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

May 10, 2021

- *Announced FDA acceptance of NDA for once-nightly FT218 and an October 15, 2021 target action PDUFA date*
- *Presented positive secondary endpoint data at the AAN 2021 Annual Meeting, which further highlights the overall clinical value proposition of FT218*
- *FT218 launch preparation progressing*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, May 10, 2021 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy, today provided a corporate update and announced its financial results for the first quarter ended March 31, 2021.

"We entered 2021 with positive momentum which included the announcement of several significant milestones for the FT218 program that will help shape our company's future, including FDA acceptance of the NDA filing for once-nightly FT218, which was assigned a PDUFA target action date of October 15th. We are now approaching the mid-point of the review timeline and remain confident in our regulatory filing strategy. We also announced the appointment of Richard Kim as Chief Commercial Officer to lead the launch of FT218, if approved. We are continuing to build our team and capabilities, and we are incredibly pleased with the experience and caliber of talent we are attracting to Avadel. We believe this is a testament to both confidence in the potential approval of FT218 and the opportunity that FT218 represents," said Greg Divis, Chief Executive Officer of Avadel.

"During the AAN annual meeting, we presented positive secondary endpoint data that further highlights the consistency with which once-nightly FT218 improved both subjective and objective symptoms of narcolepsy, as early as week three with the 6 g dose. Notably, the clinical data from the REST-ON phase 3 study presented at AAN shows that FT218 improved disturbed nocturnal sleep, with a single dose taken at bedtime. We believe the overwhelmingly positive data from this pivotal trial along with our Special Protocol Assessment agreement with FDA provides a strong foundation for our NDA," said Dr. Jennifer Gudeman, Vice President of Medical and Clinical Affairs.

"Educating the medical community on the clinical data from the REST-ON study is an important part of our broader strategy for FT218. We will be presenting the secondary data and additional clinical data from the REST-ON study at future medical congresses, including the Associated Professional Sleep Societies' annual SLEEP meeting, as well as publishing in peer-reviewed journals throughout the remainder of 2021," concluded Dr. Gudeman.

First quarter and recent Company highlights

- Announced that the New Drug Application (NDA) for FT218 was accepted for filing by the U.S. Food and Drug Administration (FDA) during the first quarter of 2021, and was assigned a Prescription Drug User Fee Act (PDUFA) target action date of October 15, 2021
- Presented positive secondary endpoint data from the REST-ON trial at the American Academy of Neurology (AAN) annual meeting, which further bolster the previously announced positive data regarding the three co-primary endpoints, including:
  - FT218 demonstrated significant consolidation of sleep, significant increase in time in deep sleep and significant decrease in light sleep compared to placebo, for all doses evaluated (6 g, 7.5 g, and 9 g), beginning by week three
  - FT218 demonstrated significant improvement in the Epworth Sleepiness Scale, a patient-reported outcome, as well as significantly improving patient perceptions of both the quality and refreshing nature of sleep, and a reduction of sleep paralysis, also for all doses evaluated (6 g, 7.5 g, and 9 g)
- Scheduled to present additional data from the REST-ON trial at the SLEEP congress in June 2021
- Continued the expansion and enrollment of 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 sodium oxybate and patient preference

Overview of First 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 March 31, 2021, compared to $12.2 million for the same period in 2020.

R&D expenses were $3.9 million in the quarter ended March 31, 2021, compared to $5.5 million for the same period in 2020. The decrease on a year-over-year basis was primarily attributed to the completion of the Phase 3 REST-ON clinical study for FT218, which concluded during the quarter ended March 31, 2020.

SG&A expenses were $11.0 million in the quarter ended March 31, 2021, compared to $7.9 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 stock-based compensation.

Income tax benefit was $2.6 million in the quarter ended March 31, 2021, compared to $9.5 million for the same period in 2020. The decrease in the income tax benefit year-over-year is primarily due to benefits recognized in 2020 from the Coronavirus Aid, Relief and Economic Security Act.

Net loss for the quarter ended March 31, 2021 was $13.4 million, or ($0.23) per diluted share, compared to a net loss of $0.9 million, or ($0.02) per diluted share, for the same period in 2020. The increase in net loss and diluted loss per share is primarily the result of the year-over-year decrease in revenue due to the sale of the sterile injectable products. The increase in diluted shares outstanding resulted primarily from equity issuances related to financing activities completed during the first half of 2020.

Cash, cash equivalents and marketable securities were $205.0 million as of March 31, 2021. The Company has convertible debt of $143.8 million due in February 2023.

