Avadel Pharmaceuticals Reports Second Quarter 2020 Financial Results and Recent Business Update

August 10, 2020

- *Presented positive topline data from the pivotal Phase 3 REST-ON study*
- *Announced today that results of the data analyses for the secondary endpoints of the REST-ON study were consistent with the primary analyses and further demonstrated the overall statistical significance of FT218 compared to placebo*
- *Completed the pre-NDA meeting for FT218 with the Food and Drug Administration*
- *First patient dosed in the open-label extension/switch study of investigational once-nightly FT218*
- *Strengthened balance sheet through completion of $125 million public equity offering to support the company's strategic priorities*
- *Completed sale of the sterile injectable drug portfolio for $42.0 million*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, Aug. 10, 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 second quarter ended June 30, 2020 and provided a company update.

"We are at a pivotal point in Avadel's transformation, as we recently completed our pre-NDA meeting with the FDA and are currently focused on completing our NDA submission and filing for FT218. A key component of the planned NDA for FT218 is the positive data from the Phase 3 REST-ON study of FT218, which was first announced in April. These data show that the three dose levels of FT218 that were tested demonstrated statistically significant ($p<0.001$) and clinically meaningful improvement for all three co-primary endpoints. In addition, FT218 was highly significant for the secondary endpoints that tested additional measures of daytime sleepiness, sleep architecture, and other narcolepsy symptoms compared to placebo at all three doses and all sensitivity analyses of the primary endpoint. If approved, FT218 could be the first once-nightly therapy to address both excessive daytime sleepiness and cataplexy in patients with narcolepsy," said Greg Divis, Chief Executive Officer of Avadel.

"In May, we strengthened our balance sheet with the completion of a public equity offering for gross proceeds of $125.0 million that will be used to support the development and plan for the go-to-market strategy of FT218. In June, we further bolstered our cash position with the sale of our legacy portfolio of sterile injectable drugs for $42.0 million. Divesting this product portfolio is in line with our overall strategy to focus the Company's resources on FT218, thus streamlining and focusing Avadel while enabling the company to maintain optionality for creating shareholder value."

"As we move forward for the balance of 2020, our highest priority remains the completion and filing of our once-nightly FT218 NDA. In addition, we are in the process of compiling additional supporting scientific data to position FT218 in the market which includes the ongoing open-label extension (OLE)/switch study of FT218," concluded Mr. Divis.

Second quarter and recent company highlights

- Presented an update on the development of FT218 and positive results from the Phase 3 Rest-On clinical trial for excessive daytime sleepiness and cataplexy in patients with narcolepsy, which were previously announced in April 2020:

◦ 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.
◦ 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%).
◦ 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.

- Announced today additional data from the REST-ON study:

◦ All three doses of FT218 studied were highly significant compared to placebo on secondary endpoints evaluating daytime sleepiness, sleep architecture, and other narcolepsy symptoms
◦ FT218 was also significant compared to placebo for all sensitivity analyses of the three co-primary endpoints at all three doses
◦ Detailed data for the secondary endpoints and sensitivity analyses will be presented at a scientific conference or in a peer-reviewed scientific publication

- Held a successful pre-NDA meeting with the FDA and are on track to move forward with filing our NDA for FT218

- First patient dosed in an OLE/switch study of FT218 as a potential treatment for excessive daytime sleepiness and cataplexy in patients with narcolepsy.
- Completed a public equity offering with gross proceeds of $125.0 million to strengthen the Company's balance sheet and provide capital to support its strategic priorities.
- Completed the sale of the legacy portfolio of sterile injectable drugs used in the hospital setting to Exela Sterile Medicines LLC for a total of $42.0 million.

Overview of Second Quarter Results

Revenues for the second quarter of 2020 were $10.1 million, compared to $17.6 million in the second 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 $4.1 million in the second quarter of 2020, compared to $10.3 million in the second 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 $7.1 million in the second quarter of 2020, compared to $6.8 million in the second quarter of 2019. The year-over-year increase is primarily the result of higher professional fees and market research costs related to FT218.

A $45.8 million pre-tax gain from the sale of the portfolio of sterile injectable drugs was recorded in the second quarter of 2020. The gain reflects the $42.0 million transaction price adjusted for the net liabilities that were transferred to Exela Sterile Medicines LLC and transaction costs incurred by the company.

Income tax provision was $5.3 million in the second quarter of 2020, compared to $1.8 million in the second quarter of 2019.

Net income for the second quarter of 2020 was $30.9 million, or $0.49 per diluted share, compared to a net loss of $8.6 million, or ($0.23) per diluted share, for the same period in 2019.

Cash, cash equivalents and marketable securities were $238.6 million as of June 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, August 10, 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 13707645. 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 potential 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.

