Avadel Pharmaceuticals Reports Third Quarter 2020 Financial Results and Provides Update on FT218 Development Program

November 9, 2020

- *NDA for once-nightly FT218 is on track for FDA submission by end of December 2020*
- *New market assessment data identifies a significant potential market expansion opportunity for once-nightly FT218 beyond existing twice-nightly sodium oxybate patients*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, Nov. 09, 2020 (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 patients with narcolepsy, today announced its financial results for the third quarter ended September 30, 2020 and provided a business update.

“Over the past several months, the Avadel clinical and regulatory teams have made substantial progress in advancing FT218 toward its anticipated FDA approval for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. The Company remains on track to submit the filing to the FDA by the end of December. We are pleased with the progress we have made despite the challenges of a global pandemic and look forward to updating our shareholders on this upcoming regulatory milestone for the FT218 program,” said Greg Divis, Chief Executive Officer of Avadel.

“We recently gained even greater insight into this evolving therapeutic area including the significant and growing opportunity for FT218. Specifically, we completed a comprehensive market assessment, which provided current and critical prescriber and patient insights. A key finding is that six out of ten sodium oxybate-eligible patients are not going on therapy today, with twice-nightly dosing being the primary reason cited. This finding suggests there could be a significantly larger potential sodium oxybate-eligible market beyond those currently being treated with twice-nightly therapy. These insights, coupled with patient discontinuation rates of nearly 50% within the first 12 months of initiating twice-nightly therapy, underscore the unmet patient need and opportunity once-nightly FT218 may have in addition to the nearly $1.8 billion[1] twice-nightly sodium oxybate market. Based on our extensive research, we believe once-nightly FT218 has the potential, if approved, to offer a meaningful treatment option for patients switching from twice-nightly sodium oxybate, as well as those patients who previously refused or discontinued twice-nightly therapy,” concluded Mr. Divis.

Third quarter and recent company highlights

• FT218 NDA is on track and expected to be filed with the FDA by the end of December.

• Completed a new comprehensive market assessment that included a review of over five years of twice-nightly sodium oxybate utilization and interviews with over 500 critical stakeholders. Key findings from the market assessment include:

- Insights from over 150 sodium oxybate prescribing physicians show that 60% of sodium oxybate-eligible patients are not receiving sodium oxybate treatment today, with the primary reason being twice-nightly dosing-related challenges.
- In a survey of current sodium oxybate-treated patients, once-nightly dosing ranked as the most important driver of their treatment preference, placing it higher in importance than efficacy and side effect profile.
- Analysis of longitudinal patient claims analysis demonstrates nearly 50% of all newly treated twice-nightly sodium oxybate patients discontinued their treatment within 12 months of initiation, including about half of that group discontinuing within the first 30 days.

• Supported a recently published article in the peer-reviewed journal *Sleep Medicine* highlighting the lack of evidence linking the sodium content of sodium oxybate with increased cardiovascular risk in patients with narcolepsy. (https://doi.org/10.1016/j.sleep.2020.09.017)

• Additional subgroup analysis of the REST-ON study demonstrated comparable, robust results for FT218 in narcolepsy patients both with and without cataplexy as well as those on concomitant wake-promoting agents compared to those not on wake-promoting agents. In addition, results of responder analyses for the Maintenance of Wakefulness Test and mean weekly cataplexy attacks further supported the potential clinical benefits of FT218.

• Continued progress of the RESTORE trial, an open-label extension/switch study of FT218 as a potential treatment for excessive daytime sleepiness and cataplexy in patients with narcolepsy.

- 29 patients have been enrolled and initiated treatment or are pending treatment initiation.
- The majority of these patients switched from twice-nightly sodium oxybate, many of which also completed the REST-ON study, and nearly all are on the same or lower stable dose of FT218 compared to their prior twice-nightly treatment.

• U.S. Patent & Trademark Office issued the second U.S. patent covering once-nightly gamma- hydroxybutyrate formulations, including FT218, with an

expiration date of mid-2037. In addition, Avadel has several patent applications pending at the USPTO, which the Company expects to result in additional issued patents in the future.

