Avadel Pharmaceuticals Provides Corporate Update and Reports Fourth Quarter and Full Year 2020 Financial Results

March 9, 2021

- *New Drug Application (NDA) for once-nightly FT218 to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy accepted for filing by the FDA; assigned a Prescription Drug User Fee Act (PDUFA) target date of October 15, 2021*
- *Completed key appointments for Commercial, Clinical and Medical Affairs functions to lead launch planning and readiness to capitalize on significant market opportunity*
- *Presenting new data highlighting the overall clinical value proposition of FT218 at upcoming medical congresses and key publications*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, March 09, 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 fourth quarter and year ended December 31, 2020.

“We are pleased with the significant and rapid progress we have made on a number of fronts with our once nightly FT218 program including clinical research, market opportunity assessment, launch preparation, and our regulatory filing strategy. In less than 10 months, we have delivered exceptional top line results, an NDA submission and now formal FDA acceptance for review of our once-nightly FT218 NDA,” said Greg Divis, Chief Executive Officer of Avadel.

Mr. Divis continued, “Our priorities between now and a launch of FT218, if approved, are very clear: the execution of our NDA filing strategy and subsequent approval; the acceleration of our launch readiness; and the externalization of our pivotal data and related market preparation activities. We believe Avadel is well positioned to bring FT218 to patients suffering from narcolepsy and potentially command a market leading share of this multi-billion-dollar opportunity.”

Fourth quarter and recent company highlights

- The NDA for FT218 was accepted for filing by the FDA and assigned a PDUFA target action date of October 15, 2021
- Appointed Richard Kim as Chief Commercial Officer to lead the commercial strategy and launch of FT218, if approved
- Appointed Dr. Jennifer Gudeman as Vice President, Medical and Clinical Affairs, leading the Company’s medical and clinical affairs activities
- Scheduled to present data from our REST-ON trial at the American Academy of Neurology in April 2021 and at SLEEP in June 2021, including all three primary endpoints, as well as a number of secondary endpoints and post-hoc analyses
- To highlight the novel technology and predictable PK profile of FT218, four of the clinically relevant Phase 1 PK studies were recently described in a *Clinical Therapeutics* publication, “Pharmacokinetics of FT218, a Once-Nightly Sodium Oxybate Formulation in Healthy Adults”

- Ongoing analysis of an internal comprehensive market assessment has provided key insights about the narcolepsy market and once nightly therapy, including:
    - Once-nightly FT218, if approved, is expected to be the preferred oxybate of choice based on results from large quantitative HCP and patient research projects
    - Oxybate eligible patients ranked a once-nightly therapy as being the most important driver of treatment preference
    - A once-nightly therapy was characterized by patients as increasing the likelihood of compliance and reducing stress and anxiety associated with the middle of the night dosing
    - Oxybate market expansion potential could benefit once-nightly FT218 due to patients and HCPs reported dosing challenges associated with the twice nightly treatment regimen of currently available oxybate products

- 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 Fourth 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 fourth quarter of 2020, compared to $11.0 million in the fourth quarter of 2019.

R&D expenses were $5.3 million in the fourth quarter of 2020, compared to $7.8 million in the fourth quarter of 2019. 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 first quarter of 2020, as well as lower headcount due to the restructuring activities initiated during 2019.

SG&A expenses were $9.0 million in the fourth quarter of 2020, compared to $7.7 million in the fourth quarter of 2019. The year-over-year increase is the result of a number of factors including FT218 NDA preparation and submission costs, commercial launch planning costs related to FT218 and higher stock-based compensation.

Net loss for the fourth quarter of 2020 was $11.3 million, or ($0.19) per diluted share, compared to a net loss of $2.7 million, or ($0.07) per diluted share, for the same period in 2019. 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 partially offset by lower operating expenses. The increase in diluted shares outstanding resulted primarily from equity issuances related to financing activities completed during the first half of the year.

Cash, cash equivalents and marketable securities were $221.4 million as of December 31, 2020. 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 Tuesday, March 9, 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 13716363. 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 (CR) 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 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 commercial launch of FT218 (if approved), and the market acceptance of FT218 (if approved). 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).

Our 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, our business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of our 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 our forward-looking statements include the risk that the NDA for FT218 is not approved by the FDA or such approval is delayed, the risk that FT218 (if approved) may not receive a 7-year Orphan Drug Exclusivity, the risk that the RESTORE study may be delayed or may not be completed at all, the risk that commercial launch of FT218 (if approved) is delayed, the risk that the potential market performance for FT218 (if approved) may differ materially from projections, and the risk that the impact of the current COVID-19 pandemic on our 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 our Annual Report on Form 10-K for the year ended December 31, 2019, which we filed with the Securities and Exchange Commission (SEC) on March 16, 2020 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. We do 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
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF (LOSS) INCOME
(In thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2020	**2019**	**2020**	**2019**
Product sales	$ —	$ 10,995	$ 22,334	$ 59,215
Operating expenses:				
Cost of products	—	2,414	5,742	12,125
Research and development expenses	5,286	7,757	20,442	32,917
Selling, general and administrative expenses	8,974	7,663	32,405	30,183
Intangible asset amortization	—	206	406	816
Changes in fair value of contingent consideration	—	(1,539)	3,327	845
Gain on sale of Hospital Products	—	—	(45,760)	—
Restructuring costs (income)	—	1,841	(43)	6,441
Total operating expenses	14,260	18,342	16,519	83,327
Operating (loss) income	(14,260)	(7,347)	5,815	(24,112)
Investment and other income (expense), net	74	(1,479)	(832)	1,069
Interest expense	(3,308)	(3,190)	(12,994)	(12,483)
Gain from release of certain liabilities	3,364	—	3,364	—
Gain (loss) on deconsolidation of subsidiary	—	162	—	(2,678)
Other income (expense) - changes in fair value of contingent consideration payable	—	118	(435)	(378)
Loss before income taxes	(14,130)	(11,736)	(5,082)	(38,582)
Income tax benefit	(2,852)	(8,997)	(12,110)	(5,356)
Net (loss) income	$ (11,278)	$ (2,739)	$ 7,028	$ (33,226)
Net loss (income) per share - basic	$ (0.19)	$ (0.07)	$ 0.13	$ (0.89)
Net loss (income) per share - diluted	(0.19)	(0.07)	0.13	(0.89)
Weighted average number of shares outstanding - basic	58,325	37,465	52,996	37,403
Weighted average number of shares outstanding - diluted	58,325	37,465	54,941	37,403

