Avadel Pharmaceuticals Provides Corporate Update and Reports Second Quarter 2022 Financial Results

August 9, 2022

- *Received tentative approval for LUMRYZ™ (sodium oxybate) extended-release for oral suspension from FDA on July 18*
- *Advancing key activities to potentially accelerate final approval and shorten launch window of LUMRYZ*
- *Extended cash runway to final FDA decision*
- *Management to host a conference call today at 8:00 a.m. ET*

DUBLIN, Ireland, Aug. 09, 2022 (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, 2022.

"The receipt of tentative approval from the FDA marks an important milestone in our pursuit to bring LUMRYZ to all oxybate eligible people living with narcolepsy. In addition to validating LUMRYZ's strong clinical and safety profile, we now know the timing to a potential final approval is June 2023 or sooner," said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. "We will continue to aggressively pursue all options for this clear unmet need in the $3 billion plus once nightly oxybate market to accelerate a final approval decision prior to June 2023 and launch as quickly as possible thereafter."

Second Quarter and Recent Company Highlights

- Received tentative approval for LUMRYZ, or FT218, Avadel's once-at-bedtime investigational formulation of extended-release sodium oxybate for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy from U.S. Food and Drug Administration (FDA) on July 18.
  - Receipt of tentative approval validates LUMRYZ's safety profile and clinical efficacy, and allows the company to accelerate potential launch preparations.
  - Confirms that the latest date of a potential final approval is after expiry of the remaining REMS patent on June 17, 2023.
- Advancing the following actions to potentially accelerate FDA's final approval decision for LUMRYZ prior to June 2023:
  - Filed a lawsuit against the FDA in the U.S. District Court for the District of Columbia alleging that the FDA's decision requiring Avadel to file a patent certification regarding U.S. Patent No. 8,731,963 (the "REMS patent") was arbitrary, capricious and contrary to law, and asks the Court to vacate the FDA's decision and order FDA to take final action on the LUMRYZ NDA.
  - Pursuing delisting action in the U.S. District Court for the District of Delaware to remove the REMS patent, which expires on June 17, 2023, from the FDA's Orange Book.
  - Preparing for a claim construction hearing ("Markman hearing") in the existing patent litigation in the U.S. District Court for the District of Delaware which is scheduled for August 31, 2022. The Court has previously stated that claim construction was needed prior to ruling on the motion to delist the REMS patent from the Orange Book.
- Continuing activities to prepare for a launch of LUMRYZ, including shortening the time of product availability post approval by:
  - Building commercial inventory in preparation for potential launch
  - Completing the build out of our LUMRYZ REMS
  - Continued engagement with sleep specialists and patients through disease education, leveraging Narcolepsy Disrupts campaign which is actively enrolling patients
- Presented clinical data at SLEEP 2022, including a total of 9 posters:
  - Interim data from the ongoing RESTORE open-label extension/switch study of our LUMRYZ drug candidate:
    - 92.5% of switched patients stated they preferred the once-nightly dosing regimen over twice-nightly
    - Additional validation that switch patients had difficulty in preparing their second dose of twice-nightly oxybate products, including 64% of patients accidentally missing their second dose in the last 3 months, and 82% of these patients feeling worse the next day
    - 72% of switch patients reported taking the second dose of a twice-nightly oxybate was somewhat, quite a bit or extremely inconvenient

        - Most participants (62%) switching from twice-nightly oxybate formulations to LUMRYZ had a stable dose of LUMRYZ equal to their starting daily dosage of twice-nightly oxybate
        - Participants not currently taking twice-nightly oxybate formulations (including oxybate naive participants) reached a stable dose of LUMRYZ with 2–4 dose titrations within 4 weeks.
        - Continued affirmation of the safety and tolerability profile, with known side effects of oxybates and low rate of discontinuation from side effects
    - 5 post hoc analyses from the completed pivotal Phase 3 REST-ON clinical trial of LUMRYZ, which reinforce the strong clinical efficacy data, including in sub-groups of NT1/NT2 and those with or without concomitant stimulants on disturbed nocturnal sleep
    - Confirmed once-at-bedtime dosing most important oxybate treatment attribute in a second discrete choice experiment (DCE) with patients and clinicians
- In June, the Company announced an optimized cost structure to reduce cash operating expenses and extend its cash runway to the middle of 2023. Quarterly cash operating expenses, excluding inventory purchases, are expected to be reduced to $12 - $14 million.

Overview of Second Quarter Results

R&D expenses were $4.5 million in the quarter ended June 30, 2022, compared to $6.8 million for the same period in 2021. The period-over-period decrease was primarily attributed to lower purchases of active pharmaceutical ingredients used in the manufacture of LUMRYZ.

SG&A expenses were $21.8 million in the quarter ended June 30, 2022, compared to $15.2 million for the same period in 2021. The period-over-period increase is primarily the result of fees associated with the exchange and an eight-month maturity extension on $117.4 million of the $143.8 million of senior unsecured convertible notes due 2023. Higher legal and compensation costs were offset by the reversal of expenses previously recorded for stock based compensation and bonuses for employees impacted by the restructuring.

A restructuring charge of $3.6 million was recorded in the quarter ended June 30, 2022, primarily for severance benefits associated with a nearly 50% reduction in the Company's workforce. The workforce reduction will be completed during the third quarter of 2022 and the Company expects to reduce quarterly cash operating expenses, excluding inventory purchases, to $12 - $14 million.

Income tax expense was $30.2 million in the quarter ended June 30, 2022, compared to income tax benefit of $3.8 million for the same period in 2021. Income tax expense in the current quarter is due primarily to a valuation allowance recorded against deferred tax assets.

