Avadel Pharmaceuticals Reports Third Quarter 2019 Financial Results and Raises Revenue Guidance for FY2019

November 12, 2019

- *Enrollment currently at 200 patients for the pivotal REST-ON Phase 3 study (97.5% complete); the Company currently expects to complete patient enrollment by end of 2019, with data readout expected in Q2 2020*
- *Revenue of $48.2 million for first nine months of 2019; increasing revenue guidance to be at or above $55 million for full year 2019*
- *Restructuring and other cost reduction actions on track to realize $80 to $90 million in annualized cost savings*
- *Cash, cash equivalents and marketable securities as of September 30, 2019 totaled $72.5 million*
- *Management to host a conference call today at 8:30 a.m. ET*

DUBLIN, Ireland, Nov. 12, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218, an investigational, once-nightly formulation of sodium oxybate for treating narcolepsy, today announced its financial results for the third quarter of 2019 and provided a company update.

“In the third quarter of 2019, Avadel achieved several milestones that were established as part of our focused business strategy announced earlier this year,” said Greg Divis, Chief Executive Officer of Avadel. “Appointments to the clinical and medical teams during the second and third quarters of 2019 strengthened our R&D focus and quickly made meaningful contributions to the clinical development of our lead asset, FT218. The team’s most important recent activities include amendments to the statistical analysis plan for our pivotal Phase 3 REST-ON trial for FT218 that were accepted by the FDA in September. As a result of these amendments, the study is now targeting the enrollment of 205 patients, reducing the estimated time for completion by up to 12 months, with enrollment expected to be completed by the end of 2019 and topline data available in the second quarter of 2020.”

“Our sterile injectable hospital business has continued to outperform our expectations in the third quarter of 2019, and we have raised our annual revenue guidance for 2019 to be at or above $55 million. We look forward to the potential launch of AV001, our fourth hospital product, pending the outcome of the FDA’s Prescription Drug User Fee Act (PDUFA) target action date of December 15, 2019. If approved, AV001 is expected to contribute to our 2020 revenue and support the development of FT218,” stated Mr. Divis.

“We have made significant progress over the first nine months of 2019 in strengthening the company financially, while primarily focusing on the clinical development of FT218. We believe these actions have put the company on a path toward long-term success and re-building shareholder value,” concluded Mr. Divis.

Third quarter and recent company highlights

- The FDA agreed to the Company’s amendments to the statistical analysis plan, ultimately resulting in a reduced sample size for the ongoing pivotal Phase 3 study for once-nightly FT218 while retaining our Special Protocol Assessment (SPA) agreement; full enrollment now expected by end of 2019 and top-line data on track to be announced in the second quarter of 2020;
- Announced pharmacokinetic (PK) data for once-nightly FT218 from four Phase 1 studies in an oral presentation at the World Sleep 2019 Congress;
- Data presented at the World Sleep 2019 Congress from four Phase 1 studies demonstrate that FT218 exhibits a pharmacokinetic profile desirable for once-nightly dosing with equivalent exposure to twice-nightly sodium oxybate at the 4.5 g and 6 g dosing levels;
- Received a new Prescription Drug User Fee Act (PDUFA) target action date of December 15, 2019 for AV001 from the U.S. Food and Drug Administration;
- Cost reductions and restructuring actions have resulted in approximately $63 million of lower SG&A and R&D spending; the Company is on track to realize $80 to $90 million of cost reductions in 2019 compared to 2018, as previously announced;

- Cash, cash equivalents and marketable securities as of September 30, 2019 totaled $72.5 million, compared to $79.3 million as of June 30, 2019 and $99.9 million as of December 31, 2018; and

- Reported revenues of $14.2 million in the third quarter of 2019; annual revenue is now expected to be at or above $55 million for 2019.

Overview of third quarter 2019 financial results

Revenues for the third quarter of 2019 were $14.2 million, compared to $19.8 million in the third quarter of 2018. The decline on a year-over-year basis was primarily attributed to lower net selling prices across the Company's hospital products as a result of increased market competition.

In thousands (Unaudited)	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenues by Product:	**2019**	**2018**	**2019**	**2018**
Bloxiverz	$ 1,466	$ 3,656	$ 6,392	$ 16,691
Vazculep	8,786	8,759	27,669	33,097
Akovaz	4,208	5,991	13,946	28,083
Other	(231)	1,420	213	4,232
Total product sales	14,229	19,826	48,220	82,103
License revenue	—	—	—	246
Total revenues	$ 14,229	$ 19,826	$ 48,220	$ 82,349

Research and development (R&D) expenses were $7.5 million in the third quarter of 2019, compared to $11.4 million in the third quarter of 2018. The Company continues to invest a substantial portion of R&D spend in its FT218 development program.

