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

May 8, 2024 at 7:00 AM EDT

-- Generated $27.2 million in net revenue from sales of LUMRYZ™ --

-- Through March 31, greater than 2,800 patients enrolled in Avadel's RYZUP patient support services and more than 1,700 patients initiated therapy --

-- Pursuing expansion opportunities for LUMRYZ with sNDA in pediatric narcolepsy; on track to enroll first patient in a Phase 3 pivotal idiopathic hypersomnia trial in the second half of 2024 --

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

DUBLIN, Ireland, May 08, 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 March 31, 2024.

"We are pleased to report another strong quarter of launch performance from LUMRYZ as we continue to serve the narcolepsy patient community. The continued positive feedback we hear daily from patients, prescribers and caregivers builds on the strong commercial foundation we established early into the launch," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "Over the course of 2024, we will be laser focused on the continued market growth of LUMRYZ for the treatment of narcolepsy as well as potentially expanding to the pediatric population and initiating our Phase 3 pivotal trial in idiopathic hypersomnia in the second half of the year."

First Quarter and Recent Company Highlights

LUMRYZ Commercial Updates:

- Greater than 1,700 patients initiated therapy as of March 31, representing an increase of greater than 70% from December 31.
    - More than 2,800 patients enrolled in Avadel's RYZUP patient support services, an increase of approximately 50% since December 31.
    - 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.

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.
    - 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 5% of all oxybate treated narcolepsy patients.
- On track to enroll the first patient in a Phase 3 pivotal trial for the use of LUMRYZ to treat idiopathic hypersomnia in the second half of 2024.

Overview of First Quarter Financial Results

Recognized $27.2 million in net product revenue and gross profit of $25.7 million for the quarter ended March 31, 2024. Net product revenue consists of LUMRYZ product sales, which was launched in the U.S. on June 5, 2023.

R&D expenses were $3.1 million in the quarter ended March 31, 2024, compared to $3.8 million for the same period in 2023. The decrease was 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 were $48.6 million in the quarter ended March 31, 2024, compared to $24.5 million for the same period in 2023. This increase was driven primarily by higher costs associated with the commercial launch of LUMRYZ, higher compensation costs due to increased headcount, higher selling and marketing activities, and higher legal fees.

Net loss for the quarter ended March 31, 2024 was $27.3 million, or ($0.30) per diluted share, compared to net loss of $30.8 million, or ($0.48) per diluted share, for the same period in 2023.

Cash, cash equivalents and marketable securities were $88.8 million as of March 31, 2024.

Conference Call Details:

To access the conference call, investors are invited to dial +1 (800) 715-9871 (U.S. and Canada) or +1 (646) 307-1963 (International) and use the conference ID 2270373. A live audio webcast of the call 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.

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 to initiate a Phase 3 pivotal trial for LUMRYZ in idiopathic hypersomnia 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 March 31,	
	2024	**2023**
Net product revenue	$ 27,178	$ —
Cost of products sold	1,522	—
Gross profit	25,656	—
Operating expenses:		
Research and development expenses	3,068	3,830
Selling, general and administrative expenses	48,623	24,468
Total operating expense	51,691	28,298
Operating loss	(26,035)	(28,298)
Investment and other income, net	1,378	193
Interest expense	(2,592)	(3,259)

Loss before income taxes	(27,249)	(31,364)
Income tax provision (benefit)	93	(580)
Net loss	$ (27,342)	$ (30,784)
Net loss per share - basic	$ (0.30)	$ (0.48)
Net loss per share - diluted	(0.30)	(0.48)
Weighted average number of shares outstanding - basic	91,693	63,886
Weighted average number of shares outstanding - diluted	91,693	63,886

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

	March 31, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,794	$ 31,167
Marketable securities	52,995	73,944
Accounts receivable, net	22,692	12,103
Inventories	11,928	10,380
Research and development tax credit receivable	1,293	1,322
Prepaid expenses and other current assets	11,333	5,286
Total current assets	136,035	134,202
Property and equipment, net	526	585
Operating lease right-of-use assets	2,374	2,591
Goodwill	16,836	16,836
Research and development tax credit receivable	360	332
Other non-current assets	11,768	10,152
Total assets	$ 167,899	$ 164,698
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of operating lease liability	$ 953	$ 934
Accounts payable	18,961	11,433
Accrued expenses	27,642	24,227
Other current liabilities	252	261
Total current liabilities	47,808	36,855
Long-term operating lease liability	1,449	1,690
Royalty financing obligation	34,333	32,760
Other non-current liabilities	5,925	5,654
Total liabilities	89,515	76,959
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; zero issued and outstanding at March 31, 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; 96,097 issued and outstanding at March 31, 2024 and 89,825 issued and outstanding at December 31, 2023	960	898
Additional paid-in capital	874,018	855,452
Accumulated deficit	(772,838)	(745,496)
Accumulated other comprehensive loss	(23,756)	(23,167)
Total shareholders' equity	78,384	87,739
Total liabilities and shareholders' equity	$ 167,899	$ 164,698

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

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (27,342)	$ (30,784)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	541	588
Amortization of debt discount and debt issuance costs	—	1,873
Share-based compensation expense	5,389	1,522
Other adjustments	(719)	(1)
Net changes in assets and liabilities		
Accounts receivable	(10,589)	—
Inventories	(1,260)	—
Prepaid expenses and other current assets	(6,093)	(4,131)
Research and development tax credit receivable	(17)	—
Accounts payable & other current liabilities	7,528	468
Accrued expenses	3,415	348
Other assets and liabilities	(557)	(116)
Net cash used in operating activities	(29,704)	(30,233)
Cash flows from investing activities:		
Proceeds from sales of marketable securities	119,066	15,295
Purchases of marketable securities	(97,679)	(10,229)
Net cash provided by investing activities	21,387	5,066
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	9,250	11,913
Proceeds from stock option exercises and employee share purchase plan	3,940	29
Net cash provided by financing activities	13,190	34,442
Effect of foreign currency exchange rate changes on cash and cash equivalents	(246)	135
Net change in cash and cash equivalents	4,627	9,410
Cash and cash equivalents at January 1,	31,167	73,981
Cash and cash equivalents at March 31,	$ 35,794	$ 83,391

Source: Avadel Pharmaceuticals plc