Net loss for the quarter ended June 30, 2022 was $63.4 million, or ($1.07) per diluted share, compared to net loss of $19.6 million, or ($0.33) per diluted share, for the same period in 2021.

Cash, cash equivalents and marketable securities were $104.1 million as of June 30, 2022. Subsequent to June, Avadel received $9.9 million of tax refunds and expects to receive an additional $7.3 million of tax refunds. The Company has $26.4 million of convertible debt that matures in February 2023 and $117.4 million that matures in October 2023.

Conference Call

To access the conference call, investors are invited to dial (833)-630-0586 or (412)-317-6701 (International). When joining the call, please ask to join the Avadel Pharmaceuticals call. A live audio webcast 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.

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. Final approval of LUMRYZ cannot be granted until the expiration or other disposition of U.S. Patent No. 8,731,963, which expires on June 17, 2023.

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 timing of the FDA's final approval of LUMRYZ, planned efforts of the Company to accelerate the FDA's final approval and to accelerate the timing between final approval and launch as well as the expected results thereof; the estimated charges and costs expected to be incurred in connection with launch (if approved) and projected cost savings in connection with cost structure optimization efforts; the market acceptance of LUMRYZ (if approved), the continued advancement of the RESTORE study to generate long-term safety, tolerability, and efficacy data for LUMRYZ; the Company's cash runway and anticipated uses of capital; and the expected maturity of the Company's convertible debt. 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, 2021, which was filed with the Securities and Exchange Commission (SEC) on March 16, 2022, 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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development expenses	$ 4,541	$ 6,762	$ 11,532	$ 10,614
Selling, general and administrative expenses	21,804	15,174	43,439	26,186
Restructuring expense (income)	3,592	—	3,592	(53)
Total operating expense	29,937	21,936	58,563	36,747
Operating loss	(29,937)	(21,936)	(58,563)	(36,747)
Investment and other income, net	192	432	55	1,042
Interest expense	(3,506)	(1,930)	(5,523)	(3,859)
Gain from release of certain liabilities	—	88	33	166
Loss before income taxes	(33,251)	(23,346)	(63,998)	(39,398)
Income tax provision (benefit)	30,193	(3,765)	25,870	(6,372)
Net loss	$ (63,444)	$ (19,581)	$ (89,868)	$ (33,026)
Net loss per share – basic	$ (1.07)	$ (0.33)	$ (1.52)	$ (0.56)
Net loss per share – diluted	(1.07)	(0.33)	(1.52)	(0.56)
Weighted average number of shares outstanding - basic	59,037	58,488	58,931	58,465
Weighted average number of shares outstanding - diluted	59,037	58,488	58,931	58,465

AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	June 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 54,128	$ 50,708
Marketable securities	49,993	106,513
Research and development tax credit receivable	2,205	2,443
Prepaid expenses and other current assets	19,387	32,826
Total current assets	125,713	192,490
Property and equipment, net	252	285
Operating lease right-of-use assets	2,180	2,652
Goodwill	16,836	16,836
Research and development tax credit receivable	1,187	1,225
Other non-current assets	11,770	33,777
Total assets	$ 157,938	$ 247,265
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 26,241	$ —
Current portion of operating lease liability	932	900
Accounts payable	7,318	7,679
Accrued expenses	9,675	7,151
Other current liabilities	2,051	5,270
Total current liabilities	46,217	21,000
Long-term debt	108,074	142,397
Long-term operating lease liability	1,263	1,707
Other non-current liabilities	5,716	3,917
Total liabilities	161,270	169,021
Shareholders' (deficit) equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at June 30, 2022 and 488 issued and outstanding at December 31, 2021	5	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 59,038 issued and outstanding at June 30, 2022 and 58,620 issued and outstanding at December 31, 2021	590	586
Additional paid-in capital	560,025	549,349
Accumulated deficit	(537,624)	(447,756)
Accumulated other comprehensive loss	(26,328)	(23,940)
Total shareholders' (deficit) equity	(3,332)	78,244
Total liabilities and shareholders' (deficit) equity	$ 157,938	$ 247,265

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (89,868)	$ (33,026)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	506	417
Amortization of debt discount and debt issuance costs	2,229	625
Change in deferred taxes	25,870	(6,228)
Stock-based compensation expense	3,163	3,729
Gain from release of certain liabilities	(33)	(166)
Other adjustments	1,239	757

Net changes in assets and liabilities		
Prepaid expenses and other current assets	13,305	(3,106)
Research and development tax credit receivable	30	3,078
Accounts payable & other current liabilities	(4,457)	176
Accrued expenses	2,559	1,199
Other assets and liabilities	(2,678)	(1,021)
Net cash used in operating activities	(48,135)	(33,566)
Cash flows from investing activities:		
Purchases of property and equipment	—	(26)
Proceeds from the disposition of the hospital products	—	16,500
Proceeds from sales of marketable securities	56,501	66,213
Purchases of marketable securities	(2,202)	(53,372)
Net cash provided by investing activities	54,299	29,315
Cash flows from financing activities:		
Payments for debt issuance costs	(4,803)	—
Proceeds from stock option exercises and employee share purchase plan	2,009	149
Net cash (used in) provided by financing activities	(2,794)	149
Effect of foreign currency exchange rate changes on cash and cash equivalents	50	(478)
Net change in cash and cash equivalents	3,420	(4,580)
Cash and cash equivalents at January 1,	50,708	71,722
Cash and cash equivalents at June 30,	$ 54,128	$ 67,142

Source: Avadel Pharmaceuticals plc