Avadel Pharmaceuticals Provides Corporate Update and Reports Fourth Quarter and Full Year 2022 Financial Results

March 30, 2023

• LUMRYZ™ NDA amendment filedMarch 1 requesting FDA final approval

• Received FDA authorization to import LUMRYZ in advance of final approval decision; shortens timeline between potential approval and product availability

• Secured $200 million of capital to fund the launch of LUMRYZ and extended the maturity of $96.2 million of the convertible notes to 2027

• Launch preparations on track to support U.S. commercial launch of LUMRYZ

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

DUBLIN, Ireland, March 30, 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 fourth quarter ended December 31, 2022.

“2023 is shaping up to be a significant year for Avadel. I am proud of all that our team has recently accomplished, including submitting an amendment to the FDA requesting final approval for LUMRYZ and securing the FDA’s approval of our PLAIR request, which has allowed us to import product into the U.S. ahead of a final approval decision. Collectively, these milestones move us closer to the potential commercialization of LUMRYZ,” said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. “In parallel, the completion of multiple strategic financings in the current market environment reinforces the potential of LUMRYZ and positions us for long-term success as we enter a pivotal stage of growth for the company. I want to thank all stakeholders including patients, healthcare practitioners, and our investors for their strong support during this process. We look forward to our continued progress as we execute on our strategic plan to bring LUMRYZ to the $3 billion plus once-at-bedtime oxybate market.”

Fourth Quarter and Recent Company Highlights

- Recently, Avadel made significant progress advancing LUMRYZ toward a final approval decision and preparing for U.S. commercial launch.
  - On March 1st, the company submitted a minor amendment to the U.S. Food and Drug Administration (“FDA”) requesting final approval of LUMRYZ for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.
    - The Company filed the amendment shortly after Jazz Pharmaceuticals filed a submission with the FDA requesting the delisting of the REMS Patent from FDA’s Orange Book in response to the unanimous 3-0 panel decision of the United States Court of Appeals for the Federal Circuit on February 24, affirming the previous ruling from the U.S. District Court for the Federal District of Delaware.
  - The FDA approved Avadel’s Pre-Launch Activities Important Requests (PLAIR) for LUMRYZ. Through PLAIR, Avadel is able to import tentatively approved LUMRYZ to the U.S. ahead of a final approval decision.
    - Importation of LUMRYZ, prior to a potential final approval, enables Avadel to shorten the duration of time between a final FDA approval and commercial availability for people with narcolepsy.
  - Advancements in commercial preparations ahead of potential U.S. launch of LUMRYZ, including finalization of specialty pharmacy network, patient services center and the LUMRYZ REMS program.
  - Continued engagement with key stakeholders including sleep specialists and payers while expanding our customer facing teams including medical science liaisons, sales leadership, territory business managers, and field reimbursement specialists.
- Successfully executed multiple strategic financing activities and secured $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 potential 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 in the U.S.
  - Completed an equity offering with gross proceeds of $125 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.

- Announced multiple data sets supporting the LUMRYZ product profile, including:
    - The publication of real-world data describing the risk of accidental dosing errors with immediate-release twice-nightly oxybate, including an analysis on post-marketing safety surveillance data from the FDA Adverse Event Reporting System (FAERS).
    - Multiple presentations at the American Neurological Association (ANA) annual meeting in October describing demographic characteristics and comorbidities of patients with narcolepsy and reinforcing positive data from completed Phase 3 REST-ON trial and patient and clinician preference for once-nightly over twice-nightly dosing.
    - Posters at the American College of Chest Physicians (CHEST) meeting in October featuring updated results from patient preference and nocturnal adverse event questionnaires from the RESTORE study with 94% of patients who switched from twice-nightly oxybates stating prefer for the once-at-bedtime dosing regime, as well as confirming challenges related to the middle-of-the-night dose.
- Expanded patent exclusivity for LUMRYZ with 5 additional U.S. patents for a current total of 13 patents, providing Orange Book-listable patent protection into early 2042.

