Avadel Pharmaceuticals Provides Corporate Update and Reports Fourth Quarter and Full Year 2021 Financial Results

March 17, 2022

- *FDA review of NDA for FT218 is ongoing; commercial and launch preparations on-track to support potential commercial launch*
- *Expanded the robust portfolio of data supporting the potential impact of FT218 on people living with narcolepsy with multiple presentations at World Sleep 2022*
- *Appointed Dr. Douglas Williamson as Chief Medical Officer and Brandi Robinson as Senior Vice President, Corporate Affairs*
- *Extended the maturity on $117.4 million of convertible notes to October 2, 2023*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, March 17, 2022 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on transforming medicines to transform lives, today provided a corporate update and announced its financial results for the fourth quarter and full year ended December 31, 2021.

“Avadel remains laser focused on working with FDA to complete the review for FT218, our once-nightly investigational sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy for people living with narcolepsy. We have been informed very recently from the FDA that they are actively working on the NDA and expect to get back to us in the near future. During this entire review process to date, we have not learned anything that compromises our belief in the full approvability of FT218,” said Greg Divis, Chief Executive Officer of Avadel Pharmaceuticals. “We are proud of the progress we’ve made during this past year, including multiple data presentations supporting the growing body of clinical evidence for FT218, the progression of the RESTORE study, expanding our organizational capabilities and readiness for the potential launch of FT218, and most recently extending the maturity date of $117.4 million of our senior convertible notes to October 2023. We will continue to work diligently towards our mission of transforming medicines to transform lives by bringing FT218 to people living with narcolepsy.”

Fourth Quarter and Recent Company Highlights

- Review of the New Drug Application (NDA) for FT218 by the U.S. Food and Drug Administration (FDA) remains on-going. The FDA has maintained that they have no outstanding questions or information requests and do not currently need any additional data.
- Presented multiple posters at World Sleep 2022, including new data that contributes to the growing body of evidence to support the potential benefit of FT218 for people living with narcolepsy.
    - In post-hoc analyses from REST-ON, FT218 demonstrated improvement in subjective measures of daytime sleepiness, sleep quality and refreshing nature of sleep as early as week 1 with the 4.5-g starting dose, with even greater improvement at week 2 soon after starting the 6-g dose compared to placebo.
    - In the first presentation of an interim safety analysis from the ongoing RESTORE study, FT218 has generally been well tolerated, with some participants receiving therapy for more than 18 months; no new safety signals have emerged.
    - The Discrete Choice Experiment (DCE) confirmed that once-nightly dosing, when compared to twice-nightly dosing, was the most important attribute driving both patient and clinician preference for overall oxybate product choice, as well as patient quality of life and reduction of patient anxiety/stress; dosing frequency was also viewed as a more important attribute versus sodium content.
        - The DCE was designed to understand patient and healthcare provider preferences associated with oxybate treatments for narcolepsy and perspectives on narcolepsy disease burden, treatment approaches and satisfaction with current narcolepsy treatment options.
- Expanded our management team to support continued advancement of FT218.
    - We announced the appointment of Dr. Douglas Williamson, MBChB, as Chief Medical Officer. Dr. Williamson brings more than 25 years of scientific, clinical and medical experience primarily focused on neuroscience to Avadel. He most recently served as Senior Vice President, Head of U.S. R&D and Deputy Global Chief Medical Officer of Lundbeck where he led the transformation of the U.S. R&D organization and oversaw multiple cross-functional teams.

    - We welcomed Brandi Robinson as Senior Vice President, Corporate Affairs. Brandi has more than 25 years of experience in the pharmaceutical, medical device and consumer health industries.
- Launch readiness activities remain on-track to support the potential commercialization of FT218, if approved, as the first and only once-at-bedtime option for managing excessive daytime sleepiness (EDS) and cataplexy in narcolepsy.
- Continued to advance the RESTORE open-label extension/switch study of FT218 designed to generate long-term safety, tolerability, and efficacy data, as well as data on switching from twice-nightly oxybates and patient preference.
    - Avadel plans to continue presenting data from RESTORE study on patient preference to dosing regimens, as well as nocturnal experiences when using twice-nightly sodium, at future medical congresses.
- Announced an exchange and an eight month maturity extension on $117.4 million of the $143.8 million of senior unsecured convertible notes due 2023.
    - $117.4 million of convertible notes that were exchanged mature on October 2, 2023.
    - $26.4 million remaining from the 2023 convertible notes mature on February 1, 2023.

Overview of Fourth Quarter Results

R&D expenses were $2.1 million in the quarter ended December 31, 2021, compared to $5.3 million for the same period in 2020. The period-over-period decrease was primarily attributed to lower clinical expenses and purchases of active pharmaceutical ingredients used in the research and development of FT218 during the current period.

SG&A expenses were $21.0 million in the quarter ended December 31, 2021, compared to $9.0 million for the same period in 2020. The period-over-period increase is the result of a number of factors including commercial launch planning costs related to FT218, higher legal and professional fees, and higher compensation costs associated with higher headcount, primarily in the areas of commercial and medical affairs.

Income tax benefit was $4.3 million in the quarter ended December 31, 2021, compared to income tax benefit of $2.9 million for the same period in 2020.

Net loss for the quarter ended December 31, 2021 was $22.3 million, or ($0.38) per diluted share, compared to net loss of $11.3 million, or ($0.19) per diluted share, for the same period in 2020.

Cash, cash equivalents and marketable securities were $157.2 million as of December 31, 2021. 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 (844) 388-0559 (U.S. and Canada) or (216) 562-0393 (International). The conference ID number is 1878871. 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 FT218

FT218 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 excessive daytime sleepiness (EDS) or cataplexy 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 FT218 in patients with narcolepsy. Among the three co-primary endpoints, FT218 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 doses when compared to placebo.