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,722	$ 9,774
Marketable securities	149,680	54,384
Accounts receivable	—	8,281
Inventories, net	—	3,570
Research and development tax credit receivable	3,326	2,107
Prepaid expenses and other current assets	38,726	4,264
Total current assets	263,454	82,380
Property and equipment, net	359	544
Operating lease right-of-use assets	2,604	3,612

Goodwill	16,836	18,491
Intangible assets, net	—	813
Research and development tax credit receivable	3,445	6,322
Other non-current assets	24,939	39,274
Total assets	$ 311,637	$ 151,436
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term contingent consideration payable	$ —	$ 5,554
Current portion of operating lease liability	474	645
Accounts payable	2,934	6,100
Accrued expenses	6,501	19,810
Other current liabilities	5,200	3,875
Total current liabilities	15,109	35,984
Long-term debt	128,210	121,686
Long-term contingent consideration payable, less current portion	—	11,773
Long-term operating lease liability	1,840	2,319
Other non-current liabilities	4,212	8,873
Total liabilities	149,371	180,635
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at December 31, 2020 and 0 issued and outstanding at December 31, 2019	5	—
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 58,396 issued and outstanding at December 31, 2020, and 42,927 issued and 37,520 outstanding at December 31, 2019	583	429
Treasury shares, at cost, 0 and 5,407 shares held at December 31, 2020 and December 31, 2019, respectively	—	(49,998)
Additional paid-in capital	566,916	434,391
Accumulated deficit	(384,187)	(391,215)
Accumulated other comprehensive loss	(21,051)	(22,806)
Total shareholders' equity (deficit)	162,266	(29,199)
Total liabilities and shareholders' equity (deficit)	$ 311,637	$ 151,436

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

	Twelve Months Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net income (loss)	$ 7,028	$ (33,226)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	1,690	2,486
Remeasurement of acquisition-related contingent consideration	3,327	845
Remeasurement of financing-related contingent consideration	435	378
Amortization of debt discount and debt issuance costs	6,524	5,995
Changes in deferred tax	(7,431)	(6,334)
Share-based compensation expense	2,999	519
Gain on the disposition of the Hospital Products	(45,760)	—
Loss on deconsolidation of subsidiary	—	1,750
Gain from the release of certain liabilities	(3,364)	—
Other adjustments	142	(254)
Net changes in assets and liabilities		
Accounts receivable	8,281	2,471
Inventories, net	(1,352)	1,155
Prepaid expenses and other current assets	1,863	(1,187)
Research and development tax credit receivable	2,213	(1,014)
Accounts payable & other current liabilities	(2,788)	4,641
Deferred revenue	—	(114)

Accrued expenses	(13,226)	357
Earn-out payments for contingent consideration in excess of acquisition-date fair value	(5,323)	(10,988)
Royalty payments for contingent consideration payable in excess of original fair value	(866)	(1,748)
Other assets and liabilities	(3,126)	(4,057)
Net cash used in operating activities	(48,734)	(38,325)
Cash flows from investing activities:		
Purchases of property and equipment	(98)	(29)
Proceeds from disposal of property and equipment	—	154
Proceeds from the disposition of the Hospital Products	25,500	—
Proceeds from sales of marketable securities	36,284	63,246
Purchases of marketable securities	(131,407)	(24,648)
Net cash (used in) provided by investing activities	(69,721)	38,723
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	2,189	118
Other financing activities, net	—	(145)
Net cash provided by (used in) financing activities	179,683	(27)
Effect of foreign currency exchange rate changes on cash and cash equivalents	720	78
Net change in cash and cash equivalents	61,948	449
Cash and cash equivalents at January 1	9,774	9,325
Cash and cash equivalents at December 31	$ 71,722	$ 9,774

AVADEL PHARMACEUTICALS PLC
UNAUDITED SUPPLEMENTAL INFORMATION
(In thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
Revenues by Product:	**2020**	**2019**	**2020**	**2019**
Bloxiverz	$ —	$ 1,087	$ 2,201	$ 7,479
Vazculep	—	5,483	10,429	33,152
Akovaz	—	4,696	9,545	18,642
Other	—	(271)	159	(58)
Product sales	$ —	$ 10,995	$ 22,334	$ 59,215

Source: Avadel Pharmaceuticals plc