Overview of Fourth Quarter Results

R&D expenses were $6.2 million in the quarter ended December 31, 2022, compared to $2.1 million for the same period in 2021. The period-over-period increase was primarily attributed to an increase in purchases of the active pharmaceutical ingredient used in the manufacture of LUMRYZ.

SG&A expenses were $17.0 million in the quarter ended December 31, 2022, compared to $21.0 million for the same period in 2021. The period-over-period decrease is the result of a number of factors including lower marketing and commercial spend. These decreases were partially offset by higher legal costs.

Net loss for the quarter ended December 31, 2022, was $27.5 million, or ($0.44) per diluted share, compared to net loss of $22.3 million, or ($0.38) per diluted share, for the same period in 2021.

Cash, cash equivalents and marketable securities were $96.5 million as of December 31, 2022. 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.

Conference Call

Avadel will host a conference all and live audio webcast to discuss its fourth quarter and full year quarter 2022 financial results and provide a corporate update today at 8:30 a.m. ET. To access the live conference call, please register here. A live audio webcast of the call and accompanying slide presentation will also be available in 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

LUMRYZ is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once at bedtime for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy.

In March 2020, Avadel completed the REST-ON study, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial, to assess the efficacy and safety of LUMRYZ in patients with narcolepsy. Among the three co-primary endpoints, LUMRYZ demonstrated statistically significant and clinically meaningful results in EDS, the clinician's overall assessment of the patient's functioning, and reduction in cataplexy attacks, for all three evaluated does when compared to placebo.

In January 2018, the U.S. Food and Drug Administration (FDA) granted LUMRYZ Orphan Drug Designation for the treatment of narcolepsy based on the plausible hypothesis that LUMRYZ may be safer than the twice-nightly formulation of sodium oxybate already approved by the FDA due to the ramifications associated with dosing regimen of that product. LUMRYZ is currently under review by the FDA.

On July 18, 2022, the FDA tentatively approved the LUMRYZ NDA for the treatment of cataplexy or EDS in adults with narcolepsy. Avadel submitted a minor amendment to the FDA on March 1, 2023, requesting final approval of LUMRYZ. This minor amendment submission occurred shortly after the delisting of the REMS Patent from FDA's Orange Book by Jazz Pharmaceuticals in response to the unanimous 3-0 panel decision by the United States Court of Appeals for the Federal Circuit on February 24, affirming the previous ruling from the United States District Court for the Federal District of Delaware, ordering Jazz to do so.

Avadel is currently evaluating the long-term safety and tolerability of LUMRYZ in the open-label RESTORE clinical study. For more information, visit: www.restore-narcolepsy-study.com.

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. Our current lead drug candidate, LUMRYZ, is an investigational formulation of sodium oxybate leveraging our proprietary drug delivery technology and designed to be taken once at bedtime for the treatment of cataplexy or EDS in adults with narcolepsy. For more information, please visit www.avadel.com.

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 FDA's potential final approval of LUMRYZ, including the timing of thereof, the Company's preparation for launch of LUMRYZ, the potential time savings between a potential final FDA approval and commercial launch of LUMRYZ attributable to the FDA's approval of the PLAIR; the market acceptance of LUMRYZ (if approved), the total addressable market size for sodium oxybate, the Company's anticipated uses of capital, including the proceeds from the recent financing; the expected maturity of the Company's convertible notes; and the anticipated duration and scope of patent exclusivity for LUMRYZ. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "could," "believe," "potential," "can," "would," "seek," "expect," "look forward," "on track," "guidance," "anticipate," "estimate," "project," "investigational," "pipeline," "launch," "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 December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development expenses	$ 6,235	$ 2,110	$ 20,700	$ 17,104
Selling, general and administrative expenses	16,981	21,026	74,516	68,495
Restructuring (income) expense	(178)	—	3,345	(53)
Total operating expenses	23,038	23,136	98,561	85,546
Operating loss	(23,038)	(23,136)	(98,561)	(85,546)
Investment and other (expense) income, net	(1,072)	646	(536)	2,343
Interest expense	(3,255)	(4,154)	(12,342)	(9,942)
Loss before income taxes	(27,365)	(26,644)	(111,439)	(93,145)
Income tax provision (benefit)	85	(4,343)	26,025	(15,816)
Net loss	$ (27,450)	$ (22,301)	$ (137,464)	$ (77,329)
Net loss per share - basic	$ (0.44)	$ (0.38)	$ (2.29)	$ (1.32)
Net loss per share - diluted	(0.44)	(0.38)	(2.29)	(1.32)
Weighted average number of shares outstanding - basic	62,276	58,620	60,094	58,535
Weighted average number of shares outstanding - diluted	62,276	58,620	60,094	58,535

