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

August 9, 2023 at 7:00 AM EDT

-- Successfully commenced U.S. commercial launch of LUMRYZ™-

-- Received final FDA approval for LUMRYZ with orphan drug exclusivity granted through May 1, 2030 --

-- Significant early progress on payor coverage, prescriber certifications and patient enrollments --

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

DUBLIN, Ireland, Aug. 09, 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 second quarter ended June 30, 2023.

"This past quarter has been transformative for our organization, underscored by U.S. FDA approval of LUMRYZ, the first and only once-at-bedtime oxybate therapy for the treatment of cataplexy or EDS in adults with narcolepsy, and subsequent U.S. commercial launch. We are pleased to have completed our first patient enrollments and commercial sales of LUMRYZ within weeks of receiving FDA approval," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "We are also encouraged with the high level of interest from sleep specialists and the initial demand observed across all patient segments. We believe the promising initial launch results we are seeing, combined with our strong commercial capabilities and robust market research, positions us to command a meaningful share of the estimated greater than fifty thousand patients who are eligible for LUMRYZ. In addition to continuing our commercialization efforts, we are focused on expanding the potential of LUMRYZ, with a supplemental NDA filing planned in the second half of 2023 for LUMRYZ in the pediatric narcolepsy population. The fundamentals of our business are strong, and we are poised for long-term growth and value creation, with potential expansion opportunities and a robust cash position to support our mission."

Second Quarter and Recent Company Highlights

LUMRYZ Commercial Updates:

- During the first two months of the U.S. commercial launch of LUMRYZ:
  - Initiated sales of LUMRYZ to the specialty pharmacies in the Company's distribution network.
  - Greater than 1,000 health care providers have completed the LUMRYZ REMS certification process, which enables them to prescribe LUMRYZ to patients.
  - Greater than 400 patients have enrolled in Avadel's RYZUP™ patient support services to begin the process of getting LUMRYZ prescriptions fulfilled and shipped.
- Secured Express Scripts (ESI) coverage on the National Preferred Formulary, effective July 1.

Clinical Updates:

- With final approval on May 1, 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, 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 does not disrupt or fragment sleep, whereas twice-nightly oxybates necessitate a nocturnal awakening to take a second dose, which disrupts sleep architecture in patients with known sleep disorders. The seven-year market exclusivity for LUMRYZ began on the date of FDA approval, May 1, 2023.
- In June, announced publication of data describing clinician preferences among oxybate treatments for patients with narcolepsy.
  - The discrete choice experiment indicated that among sleep clinicians, the frequency of oxybate treatment dosing was the most important driver for overall product choice, improved patient quality of life, and reduced patient anxiety and stress.
  - Once-nightly dosing was preferred over twice-nightly dosing, and these data underscore the unmet need for an oxybate treatment that does not require middle-of-the-night dosing.
- In May, announced new data supporting the clinical profile for LUMRYZ at SLEEP 2023, the 37th annual joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society.
  - With 12 posters presented, including 6 oral presentations, the Company highlighted its leadership in the narcolepsy space, and the data adds to the growing body of evidence demonstrating positive clinical benefit and patient preference of once-at-bedtime LUMRYZ.

- In June, for the third year in a row, Avadel was the lead sponsor of the Academy of Sleep Medicine Foundation's 2023 Young Investigators Research Forum.
- In May, post-hoc analysis of Phase 3 REST-ON Trial of LUMRYZ (sodium oxybate) published in *SLEEP*. The paper, titled "Efficacy of Once-Nightly Sodium Oxybate (FT218) in Narcolepsy Type 1 and Type 2: Post Hoc Analysis From the Phase 3 REST-ON Trial," can be accessed here. By stratifying NT1 and NT2 at baseline in the study design, the REST-ON data provides insight that LUMRYZ improves excessive daytime sleepiness and disrupted nighttime sleep in either narcolepsy type.

Upcoming Milestones:

- On track to submit sNDA for LUMRYZ in pediatric narcolepsy population for treatment of cataplexy or excessive daytime sleepiness (EDS) in the second half of 2023.

Overview of Second Quarter Results

Recognized $1.5 million in net product revenues for the second quarter 2023. Net product revenue consists of LUMRYZ product sales, which was launched in the U.S. on June 5, 2023.

R&D expenses were $4.2 million in the quarter ended June 30, 2023, compared to $4.5 million for the same period in 2022. R&D expense in the current period includes $1.5 million of commercial inventory that was purchased prior to FDA approval of LUMRYZ. Commercial inventory purchased subsequent to FDA approval will be capitalized and expensed through cost of product sales as LUMRYZ is sold.

SG&A expenses were $46.8 million in the quarter ended June 30, 2023, compared to $21.8 million for the same period in 2022. This increase was driven by higher costs for legal fees of $6.9 million, marketing and market research activities of $5.5 million, commercial launch activities of $2.6 million and compensation costs of $3.0 million. Selling, general, and administrative expense in the quarter ended June 30, 2023, also includes a $7.8 million cumulative adjustment for certain compensation awards tied to the achievement of performance conditions.

Net loss for the quarter ended June 30, 2023, was $64.4 million, or ($0.83) per diluted share, compared to net loss of $63.4 million, or ($1.07) per diluted share, for the same period in 2022.

