Avadel Pharmaceuticals Reports First Quarter 2020 Financial Results

May 11, 2020

- *Reported positive topline data from the pivotal Phase 3 REST-ON study*
- *Strengthened balance sheet with $190 million in gross proceeds from a private placement in February 2020 and public equity offering in May 2020*
- *Reported revenue of $12.2 million for the first quarter of 2020*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, May 11, 2020 (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 and cataplexy in patients with narcolepsy, today announced its financial results for the first quarter ended March 31, 2020 and provided a company update.

“During the first quarter of 2020, we made significant progress advancing the development program for once-nightly FT218 with the completion of the pivotal Phase 3 REST-ON study. In April, we delivered positive topline data from the study, which showed that all three dose levels of once-nightly FT218 demonstrated statistically significant ($p<0.001$) and clinically meaningful improvement for all three co-primary endpoints compared to placebo,” said Greg Divis, Chief Executive Officer of Avadel.

“Looking ahead, we have a multi-pronged strategy to continue advancing towards achieving our objective of bringing once-nightly FT218, if approved, to patients. Our strategic priorities include finalizing the New Drug Application (NDA), compiling additional supporting scientific data to position FT218 in the market and expanding our capabilities to prepare for product launch. We look forward to keeping patients, healthcare providers, and shareholders updated on our progress. If approved, FT218 could be the first once-nightly therapy to address both excessive daytime sleepiness and cataplexy in patients with narcolepsy. As such, we believe once-nightly FT218 could offer a meaningful alternative for patients in the approximate $1.7 billion twice-nightly sodium oxybate market.[1]”

First quarter and recent company highlights

- Announced positive topline data for the pivotal Phase 3 REST-ON trial of FT218 for excessive daytime sleepiness and cataplexy in patients with narcolepsy:

◦ Once-nightly FT218 at the 9 g dose demonstrated highly statistically significant ($p<0.001$) and clinically meaningful improvement across all three co-primary endpoints (Maintenance of Wakefulness Test, Clinical Global Impression-Improvement and Mean Weekly Cataplexy Attacks) compared to placebo.
◦ Once-nightly FT218 at the 9 g dose was generally well-tolerated, with commonly known sodium oxybate adverse reactions occurring at low rates (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3%, enuresis 9%; discontinuation rate due to adverse reactions 3.9%).
◦ Once-nightly FT218 at the 7.5 g and 6 g dose levels also achieved highly statistically significant ($p<0.001$), clinically meaningful improvements across all three co-primary endpoints compared to placebo, as soon as 3 weeks after initiating FT218.

- Raised $190 million of gross proceeds to strengthen the Company’s balance sheet and provide the capital to support its strategic priorities to bring FT218 to market:

◦ Completed a private placement in February 2020 with gross proceeds of $65 million.
◦ Completed a public equity offering in May 2020 with gross proceeds of $125 million.

- Reported revenues of $12.2 million for the first quarter of 2020.

Overview of first quarter 2020 financial results

Revenues for the first quarter of 2020 were $12.2 million, compared to $16.4 million in the first quarter of 2019. The decline on a year-over-year basis was primarily attributed to lower overall sales volume across the Company’s hospital products as a result of increased market competition.

R&D expenses were $5.5 million in the first quarter of 2020, compared to $7.3 million in the first quarter of 2019. The decrease on a year-over-year basis was primarily attributed to lower headcount due to the restructuring activities completed during 2019.

SG&A expenses were $7.9 million in the first quarter of 2020, compared to $10.4 million in the first quarter of 2019. The year-over-year decline is

primarily the result of realized cost reductions and restructuring actions completed during 2019.

Income tax benefit was $9.5 million in the first quarter of 2020, compared to $0.4 million in the first quarter of 2019. The year-over-year increase is primarily the result of the passage of H.R. 748, the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), enacted on March 27, 2020, which allows the company to carry back Net Operating Losses (NOLs) incurred to periods when the statutory tax rate was 35% versus our current tax rate of 21%.

Net loss for the first quarter of 2020 was $0.9 million, or $0.02 per share, compared to a net loss of $13.0 million, or $0.35 per share, for the same period in 2019.

Cash, cash equivalents and marketable securities were $113.5 million as of March 31, 2020. Subsequent to the end of the quarter, in May 2020, the Company completed a public offering and received net proceeds of approximately $117 million after deducting estimated offering expenses. 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 11, 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 13703221. 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.

Footnote:
1. Annualized Xyrem revenues from the Jazz Pharmaceuticals Full Year and Fourth Quarter 2019 Financial Results press release dated February 25, 2020 and press release dated May 5, 2020 announcing First Quarter 2020 Financial Results.

