Avadel Pharmaceuticals Provides Corporate Update and Reports Third Quarter 2021 Financial Results

November 8, 2021

- *FDA review of NDA for FT218 ongoing; commercial and launch preparations progressing*
- *Presentation of new data from pivotal REST-ON clinical trial at CHEST 2021 demonstrating that treatment with FT218 causes meaningful improvement in cataplexy attacks and measurements of EDS with a dosing regimen preferred by patients*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, Nov. 08, 2021 (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 third quarter ended September 30, 2021.

“The need for patients living with the chronic, debilitating condition of narcolepsy to have a single bedtime dose of sodium oxybate is clear. We are confident in the strength of our data and our regulatory filing strategy for FT218, as the FDA continues their review of our NDA. Importantly, there are no outstanding requests from the FDA at this time, and questions previously received have been addressed. We remain committed to patients and sleep specialists, demonstrated by the significant advances we made during 2021 to support a successful launch of FT218, if approved,” said Greg Divis, Chief Executive Officer of Avadel. “This quarter, we published the primary REST-ON results in the SLEEP journal and continued to externalize the robust dataset supporting the potential of FT218 in various scientific congresses. Additionally, payor discussions continue to advance, and we are growing our commercial team, all with the vision of disrupting the narcolepsy market and fulfilling our promise to the narcolepsy community by bring FT218 to patients.”

Third Quarter and Recent Company Highlights

- In October 2021, the U.S. Food and Drug Administration (FDA) informed the company that the review of its New Drug Application (NDA) for FT218 was ongoing beyond its previously assigned target action date.
- Continued preparations and launch readiness activities for the potential commercialization of FT218 as the first and only once-at-bedtime option for managing excessive daytime sleepiness (EDS) and cataplexy in narcolepsy
- Multiple presentations and publications in peer-reviewed forums of data from the pivotal Phase 3 REST-ON study of FT218 throughout the quarter, including:
  - Published the previously announced primary results in SLEEP, the journal of the Sleep Research Society
  - Presented new data at the American College of Chest Physicians (CHEST) annual meeting supporting the clinical benefit of once-at-bedtime FT218 and patient preference for once-nightly dosing:
    - New post-hoc responder analyses demonstrated FT218 treatment was associated with statistically significant improvements compared to placebo on the number of weekly cataplexy episodes and statistically significant improvements compared to placebo on mean sleep latency
    - Discrete choice experiment demonstrated that the strongest driver of patient preference for sodium oxybate was dosing frequency with once-nightly dosing preferred
  - Presented encore posters featuring post hoc analyses from the REST-ON study at the meeting of the American Neurological Association
- Progressed 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 present data from RESTORE study on patient preference to once-nightly or twice-nightly dosing regimens, as well as nocturnal experiences when using twice-nightly sodium, at future medical congresses

Overview of Third Quarter Results

R&D expenses were $4.4 million in the quarter ended September 30, 2021, compared to $5.6 million for the same period in 2020. The decrease on a period-over-period basis was primarily attributed to lower clinical studies expenses and purchases of active pharmaceutical ingredients used in the research and development of FT218 during the current period.

SG&A expenses were $21.3 million in the quarter ended September 30, 2021, compared to $8.4 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 $5.1 million in the quarter ended September 30, 2021, compared to income tax benefit of $5.0 million for the same period in 2020.

Net loss for the quarter ended September 30, 2021 was $22.0 million, or ($0.38) per diluted share, compared to net loss of $11.7 million, or ($0.20) per diluted share, for the same period in 2020.

Cash, cash equivalents and marketable securities were $181.1 million as September 30, 2021. The Company has convertible debt of $143.8 million due in February 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 6187211. 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 does 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 or 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 sufficiency of data supporting the NDA for FT218, the commercial launch of FT218 (if approved), the market acceptance of FT218 (if approved), and the advancement and expected timing of the RESTORE study to generate long-term safety, tolerability, and efficacy data for FT218, and the publication of data from the RESTORE study. 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, 2020, which was filed with the Securities and Exchange Commission (SEC) on March 9, 2021 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.

