027.

Overview of Fourth Quarter Results

R&D expenses were $3.8 million in the quarter ended March 31, 2023, compared to $7.0 million for the same period in 2022. The period-over-period decrease was primarily attributed to a decrease in purchases of the active pharmaceutical ingredient used in the manufacture of LUMRYZ.

SG&A expenses were $24.5 million in the quarter ended March 31, 2023, compared to $21.6 million for the same period in 2022. The period-over-period increase is primarily the result of higher legal costs and costs related to financing activities.

Net loss for the quarter ended March 31, 2023, was $30.8 million, or ($0.48) per diluted share, compared to net loss of $26.4 million, or ($0.45) per diluted share, for the same period in 2022.

Cash, cash equivalents and marketable securities were $100.9 million as of March 31, 2023. The Company extended the maturity of $96.2 million of its convertible notes to April 2027, and $21.2 million will mature in October 2023.

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 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; the anticipated market availability of LUMRYZ; the Company's anticipated uses of capital, including the proceeds from the recent financing; and the expected maturity of the Company's convertible notes. 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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AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF LOSS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development expenses	$ 3,830	$ 6,991
Selling, general and administrative expenses	24,468	21,635
Total operating expense	28,298	28,626
Operating loss	(28,298)	(28,626)
Investment and other income (expense), net	193	(104)
Interest expense	(3,259)	(2,017)
Loss before income taxes	(31,364)	(30,747)
Income tax benefit	(580)	(4,323)
Net loss	$ (30,784)	$ (26,424)

Net loss per share - basic	$ (0.48)	$ (0.45)
Net loss per share - diluted	(0.48)	(0.45)
Weighted average number of shares outstanding - basic	63,886	58,824
Weighted average number of shares outstanding - diluted	63,886	58,824

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

	March 31, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 83,391	$ 73,981
Marketable securities	17,532	22,518
Research and development tax credit receivable	2,283	2,248
Prepaid expenses and other current assets	6,264	2,096
Total current assets	109,470	100,843
Property and equipment, net	782	839
Operating lease right-of-use assets	1,475	1,713
Goodwill	16,836	16,836
Research and development tax credit receivable	1,245	1,232
Other non-current assets	10,931	11,322
Total assets	$ 140,739	$ 132,785
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 20,515	$ 37,668
Current portion of operating lease liability	871	960
Accounts payable	10,023	7,890
Accrued expenses	7,683	7,334
Proceeds received in advance of Series B Preferred Shares issuance	40,000	—
Other current liabilities	269	1,941
Total current liabilities	79,361	55,793
Long-term debt	93,139	91,614
Long-term operating lease liability	638	780
Other non-current liabilities	5,767	5,743
Total liabilities	178,905	153,930
Shareholders' (deficit) equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at March 31, 2023 and 488 issued and outstanding at December 31, 2022	5	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 64,478 issued and outstanding at March 31, 2023 and 62,878 issued and outstanding at December 31, 2022	644	628
Additional paid-in capital	603,215	589,783
Accumulated deficit	(616,004)	(585,220)
Accumulated other comprehensive loss	(26,026)	(26,341)
Total shareholders' (deficit) equity	(38,166)	(21,145)
Total liabilities and shareholders' (deficit) equity	$ 140,739	$ 132,785

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

	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities:		

Net loss	$ (30,784)	$ (26,424)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	588	259
Amortization of debt discount and debt issuance costs	1,873	312
Changes in deferred taxes	—	(4,323)
Share-based compensation expense	1,522	2,505
Other adjustments	(1)	669
Net changes in assets and liabilities		
Prepaid expenses and other current assets	(4,131)	(2,058)
Research and development tax credit receivable	—	(19)
Accounts payable & other current liabilities	468	(5,613)
Accrued expenses	348	2,314
Other assets and liabilities	(116)	(1,667)
Net cash used in operating activities	(30,233)	(34,045)
Cash flows from investing activities:		
Proceeds from sales of marketable securities	15,295	44,341
Purchases of marketable securities	(10,229)	(2,090)
Net cash provided by investing activities	5,066	42,251
Cash flows from financing activities:		
Proceeds received in advance of Series B Preferred Shares Issuance	40,000	—
Payments for February 2023 Notes	(17,500)	—
Proceeds from issuance of shares off the at-the-market offering program	11,913	—
Proceeds from stock option exercises and employee share purchase plan	29	2,009
Net cash provided by financing activities	34,442	2,009
Effect of foreign currency exchange rate changes on cash and cash equivalents	135	(50)
Net change in cash and cash equivalents	9,410	10,165
Cash and cash equivalents at January 1,	73,981	50,708
Cash and cash equivalents at March 31,	$ 83,391	$ 60,873

Source: Avadel Pharmaceuticals plc