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

August 9, 2021

- *Commercial and launch preparations on track to support potential U.S. FDA approval of FT218 for the treatment of excessive daytime sleepiness and cataplexy in adults suffering from narcolepsy*
- *Presentation of post hoc analyses from pivotal REST-ON clinical trial at SLEEP 2021 further support positive primary and secondary endpoint data for all evaluated doses of FT218, beginning as early as week three of treatment*
- *Expansion of leadership team with addition of established biopharma industry leaders*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, Aug. 09, 2021 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for treating excessive daytime sleepiness (EDS) and cataplexy in adults with narcolepsy, today provided a corporate update and announced its financial results for the second quarter ended June 30, 2021.

“This quarter, we made significant progress advancing FT218, which we believe holds tremendous potential to transform the treatment landscape for patients as a once-at-bedtime option for managing EDS and cataplexy in adult patients with narcolepsy. The data presented at SLEEP 2021 demonstrates the additional benefit of consolidating sleep, which we believe holds great promise as many people with narcolepsy also suffer from fragmented sleep,” said Greg Divis, Chief Executive Officer of Avadel. “As we enter the final stages of NDA review and approach our October PDUFA date, we remain confident in the strength of our regulatory filing strategy. In parallel, our commercial and launch preparations are on track, including the addition of key hires to our leadership team, and we look forward to providing more detail on our commercial strategy following potential approval of FT218.”

Second Quarter and Recent Company Highlights

- Progressed preparations and launch readiness activities for the potential commercialization of FT218 as the first and only once-at-bedtime option for managing EDS and cataplexy in narcolepsy
  - New Drug Application (NDA) for FT218 was accepted for filing by the U.S. Food and Drug Administration (FDA) in February 2021, and was assigned a Prescription Drug User Fee Act (PDUFA) target action date of October 15, 2021
  - Conducting scientific and medical community engagement and education, as well as payor clinical presentations
- Presented new clinical post-hoc analyses from the pivotal Phase 3 REST-ON clinical study at SLEEP 2021 further supporting clinical benefit of all evaluated doses of FT218, beginning as early as week three of treatment
  - Data demonstrated improvement in EDS for both narcolepsy subtypes with and without stimulant use as well as decreases in weight and body mass index
- Expanded leadership team with addition of established biopharma industry leaders to support anticipated regulatory approval and commercialization of FT218
  - Appointed Jeff Cruikshank as Vice President, Sales; Denise Strauss as Vice President, Marketing and New Product Strategy; and Angela Woods as Vice President, People and Culture
- 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 Second Quarter Results
As a result of the sale of the sterile injectable products to Exela Sterile Medicines LLC on June 30, 2020, the Company did not report any revenue for the quarter ended June 30, 2021, compared to $10.1 million for the same period in 2020.

R&D expenses were $6.8 million in the quarter ended June 30, 2021, compared to $4.1 million for the same period in 2020. The increase on a year-over-year basis was primarily attributed to increased costs associated with pre-NDA approval activities, primarily the purchase of raw materials, in preparation for product launch, if FT218 is approved.

SG&A expenses were $15.2 million in the quarter ended June 30, 2021, compared to $7.1 million for the same period in 2020. The year-over-year increase is the result of a number of factors including commercial launch planning costs related to FT218 and higher compensation costs associated with higher headcount, primarily in the areas of commercial and medical affairs.

Income tax benefit was $3.8 million in the quarter ended June 30, 2021, compared to income tax expense of $5.3 million for the same period in 2020. The income tax expense recorded in 2020 was the result of taxes recorded on the gain from the sale of the hospital products.

Net loss for the quarter ended June 30, 2021 was $19.6 million, or ($0.33) per diluted share, compared to net income of $30.9 million, or $0.49 per diluted share, for the same period in 2020. The Company reported net income and diluted income per share for the quarter ending June 30, 2020, resulting from the $45.8 million pre-tax gain from sale of the sterile injectable products.

Cash, cash equivalents and marketable securities were $202.8 million as of June 30, 2021. The Company has convertible debt of $143.8 million due in February 2023.

Conference Call
A conference call to discuss these results is scheduled for Monday, August 9, 2021 at 8:30 a.m. ET. 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 4560878. 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, once-nightly formulation of sodium oxybate. In March of 2020, the Company completed the REST-ON study, a pivotal, double-blind, randomized, placebo-controlled Phase 3 trial, to assess the efficacy and safety of FT218 in the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. In December 2020, the Company submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for FT218 to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy. The NDA for FT218 was accepted by the FDA in February 2021 and assigned a Prescription Drug User Fee Act (PDUFA) target action date of October 15, 2021. FT218 has been granted Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of narcolepsy. The designation was granted on the plausible hypothesis that FT218 may be clinically superior to the twice-nightly formulation of sodium oxybate already approved by the FDA for the same indication. In particular, FT218 may be safer due to ramifications associated with the dosing regimen of the previously approved product.