About FT218
FT218 is an investigational, once-nightly formulation of Micropump™ controlled-release (CR) sodium oxybate. The Company recently 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 potential FDA approval of FT218, which has completed a Phase 3 clinical trial for the treatment of narcolepsy patients suffering from excessive daytime sleepiness (EDS) and cataplexy. In addition, Avadel develops and markets a portfolio of sterile injectable drugs used in the hospital setting. 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 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 of our research, development and commercialization activities 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 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

(In thousands, except per share data)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Product sales	$ 12,243	$ 16,437
Operating expenses:		
Cost of products	2,457	3,266
Research and development expenses	5,530	7,329
Selling, general and administrative expenses	7,913	10,446
Intangible asset amortization	203	201
Changes in fair value of contingent consideration	2,478	2,134
Restructuring costs	159	1,228
Total operating expenses	18,740	24,604
Operating loss	(6,497)	(8,167)
Investment and other income, net	(378)	817
Interest expense	(3,190)	(3,062)
Loss on deconsolidation of subsidiary	—	(2,673)
Other expense - changes in fair value of contingent consideration payable	(310)	(307)
Loss before income taxes	(10,375)	(13,392)
Income tax benefit	(9,510)	(374)
Net loss	$ (865)	$ (13,018)
Net loss per share - basic	$ (0.02)	$ (0.35)
Net loss per share - diluted	(0.02)	(0.35)
Weighted average number of shares outstanding - basic	41,057	37,354
Weighted average number of shares outstanding - diluted	41,057	37,354

AVADEL PHARMACEUTICALS PLC

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

	March 31, 2020	**December 31, 2019**
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 73,506	$ 9,774
Marketable securities	39,977	54,384
Accounts receivable	8,797	8,281
Inventories	3,523	3,570
Research and development tax credit receivable	1,835	2,107
Prepaid expenses and other current assets	3,337	4,264
Total current assets	130,975	82,380
Property and equipment, net	472	544
Operating lease right-of-use assets	3,365	3,612
Goodwill	18,491	18,491
Intangible assets, net	610	813
Research and development tax credit receivable	6,288	6,322
Other non-current assets	47,524	39,274
Total assets	$ 207,725	$ 151,436
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term contingent consideration payable	$ 5,855	$ 5,554
Current portion of operating lease liability	604	645
Accounts payable	6,790	6,100
Accrued expenses	14,858	19,810
Income taxes	2,297	43

Other current liabilities	1,932	3,832
Total current liabilities	32,336	35,984
Long-term debt	123,258	121,686
Long-term contingent consideration payable, less current portion	12,195	11,773
Long-term operating lease liability	2,205	2,319
Other non-current liabilities	5,664	8,873
Total liabilities	175,658	180,635
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at March 31, 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; 51,812 issued and 46,404 outstanding at March 31, 2020 and 42,927 issued and 37,520 outstanding at December 31, 2019	518	429
Treasury shares, at cost, 5,407 shares held at March 31, 2020 and December 31, 2019, respectively	(49,998)	(49,998)
Additional paid-in capital	497,249	434,391
Accumulated deficit	(392,080)	(391,215)
Accumulated other comprehensive loss	(23,627)	(22,806)
Total shareholders' equity (deficit)	32,067	(29,199)
Total liabilities and shareholders' equity (deficit)	$ 207,725	$ 151,436

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

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (865)	$ (13,018)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	456	369
Remeasurement of acquisition-related contingent consideration	2,478	2,134
Remeasurement of financing-related contingent consideration	310	307
Amortization of debt discount and debt issuance costs	1,573	1,445
Change in deferred tax and income tax deferred charge	(8,440)	(222)
Stock-based compensation expense	742	351
Loss on deconsolidation of subsidiary	—	1,750
Other adjustments	573	(541)
Net changes in assets and liabilities		
Accounts receivable	(517)	(1,021)
Inventories	47	467
Prepaid expenses and other current assets	899	(3,228)
Research and development tax credit receivable	160	(449)
Accounts payable & other current liabilities	(1,187)	752
Accrued expenses	(4,905)	(4,750)
Accrued income taxes	2,253	(46)
Earn-out payments for contingent consideration in excess of acquisition-date fair value	(1,774)	(3,181)
Royalty payments for contingent consideration payable in excess of original fair value	(291)	(507)
Other assets and liabilities	(3,148)	(1,818)
Net cash used in operating activities	(11,636)	(21,206)
Cash flows from investing activities:		
Purchases of property and equipment	—	(30)
Proceeds from sales of marketable securities	14,788	34,864
Purchases of marketable securities	(1,562)	(13,444)
Net cash provided by investing activities	13,226	21,390

Cash flows from financing activities:		
Proceeds from February 2020 private placement	60,733	—
Proceeds from stock option exercises and ESPP	1,477	92
Net cash provided by financing activities	62,210	92
Effect of foreign currency exchange rate changes on cash and cash equivalents	(68)	29
Net change in cash and cash equivalents	63,732	305
Cash and cash equivalents at January 1,	9,774	9,325
Cash and cash equivalents at March 31,	$ 73,506	$ 9,630

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

	Three Months Ended March 31,	
Revenues by Product:	**2020**	**2019**
Bloxiverz	$ 1,401	$ 2,568
Vazculep	5,514	9,473
Akovaz	5,349	3,792
Other	(21)	604
Total product sales	$ 12,243	$ 16,437

Source: Avadel Pharmaceuticals plc