Cash, cash equivalents and marketable securities were $160.5 million as of June 30, 2023. In May 2023, the Company exercised its option to exchange $106.3 million in senior convertible notes due 2027 for approximately 12.3 million American Depositary Shares and cash payment of $1.5 million for accrued interest. The Company has $21.2 million of convertible notes remaining, which will mature in October 2023.

Conference Call

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. 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 Orphan Drug Exclusivity for LUMRYZ and potential benefits resulting from such designation; the success of the commercialization for LUMRYZ; expectations regarding the potential market impact of LUMRYZ; the anticipated market availability and sales opportunity of LUMRYZ; the potential expansion of LUMRYZ into the pediatric narcolepsy population and expected timing thereof; 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 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net product revenue	$ 1,496	$ —	$ 1,496	$ —
Cost of products sold	36	—	36	—
Gross profit	1,460	—	1,460	—
Operating expenses:				
Research and development expenses	4,223	4,541	8,053	11,532
Selling, general and administrative expenses	46,778	21,804	71,246	43,439
Restructuring expense	—	3,592	—	3,592
Total operating expense	51,001	29,937	79,299	58,563
Operating loss	(49,541)	(29,937)	(77,839)	(58,563)
Investment and other income, net	623	192	816	88
Interest expense	(2,295)	(3,506)	(5,554)	(5,523)
Loss on extinguishment of debt	(13,129)	—	(13,129)	—
Loss before income taxes	(64,342)	(33,251)	(95,706)	(63,998)
Income tax provision (benefit)	90	30,193	(490)	25,870
Net loss	$ (64,432)	$ (63,444)	$ (95,216)	$ (89,868)
Net loss per share – basic	$ (0.83)	$ (1.07)	$ (1.35)	$ (1.52)
Net loss per share – diluted	(0.83)	(1.07)	(1.35)	(1.52)
Weighted average number of shares outstanding - basic	77,246	59,037	70,603	58,931
Weighted average number of shares outstanding - diluted	77,246	59,037	70,603	58,931

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

	June 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 49,985	$ 73,981
Marketable securities	110,525	22,518
Accounts receivable, net	1,775	—
Inventories	1,439	—
Research and development tax credit receivable	974	2,248
Prepaid expenses and other current assets	6,532	2,096
Total current assets	171,230	100,843
Property and equipment, net	715	839
Operating lease right-of-use assets	1,235	1,713
Goodwill	16,836	16,836

Research and development tax credit receivable	420	1,232
Other non-current assets	10,540	11,322
Total assets	$ 200,976	$ 132,785
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term debt	$ 20,851	$ 37,668
Current portion of operating lease liability	783	960
Accounts payable	11,786	7,890
Accrued expenses	17,582	7,334
Other current liabilities	500	1,941
Total current liabilities	51,502	55,793
Long-term debt	—	91,614
Long-term operating lease liability	490	780
Other non-current liabilities	5,792	5,743
Total liabilities	57,784	153,930
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 5,194 issued and outstanding at June 30, 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; 89,321 issued and outstanding at June 30, 2023 and 62,878 issued and outstanding at December 31, 2022	893	628
Additional paid-in capital	848,626	589,783
Accumulated deficit	(680,436)	(585,220)
Accumulated other comprehensive loss	(25,943)	(26,341)
Total shareholders' equity (deficit)	143,192	(21,145)
Total liabilities and shareholders' equity (deficit)	$ 200,976	$ 132,785

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

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (95,216)	$ (89,868)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,189	506
Amortization of debt discount and debt issuance costs	2,460	2,229
Changes in deferred taxes	—	25,870
Share-based compensation expense	9,166	3,163
Loss on extinguishment of debt	13,129	—
Other adjustments	42	1,206
Net changes in assets and liabilities		
Accounts receivable	(1,775)	—
Inventories	(1,439)	—
Prepaid expenses and other current assets	(4,400)	13,305
Research and development tax credit receivable	2,127	30
Accounts payable & other current liabilities	2,470	(4,457)
Accrued expenses	10,246	2,559
Other assets and liabilities	(255)	(2,678)
Net cash used in operating activities	(62,256)	(48,135)
Cash flows from investing activities:		
Proceeds from sales of marketable securities	25,618	56,501
Purchases of marketable securities	(113,460)	(2,202)
Net cash (used in) provided by investing activities	(87,842)	54,299

Cash flows from financing activities:		
Proceeds from April 2023 public offering, net of issuance costs	134,151	—
Payments for February 2023 Notes	(17,500)	—
Payments for debt issuance costs	(4,357)	(4,803)
Proceeds from issuance of shares off the at-the-market offering program	11,913	—
Proceeds from stock option exercises and employee share purchase plan	1,779	2,009
Net cash provided by (used in) financing activities	125,986	(2,794)
Effect of foreign currency exchange rate changes on cash and cash equivalents	116	50
Net change in cash and cash equivalents	(23,996)	3,420
Cash and cash equivalents at January 1,	73,981	50,708
Cash and cash equivalents at June 30,	$ 49,985	$ 54,128

Source: Avadel Pharmaceuticals plc