About Avadel Pharmaceuticals plc
Avadel Pharmaceuticals plc (Nasdaq: AVDL) is a biopharmaceutical company primarily focused on the development and FDA approval of FT218, an investigational, once-nightly, extended-release formulation of sodium oxybate designed to treat 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, the FDA's review of the NDA for FT218, the sufficiency of data supporting the NDA for FT218, the publication of additional clinical trial data 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. 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 risk that: positive results from the REST-ON trial may not necessarily be predictive of the results of future or ongoing clinical studies; the NDA for FT218 is not approved by the FDA or such approval is delayed; the risk that commercial launch of FT218 (if approved) is delayed or never occurs; the risk that the potential market acceptance of FT218 (if approved) may differ materially from projections; the risk that FT218 may be found to infringe one or more patents of third parties; the risk that the RESTORE study may be delayed or may not be completed at all; and the risk that the impact of the current COVID-19 pandemic on the Company's financial results and results of operations could be greater than we anticipate and 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Product sales	$ —	$ 10,091	$ —	$ 22,334
Operating expenses:				
Cost of products	—	3,285	—	5,742
Research and development expenses	6,762	4,057	10,614	9,587
Selling, general and administrative expenses	15,174	7,095	26,186	15,008
Intangible asset amortization	—	203	—	406
Changes in fair value of contingent consideration	—	918	—	3,396
Gain on sale of Hospital Products	—	(45,760)	—	(45,760)
Restructuring costs (income)	—	24	(53)	183
Total operating expense (income)	21,936	(30,178)	36,747	(11,438)
Operating (loss) income	(21,936)	40,269	(36,747)	33,772
Investment and other income (expense), net	432	(741)	1,042	(1,119)
Interest expense	(1,930)	(3,237)	(3,859)	(6,427)
Gain from release of certain liabilities	88	—	166	—
Other expense - changes in fair value of contingent consideration payable	—	(125)	—	(435)
(Loss) income before income taxes	(23,346)	36,166	(39,398)	25,791
Income tax (benefit) expense	(3,765)	5,292	(6,372)	(4,218)
Net (loss) income	$ (19,581)	$ 30,874	$ (33,026)	$ 30,009
Net (loss) income per share - basic	$ (0.33)	$ 0.57	$ (0.56)	$ 0.63
Net (loss) income per share - diluted	(0.33)	0.49	(0.56)	0.58
Weighted average number of shares outstanding - basic	58,488	54,272	58,465	47,665
Weighted average number of shares outstanding - diluted	58,488	69,942	58,465	63,083

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

	June 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 67,142	$ 71,722
Marketable securities	135,701	149,680
Research and development tax credit receivable	2,551	3,326
Prepaid expenses and other current assets	25,308	38,726
Total current assets	230,702	263,454
Property and equipment, net	321	359
Operating lease right-of-use assets	2,249	2,604
Goodwill	16,836	16,836
Research and development tax credit receivable	983	3,445
Other non-current assets	31,500	24,939
Total assets	$ 282,591	$ 311,637
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of operating lease liability	494	474
Accounts payable	5,116	2,934
Accrued expenses	7,524	6,501
Other current liabilities	3,146	5,200
Total current liabilities	16,280	15,109

Long-term debt	141,774	128,210
Long-term operating lease liability	1,589	1,840
Other non-current liabilities	4,068	4,212
Total liabilities	163,711	149,371
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at June 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; 58,488 issued and outstanding at June 30, 2021 and 58,396 issued and outstanding at December 31, 2020	584	583
Additional paid-in capital	544,094	566,916
Accumulated deficit	(403,453)	(384,187)
Accumulated other comprehensive loss	(22,350)	(21,051)
Total shareholders' equity	118,880	162,266
Total liabilities and shareholders' equity	$ 282,591	$ 311,637

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

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net (loss) income	$ (33,026)	$ 30,009
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	417	975
Remeasurement of acquisition-related contingent consideration	—	3,396
Remeasurement of financing-related contingent consideration	—	435
Amortization of debt discount and debt issuance costs	625	3,193
Change in deferred tax and income tax deferred charge	(6,228)	161
Stock-based compensation expense	3,729	1,511
Gain on the disposition of the hospital products	—	(45,760)
Gain from the release of certain liabilities	(166)	—
Other adjustments	757	477
Net changes in assets and liabilities		
Accounts receivable	—	2,589
Inventories	—	(1,353)
Prepaid expenses and other current assets	(3,106)	(1,149)
Research and development tax credit receivable	3,078	2,036
Accounts payable & other current liabilities	176	(1,550)
Accrued expenses	1,199	(6,906)
Accrued income taxes	—	321
Earn-out payments for contingent consideration in excess of acquisition-date fair value	—	(3,736)
Royalty payments for contingent consideration payable in excess of original fair value	—	(608)
Other assets and liabilities	(1,021)	(3,458)
Net cash used in operating activities	(33,566)	(19,417)
Cash flows from investing activities:		
Purchases of property and equipment	(26)	—
Proceeds from the disposition of the hospital products	16,500	14,500
Proceeds from sales of marketable securities	66,213	15,716
Purchases of marketable securities	(53,372)	(97,878)
Net cash provided by (used in) investing activities	29,315	(67,662)
Cash flows from financing activities:		

Proceeds from the February 2020 private placement	—	60,639
Proceeds from the May 2020 public offering	—	116,974
Proceeds from stock option exercises and employee stock purchase plan	149	1,903
Net cash provided by financing activities	149	179,516
Effect of foreign currency exchange rate changes on cash and cash equivalents	(478)	(37)
Net change in cash and cash equivalents	(4,580)	92,400
Cash and cash equivalents at January 1,	71,722	9,774
Cash and cash equivalents at June 30,	$ 67,142	$ 102,174

Source: Avadel Pharmaceuticals plc