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

	December 31, 2022	December 31, 2021

ASSETS		
Current assets:		
Cash and cash equivalents	$ 73,981	$ 50,708
Marketable securities	22,518	106,513
Research and development tax credit receivable	2,248	2,443
Prepaid expenses and other current assets	2,096	32,826
Total current assets	100,843	192,490
Property and equipment, net	839	285
Operating lease right-of-use assets	1,713	2,652
Goodwill	16,836	16,836
Research and development tax credit receivable	1,232	1,225
Other non-current assets	11,322	33,777
Total assets	$ 132,785	$ 247,265
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 37,668	$ —
Current portion of operating lease liability	960	900
Accounts payable	7,890	7,679
Accrued expenses	7,334	7,151
Other current liabilities	1,941	5,270
Total current liabilities	55,793	21,000
Long-term debt	91,614	142,397
Long-term operating lease liability	780	1,707
Other non-current liabilities	5,743	3,917
Total liabilities	153,930	169,021
Shareholders' (deficit) equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at December 31, 2022 and 2021, respectively	5	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 62,878 and 58,620 issued and outstanding at December 31, 2022 and 2021, respectively	628	586
Additional paid-in capital	589,783	549,349
Accumulated deficit	(585,220)	(447,756)
Accumulated other comprehensive loss	(26,341)	(23,940)
Total shareholders' (deficit) equity	(21,145)	78,244
Total liabilities and shareholders' (deficit) equity	$ 132,785	$ 247,265

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

	Twelve Months Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (137,464)	$ (77,329)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,493	815
Amortization of debt discount and debt issuance costs	6,052	1,248
Changes in deferred tax	26,025	(15,666)
Share-based compensation expense	7,013	8,872
Other adjustments	2,042	1,055
Net changes in assets and liabilities		
Prepaid expenses and other current assets	30,815	(439)
Research and development tax credit receivable	30	2,796
Accounts payable & other current liabilities	(3,108)	4,232
Accrued expenses	227	895
Other assets and liabilities	(3,429)	(3,789)

Net cash used in operating activities	(70,304)	(77,310)
Cash flows from investing activities:		
Purchases of property and equipment	(716)	(26)
Proceeds from the disposition of the Hospital Products	—	16,500
Proceeds from sales of marketable securities	83,828	102,224
Purchases of marketable securities	(3,414)	(61,769)
Net cash provided by investing activities	79,698	56,929
Cash flows from financing activities:		
Payments for debt issuance costs	(4,804)	—
Payments for extinguishment of February 2023 Notes	(8,653)	—
Proceeds from stock option exercises and employee share purchase plan	2,682	263
Proceeds from issuance of shares off the at-the-market offering program	25,318	—
Net cash provided by financing activities	14,543	263
Effect of foreign currency exchange rate changes on cash and cash equivalents	(664)	(896)
Net change in cash and cash equivalents	23,273	(21,014)
Cash and cash equivalents at January 1	50,708	71,722
Cash and cash equivalents at December 31	$ 73,981	$ 50,708

Source: Avadel Pharmaceuticals plc