In January 2018, the U.S. Food and Drug Administration (FDA) granted FT218 Orphan Drug Designation for the treatment of narcolepsy based on the plausible hypothesis that FT218 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. FT218 is currently under review by the FDA.

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, FT218, 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 excessive daytime sleepiness and cataplexy 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 review of the NDA for FT218, the commercial launch of FT218 (if approved), the market acceptance of FT218 (if approved), the continued advancement of the RESTORE study to generate long-term safety, tolerability, and efficacy data for FT218, and the expected maturity of the Company's 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, 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) INCOME
(In thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
	(Unaudited)	*(Unaudited)*		
Product sales	$ —	$ —	$ —	$ 22,334
Operating expenses:				
Cost of products	—	—	—	5,742
Research and development expenses	2,110	5,286	17,104	20,442
Selling, general and administrative expenses	21,026	8,974	68,495	32,405
Intangible asset amortization	—	—	—	406
Changes in fair value of contingent consideration	—	—	—	3,327
Gain on sale of Hospital Products	—	—	—	(45,760)
Restructuring income	—	—	(53)	(43)
Total operating expenses	23,136	14,260	85,546	16,519
Operating (loss) income	(23,136)	(14,260)	(85,546)	5,815
Investment and other income (expense), net	595	74	2,126	(832)
Interest expense	(4,154)	(3,308)	(9,942)	(12,994)
Gain from release of certain liabilities	51	3,364	217	3,364
Other expense - changes in fair value of contingent consideration payable	—	—	—	(435)
Loss before income taxes	(26,644)	(14,130)	(93,145)	(5,082)
Income tax benefit	(4,343)	(2,852)	(15,816)	(12,110)
Net (loss) income	$ (22,301)	$ (11,278)	$ (77,329)	$ 7,028
Net (loss) income per share - basic	$ (0.38)	$ (0.19)	$ (1.32)	$ 0.13
Net (loss) income per share - diluted	$ (0.38)	$ (0.19)	$ (1.32)	$ 0.13
Weighted average number of shares outstanding - basic	58,620	58,325	58,535	52,996
Weighted average number of shares outstanding - diluted	58,620	58,325	58,535	54,941

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		

Cash and cash equivalents	$	50,708	$	71,722
Marketable securities		106,513		149,680
Research and development tax credit receivable		2,443		3,326
Prepaid expenses and other current assets		32,826		38,726
Total current assets		192,490		263,454
Property and equipment, net		285		359
Operating lease right-of-use assets		2,652		2,604
Goodwill		16,836		16,836
Research and development tax credit receivable		1,225		3,445
Other non-current assets		33,777		24,939
Total assets	$	247,265	$	311,637
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current liabilities:				
Current portion of operating lease liability	$	900	$	474
Accounts payable		7,679		2,934
Accrued expenses		7,151		6,501
Other current liabilities		5,270		5,200
Total current liabilities		21,000		15,109
Long-term debt		142,397		128,210
Long-term operating lease liability		1,707		1,840
Other non-current liabilities		3,917		4,212
Total liabilities		169,021		149,371
Shareholders' equity:				
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at December 31, 2021 and 2020, respectively		5		5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 58,620 and 58,396 issued and outstanding at December 31, 2021 and 2020, respectively		586		583
Additional paid-in capital		549,349		566,916
Accumulated deficit		(447,756)		(384,187)
Accumulated other comprehensive loss		(23,940)		(21,051)
Total shareholders' equity		78,244		162,266
Total liabilities and shareholders' equity	$	247,265	$	311,637

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

	Twelve Months Ended December 31,			
	2021		**2020**	
Cash flows from operating activities:				
Net (loss) income	$	(77,329)	$	7,028
Adjustments to reconcile net (loss) income to net cash used in operating activities:				
Depreciation and amortization		815		1,690
Remeasurement of acquisition-related contingent consideration		—		3,327
Remeasurement of financing-related contingent consideration		—		435
Amortization of debt discount and debt issuance costs		1,248		6,524
Changes in deferred tax		(15,666)		(7,431)
Share-based compensation expense		8,872		2,999
Gain on the disposition of the Hospital Products		—		(45,760)
Gain from the release of certain liabilities		(217)		(3,364)
Other adjustments		1,272		142
Net changes in assets and liabilities				
Accounts receivable		—		8,281
Inventories, net		—		(1,352)
Prepaid expenses and other current assets		(439)		1,863
Research and development tax credit receivable		2,796		2,213

Accounts payable & other current liabilities	4,232	(2,788)
Accrued expenses	895	(13,226)
Earn-out payments for contingent consideration in excess of acquisition-date fair value	—	(5,323)
Royalty payments for contingent consideration payable in excess of original fair value	—	(866)
Other assets and liabilities	(3,789)	(3,126)
Net cash used in operating activities	(77,310)	(48,734)
Cash flows from investing activities:		
Purchases of property and equipment	(26)	(98)
Proceeds from the disposition of the Hospital Products	16,500	25,500
Proceeds from sales of marketable securities	102,224	36,284
Purchases of marketable securities	(61,769)	(131,407)
Net cash provided by (used in) investing activities	56,929	(69,721)
Cash flows from financing activities:		
Proceeds from the February 2020 private placement	—	60,570
Proceeds from the May 2020 public offering	—	116,924
Proceeds from issuance of ordinary shares	263	2,189
Net cash provided by financing activities	263	179,683
Effect of foreign currency exchange rate changes on cash and cash equivalents	(896)	720
Net change in cash and cash equivalents	(21,014)	61,948
Cash and cash equivalents at January 1	71,722	9,774
Cash and cash equivalents at December 31	$ 50,708	$ 71,722

Source: Avadel Pharmaceuticals plc