Overview of Third Quarter Results

As a result of the sale of the sterile injectable products to Exela Sterile Medicines LLC, which closed on June 30, 2020, the Company did not report any revenue for the third quarter of 2020, compared to $14.2 million in the third quarter of 2019.

R&D expenses were $5.6 million in the third quarter of 2020, compared to $7.5 million in the third quarter of 2019. The decrease on a year-over-year basis was primarily attributed to the completion of the FT218 clinical study during the first quarter of 2020, as well as lower headcount due to the restructuring activities initiated during 2019.

SG&A expenses were $8.4 million in the third quarter of 2020, compared to $5.3 million in the third quarter of 2019. The year-over-year increase is primarily the result of higher stock-based compensation, professional fees and market preparation costs related to FT218.

Net loss for the third quarter of 2020 was $11.7 million, or ($0.20) per diluted share, compared to a net loss of $8.9 million, or ($0.24) per diluted share, for the same period in 2019. The increase in net loss is primarily the result of the year-over-year decline in revenue due to the sale of the sterile injectable products to Exela Sterile Medicines LLC on June 30, 2020. The decrease in diluted loss per share is due to a higher number of shares outstanding resulting from equity issuances completed during the first half of the year.

Cash, cash equivalents and marketable securities were $231.6 million as of September 30, 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 Monday, November 9, 2020 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 13712485. 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 Micropump™ controlled-release (CR) 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. 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 an emerging biopharmaceutical company. The Company's primary focus is the development and FDA approval of FT218, an investigational, once-nightly formulation of sodium oxybate designed to treat excessive daytime sleepiness and cataplexy in patients with narcolepsy. For more information, please visit www.avadel.com.

Footnote: 1. Annualized Xyrem revenues from the Jazz Pharmaceuticals third quarter and year to date results reported in their press release dated November 2, 2020.

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 planned submission of the FT218 NDA to the FDA and commercial launch 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 we do not file the NDA for FT218 on a timely basis or at all, the risk that the FDA does accept such NDA, the risk that such NDA is not approved by the FDA or such approval is delayed, 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)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Product sales	$ —	$ 14,229	$ 22,334	$ 48,220
Operating expenses:				
Cost of products	—	2,823	5,742	9,711
Research and development expenses	5,569	7,539	15,156	25,160
Selling, general and administrative expenses	8,423	5,316	23,431	22,520
Intangible asset amortization	—	205	406	610
Changes in fair value of contingent consideration	(69)	627	3,327	2,384
Gain on sale of Hospital Products	—	—	(45,760)	—
Restructuring (income) costs	(226)	1,866	(43)	4,600
Total operating expense	13,697	18,376	2,259	64,985
Operating (loss) income	(13,697)	(4,147)	20,075	(16,765)
Investment and other income (expense), net	213	781	(906)	2,548
Interest expense	(3,259)	(3,125)	(9,686)	(9,293)
Loss on deconsolidation of subsidiary	—	—	—	(2,840)
Other expense - changes in fair value of contingent consideration payable	—	(139)	(435)	(496)
(Loss) income before income taxes	(16,743)	(6,630)	9,048	(26,846)
Income tax (benefit) provision	(5,040)	2,234	(9,258)	3,641
Net (loss) income	$ (11,703)	$ (8,864)	$ 18,306	$ (30,487)
Net (loss) income per share - basic	$ (0.20)	$ (0.24)	$ 0.36	$ (0.82)
Net (loss) income per share - diluted	(0.20)	(0.24)	0.35	(0.82)
Weighted average number of shares outstanding - basic	58,213	37,436	51,206	37,382
Weighted average number of shares outstanding - diluted	58,213	37,436	52,849	37,382