Investor Contact:
Courtney Turiano
Stern Investor Relations, Inc.
Courtney.Turiano@sternir.com
(212) 698-8687

Media Contact:
Nicole Raisch Goelz
Real Chemistry
ngoelz@realchemistry.com
(408) 568-4292

AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF (LOSS) INCOME
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,	Nine Months Ended September 30,

	2021	2020	2021	2020
Product sales	$ —	$ —	$ —	$ 22,334
Operating expenses:				
Cost of products	—	—	—	5,742
Research and development expenses	4,380	5,569	14,994	15,156
Selling, general and administrative expenses	21,283	8,423	47,469	23,431
Intangible asset amortization	—	—	—	406
Changes in fair value of contingent consideration	—	(69)	—	3,327
Gain on sale of Hospital Products	—	—	—	(45,760)
Restructuring income	—	(226)	(53)	(43)
Total operating expense	25,663	13,697	62,410	2,259
Operating (loss) income	(25,663)	(13,697)	(62,410)	20,075
Investment and other income (expense), net	489	213	1,531	(906)
Interest expense	(1,929)	(3,259)	(5,788)	(9,686)
Gain from release of certain liabilities	—	—	166	—
Other expense - changes in fair value of contingent consideration payable	—	—	—	(435)
(Loss) income before income taxes	(27,103)	(16,743)	(66,501)	9,048
Income tax benefit	(5,101)	(5,040)	(11,473)	(9,258)
Net (loss) income	$ (22,002)	$ (11,703)	$ (55,028)	$ 18,306
Net (loss) income per share - basic	$ (0.38)	$ (0.20)	$ (0.94)	$ 0.36
Net (loss) income per share - diluted	(0.38)	(0.20)	(0.94)	0.35
Weighted average number of shares outstanding - basic	58,585	58,213	58,506	51,206
Weighted average number of shares outstanding - diluted	58,585	58,213	58,506	52,849

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

	September 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,169	$ 71,722
Marketable securities	122,924	149,680
Research and development tax credit receivable	2,493	3,326
Prepaid expenses and other current assets	22,234	38,726
Total current assets	205,820	263,454
Property and equipment, net	304	359
Operating lease right-of-use assets	2,070	2,604
Goodwill	16,836	16,836
Research and development tax credit receivable	961	3,445
Other non-current assets	38,098	24,939
Total assets	$ 264,089	$ 311,637
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of operating lease liability	$ 504	$ 474
Accounts payable	6,874	2,934
Accrued expenses	8,738	6,501
Other current liabilities	1,471	5,200
Total current liabilities	17,587	15,109
Long-term debt	142,086	128,210
Long-term operating lease liability	1,460	1,840
Other non-current liabilities	3,999	4,212
Total liabilities	165,132	149,371
Shareholders' equity:		

Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at September 30, 2021 and 488 issued and outstanding at December 31, 2020, respectively	5	5
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 58,616 issued and outstanding at September 30, 2021 and 58,396 issued and outstanding at December 31, 2020	586	583
Additional paid-in capital	546,565	566,916
Accumulated deficit	(425,455)	(384,187)
Accumulated other comprehensive loss	(22,744)	(21,051)
Total shareholders' equity	98,957	162,266
Total liabilities and shareholders' equity	$ 264,089	$ 311,637

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net (loss) income	$ (55,028)	$ 18,306
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	614	1,297
Remeasurement of acquisition-related contingent consideration	—	3,327
Remeasurement of financing-related contingent consideration	—	435
Amortization of debt discount and debt issuance costs	937	4,835
Change in deferred taxes	(11,322)	(4,582)
Stock-based compensation expense	6,088	1,705
Gain on the disposition of the hospital products	—	(45,760)
Gain from the release of certain liabilities	(166)	—
Other adjustments	1,056	306
Net changes in assets and liabilities		
Accounts receivable	—	8,281
Inventories	—	(1,352)
Prepaid expenses and other current assets	(54)	1,759
Research and development tax credit receivable	3,079	2,036
Accounts payable & other current liabilities	(201)	(4,051)
Accrued expenses	2,421	(6,625)
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	(2,228)	(3,337)
Net cash used in operating activities	(54,804)	(29,609)
Cash flows from investing activities:		
Purchases of property and equipment	(26)	(33)
Proceeds from the disposition of the hospital products	16,500	17,250
Proceeds from sales of marketable securities	83,726	30,075
Purchases of marketable securities	(58,591)	(124,254)
Net cash provided by (used in) investing activities	41,609	(76,962)
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 stock option exercises and employee stock purchase plan	263	2,006
Net cash provided by financing activities	263	179,500
Effect of foreign currency exchange rate changes on cash and cash equivalents	(621)	406
Net change in cash and cash equivalents	(13,553)	73,335
Cash and cash equivalents at January 1,	71,722	9,774
Cash and cash equivalents at September 30,	$ 58,169	$ 83,109

Source: Avadel Pharmaceuticals plc