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 (including, without limitation, the continued advancement and development of FT218 and benefits and cost savings from the sale of our hospital products) 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 INCOME (LOSS)
(In thousands, except per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Product sales	$ 10,091	$ 17,554	$ 22,334	$ 33,991
Operating expenses:				
Cost of products	3,285	3,622	5,742	6,888
Research and development expenses	4,057	10,292	9,587	17,621
Selling, general and administrative expenses	7,095	6,758	15,008	17,204
Intangible asset amortization	203	204	406	405
Changes in fair value of contingent consideration	918	(377)	3,396	1,757
Gain on sale of hospital business	(45,760)	—	(45,760)	—
Restructuring costs	24	1,506	183	2,734
Total operating (income) expense	(30,178)	22,005	(11,438)	46,609
Operating income (loss)	40,269	(4,451)	33,772	(12,618)
Investment and other (expense) income, net	(741)	950	(1,119)	1,767
Interest expense	(3,237)	(3,106)	(6,427)	(6,168)
Loss on deconsolidation of subsidiary	—	(167)	—	(2,840)
Other expense - changes in fair value of contingent consideration payable	(125)	(50)	(435)	(357)
Income (loss) before income taxes	36,166	(6,824)	25,791	(20,216)
Income tax provision (benefit)	5,292	1,781	(4,218)	1,407
Net income (loss)	$ 30,874	$ (8,605)	$ 30,009	$ (21,623)
Net income (loss) per share - basic	$ 0.57	$ (0.23)	$ 0.63	$ (0.58)
Net income (loss) per share - diluted	0.49	(0.23)	0.58	(0.58)
Weighted average number of shares outstanding - basic	54,272	37,356	47,665	37,355
Weighted average number of shares outstanding - diluted	69,942	37,356	63,083	37,355

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

	June 30, 2020	**December 31, 2019**
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 102,174	$ 9,774
Marketable securities	136,380	54,384
Accounts receivable	5,692	8,281
Inventories	—	3,570
Research and development tax credit receivable	—	2,107

Prepaid expenses and other current assets	32,773	4,264
Total current assets	277,019	82,380
Property and equipment, net	407	544
Operating lease right-of-use assets	3,117	3,612
Goodwill	16,836	18,491
Intangible assets, net	—	813
Research and development tax credit receivable	6,407	6,322
Other non-current assets	37,615	39,274
Total assets	$ 341,401	$ 151,436
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term contingent consideration payable	$ 1,914	$ 5,554
Current portion of operating lease liability	563	645
Accounts payable	4,879	6,100
Accrued expenses	15,820	19,810
Income taxes	354	43
Other current liabilities	3,488	3,832
Total current liabilities	27,018	35,984
Long-term debt	124,879	121,686
Long-term contingent consideration payable, less current portion	—	11,773
Long-term operating lease liability	2,087	2,319
Other non-current liabilities	5,292	8,873
Total liabilities	159,276	180,635
Shareholders' equity (deficit):		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at June 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; 63,536 issued and 58,129 outstanding at June 30, 2020 and 42,927 issued and 37,520 outstanding at December 31, 2019	635	429
Treasury shares, at cost, 5,407 shares held at June 30, 2020 and December 31, 2019, respectively	(49,998)	(49,998)
Additional paid-in capital	615,207	434,391
Accumulated deficit	(361,206)	(391,215)
Accumulated other comprehensive loss	(22,518)	(22,806)
Total shareholders' equity (deficit)	182,125	(29,199)
Total liabilities and shareholders' equity (deficit)	$ 341,401	$ 151,436

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

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net income (loss)	$ 30,009	$ (21,623)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	975	1,064
Loss on disposal of property and equipment	—	478
Remeasurement of acquisition-related contingent consideration	3,396	1,757
Remeasurement of financing-related contingent consideration	435	357
Amortization of debt discount and debt issuance costs	3,193	2,918
Change in deferred tax and income tax deferred charge	161	1,900
Stock-based compensation expense	1,511	406
Gain on the disposition of the hospital business	(45,760)	—
Loss on deconsolidation of subsidiary	—	1,750
Other adjustments	477	(995)
Net changes in assets and liabilities		
Accounts receivable	2,589	579
Inventories	(1,353)	2,124

Prepaid expenses and other current assets	(1,149)	(1,829)
Research and development tax credit receivable	2,036	(593)
Accounts payable & other current liabilities	(1,550)	3,127
Accrued expenses	(6,906)	(3,737)
Accrued income taxes	321	(71)
Earn-out payments for contingent consideration in excess of acquisition-date fair value	(3,736)	(5,790)
Royalty payments for contingent consideration payable in excess of original fair value	(608)	(917)
Other assets and liabilities	(3,458)	(3,558)
Net cash used in operating activities	(19,417)	(22,653)
Cash flows from investing activities:		
Purchases of property and equipment	—	(29)
Proceeds from the disposal of property and equipment	—	154
Proceeds from the disposition of the hospital business	14,500	—
Proceeds from sales of marketable securities	15,716	52,202
Purchases of marketable securities	(97,878)	(21,991)
Net cash (used in) provided by investing activities	(67,662)	30,336
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 ESPP	1,903	92
Other financing activities, net	—	(37)
Net cash provided by financing activities	179,516	55
Effect of foreign currency exchange rate changes on cash and cash equivalents	(37)	48
Net change in cash and cash equivalents	92,400	7,786
Cash and cash equivalents at January 1,	9,774	9,325
Cash and cash equivalents at June 30,	$ 102,174	$ 17,111

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Revenues by Product:	**2020**	**2019**	**2020**	**2019**
Bloxiverz	$ 800	$ 2,358	$ 2,201	$ 4,926
Vazculep	4,915	9,410	10,429	18,883
Akovaz	4,196	5,946	9,545	9,738
Other	180	(160)	159	444
Total product sales	$ 10,091	$ 17,554	$ 22,334	$ 33,991

Source: Avadel Pharmaceuticals plc