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

	September 30, 2020 *(unaudited)*	**December 31, 2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 83,109	$ 9,774
Marketable securities	148,467	54,384
Accounts receivable	—	8,281
Inventories	—	3,570
Research and development tax credit receivable	3,058	2,107
Prepaid expenses and other current assets	47,054	4,264
Total current assets	281,688	82,380
Property and equipment, net	373	544
Operating lease right-of-use assets	2,866	3,612
Goodwill	16,836	18,491
Intangible assets, net	—	813

Research and development tax credit receivable	3,608	6,322
Other non-current assets	22,264	39,274
Total assets	$ 327,635	$ 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	520	645
Accounts payable	2,660	6,100
Accrued expenses	16,398	19,810
Other current liabilities	3,431	3,875
Total current liabilities	23,009	35,984
Long-term debt	126,520	121,686
Long-term contingent consideration payable, less current portion	—	11,773
Long-term operating lease liability	1,968	2,319
Other non-current liabilities	4,938	8,873
Total liabilities	156,435	180,635
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at September 30, 2020 and none issued and outstanding at December 31, 2019, respectively	5	—
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 58,243 issued and outstanding at September 30, 2020 and 42,927 issued and 37,520 outstanding at December 31, 2019	582	429
Treasury shares, at cost, 0 and 5,407 shares held at September 30, 2020 and December 31, 2019, respectively	—	(49,998)
Additional paid-in capital	565,440	434,391
Accumulated deficit	(372,909)	(391,215)
Accumulated other comprehensive loss	(21,918)	(22,806)
Total shareholders' equity (deficit)	171,200	(29,199)
Total liabilities and shareholders' equity (deficit)	$ 327,635	$ 151,436

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

	Nine Months Ended September 30,	
	2020	**2019**
Cash flows from operating activities:		
Net income (loss)	$ 18,306	$ (30,487)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	1,297	1,690
Loss on disposal of property and equipment	—	478
Remeasurement of acquisition-related contingent consideration	3,327	2,384
Remeasurement of financing-related contingent consideration	435	496
Amortization of debt discount and debt issuance costs	4,835	4,424
Change in deferred tax and income tax deferred charge	(4,582)	1,333
Stock-based compensation expense	1,705	177
Gain on the disposition of the hospital products	(45,760)	—
Loss on deconsolidation of subsidiary	—	1,750
Other adjustments	306	(667)
Net changes in assets and liabilities		
Accounts receivable	8,281	2,026
Inventories	(1,352)	2,465
Prepaid expenses and other current assets	1,759	(1,859)
Research and development tax credit receivable	2,036	(749)
Accounts payable & other current liabilities	(4,051)	259
Accrued expenses	(6,625)	(2,379)
Earn-out payments for contingent consideration in excess of acquisition-date fair value	(5,323)	(8,640)
Royalty payments for contingent consideration payable in excess of original fair value	(866)	(1,374)

Other assets and liabilities	(3,337)	(1,399)
Net cash used in operating activities	(29,609)	(30,072)
Cash flows from investing activities:		
Purchases of property and equipment	(33)	(29)
Proceeds from the disposal of property and equipment	—	154
Proceeds from the disposition of the hospital products	17,250	—
Proceeds from sales of marketable securities	30,075	57,242
Purchases of marketable securities	(124,254)	(23,814)
Net cash (used in) provided by investing activities	(76,962)	33,553
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 ESPP	2,006	123
Other financing activities, net	—	(109)
Net cash provided by financing activities	179,500	14
Effect of foreign currency exchange rate changes on cash and cash equivalents	406	47
Net change in cash and cash equivalents	73,335	3,542
Cash and cash equivalents at January 1,	9,774	9,325
Cash and cash equivalents at September 30,	$ 83,109	$ 12,867

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenues by Product:	**2020**	**2019**	**2020**	**2019**
Bloxiverz	$ —	$ 1,466	$ 2,201	$ 6,392
Vazculep	—	8,786	10,429	27,669
Akovaz	—	4,208	9,545	13,946
Other	—	(231)	159	213
Total product sales	$ —	$ 14,229	$ 22,334	$ 48,220

Source: Avadel Pharmaceuticals plc