Conference Call
A conference call to discuss these results has been scheduled for Monday, May 10, 2021 at 8:30 a.m. ET. To access the conference call, investors are invited to dial (877) 407-9716 (U.S. and Canada) or (201) 493-6779 (International). The conference ID number is 13719428. 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 that includes Avadel's MicroPump™ controlled-release technology. 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 NDA to the 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 PDUFA target action date of October 15, 2021. FT218 has been granted Orphan Drug Designation from the 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 presentation of additional clinical trial data for FT218, the commercial launch of FT218 (if approved), the market acceptance of FT218 (if approved), and the advancement 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 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
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Product sales	$ —	$ 12,243
Operating expenses:		
Cost of products	—	2,457
Research and development expenses	3,852	5,530
Selling, general and administrative expenses	11,012	7,913
Intangible asset amortization	—	203
Changes in fair value of contingent consideration	—	2,478
Restructuring (income) costs	(53)	159
Total operating expense	14,811	18,740
Operating loss	(14,811)	(6,497)
Investment and other income (expense), net	610	(378)
Interest expense	(1,929)	(3,190)
Gain from release of certain liabilities	78	—
Other expense - changes in fair value of contingent consideration payable	—	(310)
Loss before income taxes	(16,052)	(10,375)
Income tax benefit	(2,607)	(9,510)
Net loss	$ (13,445)	$ (865)
Net loss per share - basic	$ (0.23)	$ (0.02)
Net loss per share - diluted	(0.23)	(0.02)
Weighted average number of shares outstanding - basic	58,443	41,057
Weighted average number of shares outstanding - diluted	58,443	41,057

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

	March 31, 2021	**December 31, 2020**
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 59,172	$ 71,722
Marketable securities	145,803	149,680
Research and development tax credit receivable	3,108	3,326
Prepaid expenses and other current assets	34,231	38,726
Total current assets	242,314	263,454
Property and equipment, net	344	359
Operating lease right-of-use assets	2,427	2,604
Goodwill	16,836	16,836
Research and development tax credit receivable	3,303	3,445
Other non-current assets	27,717	24,939
Total assets	$ 292,941	$ 311,637
LIABILITIES AND SHAREHOLDERS' EQUITY		

Current liabilities:		
Current portion of operating lease liability	$ 484	$ 474
Accounts payable	2,824	2,934
Accrued expenses	4,297	6,501
Other current liabilities	1,515	5,200
Total current liabilities	9,120	15,109
Long-term debt	141,461	128,210
Long-term operating lease liability	1,717	1,840
Other non-current liabilities	4,139	4,212
Total liabilities	156,437	149,371
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at March 31, 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 March 31, 2021 and 58,396 issued and outstanding at December 31, 2020	584	583
Additional paid-in capital	542,093	566,916
Accumulated deficit	(383,872)	(384,187)
Accumulated other comprehensive loss	(22,306)	(21,051)
Total shareholders' equity	136,504	162,266
Total liabilities and shareholders' equity	$ 292,941	$ 311,637

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

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (13,445)	$ (865)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	218	456
Remeasurement of acquisition-related contingent consideration	—	2,478
Remeasurement of financing-related contingent consideration	—	310
Amortization of debt discount and debt issuance costs	312	1,573
Change in deferred tax and income tax deferred charge	(2,534)	(8,440)
Stock-based compensation expense	1,728	742
Gain from the release of certain liabilities	(78)	—
Other adjustments	561	573
Net changes in assets and liabilities		
Accounts receivable	—	(517)
Inventories	—	47
Prepaid expenses and other current assets	(3,736)	899
Research and development tax credit receivable	80	160
Accounts payable & other current liabilities	(3,789)	(1,187)
Accrued expenses	(2,112)	(4,905)
Accrued income taxes	—	2,253
Earn-out payments for contingent consideration in excess of acquisition-date fair value	—	(1,774)
Royalty payments for contingent consideration payable in excess of original fair value	—	(291)
Other assets and liabilities	(618)	(3,148)
Net cash used in operating activities	(23,413)	(11,636)
Cash flows from investing activities:		
Purchases of property and equipment	(26)	—
Proceeds from the disposition of the hospital products	8,250	—
Proceeds from sales of marketable securities	40,736	14,788
Purchases of marketable securities	(37,769)	(1,562)
Net cash provided by investing activities	11,191	13,226

Cash flows from financing activities:		
Proceeds from the February 2020 private placement	—	60,733
Proceeds from stock option exercises and employee stock purchase plan	149	1,477
Net cash provided by financing activities	149	62,210
Effect of foreign currency exchange rate changes on cash and cash equivalents	(477)	(68)
Net change in cash and cash equivalents	(12,550)	63,732
Cash and cash equivalents at January 1,	71,722	9,774
Cash and cash equivalents at March 31,	$ 59,172	$ 73,506

Source: Avadel Pharmaceuticals plc