Selling, general and administrative (SG&A) expenses were $5.3 million in the third quarter of 2019, compared to $24.8 million in the third quarter of 2018 and $6.8 million in the second quarter of 2019. The year-over-year and sequential quarterly declines are primarily the result of realized cost reductions resulting from the exit of Noctiva™ and the Company's cost reduction and restructuring actions.

Net loss for the third quarter of 2019 was $8.9 million, or $0.24 per share, compared to a net loss of $15.8 million or $0.43 per share for the same period in 2018.

Cash, cash equivalents and marketable securities were $72.5 million as of September 30, 2019, compared to $79.3 million as of June 30, 2019 and $99.9 million as of December 31, 2018. Based on Avadel's current FT218 clinical development plan, anticipated cost structure improvements and hospital products revenue projections, the Company expects its cash to be sufficient to fund operations well into 2021. The Company believes that the commercial launch of AV001, pending regulatory approval, could further fund operations and support the development of FT218. The Company has convertible debt of $144 million due in 2023.

2019 Guidance:
Based on recent hospital products sales performance, increased competition from additional products launched in 2019, and recent market price actions, annual revenue for 2019 is now expected to be at or above $55 million.

The U.S. Food and Drug Administration (FDA) is reviewing an NDA for a fourth hospital product, AV001, with a PDUFA target action date of December 15, 2019. If approved, AV001 is expected to contribute to revenues in 2020 and beyond.

Conference Call:
A conference call to discuss these results has been scheduled for Tuesday, November 12, 2019 at 8:30 a.m. EST. 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 13696031. 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 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 is in 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. In some cases, forward-looking statements can be identified by the use of words such as "will," "may," "believe," "expect," "look forward," "on track," "could," "guidance," "anticipate," "estimate," "project" 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:

(a) risks relating to our recent net losses and restructuring plan, including risks relating to the following:
due to a decrease in our available liquid assets, our business strategy has been refocused and is now substantially directed to development of a single

product, FT218; our recent restructuring plan may not be as effective as we anticipate and may have unintended negative impacts; further restructuring actions, if needed, may require third-party consents (including consents under the indenture governing our convertible debt), and such consents may not be granted; and the Chapter 11 bankruptcy filing by our subsidiary Avadel Specialty Pharmaceuticals, LLC may have unexpected adverse results. While our financial resources are currently anticipated to be sufficient to finance our operations well into 2021, it may be necessary for us to seek additional financial resources to continue our operations, and such financial resources may not be available to us on reasonable terms or at all.

b) risks relating to the following: our three products Bloxiverz®, Vazculep® and Akovaz®, which are not patent protected and have a small number of customers, currently produce substantially all of our revenues and could face further competition resulting in a further loss of market share and/or forcing us to further reduce our prices for those products; our current "unapproved marketed drug" (UMD) product candidate, AV001, could fail to achieve FDA approval; we could fail to develop future potential UMD product candidates, or competitors could develop such products and market such products with FDA approval before us; we could experience failure or further delay in completing the Phase III clinical trial for FT218, and if the FDA ultimately approves such product, the approval may not include any period of market exclusivity; we may not have sufficient cash or the ability to raise sufficient cash to service our $143.75 million Exchangeable Senior Notes due 2023 ("Notes"), including cash necessary to repay such Notes at maturity, to settle exchanges of such Notes in cash, or to repurchase such Notes as required following a "fundamental change" event described in the indenture governing such Notes; we depend on a limited number of third parties to manufacture certain of our products and to provide certain raw materials used in our products; our competitors may develop and market technologies or products that are more effective or safer than ours, or obtain regulatory approval and market such technologies or products before we do; we may face challenges in obtaining intellectual property protecting our products and drug delivery technologies; and we depend on key personnel to execute our business plan.

(c) the other 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, 2018, which we filed with the Securities and Exchange Commission on March 15, 2019.

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 the forward-looking statements contained in this Annual Report.

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AVADEL PHARMACEUTICALS PLC
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF LOSS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product sales	$ 14,229	$ 19,826	$ 48,220	$ 82,103
License revenue	—	—	—	246
Total revenues	14,229	19,826	48,220	82,349
Operating expenses:				
Cost of products	2,823	3,120	9,711	13,224
Research and development expenses	7,539	11,402	25,160	33,243
Selling, general and administrative expenses	5,316	24,829	22,520	77,159
Intangible asset amortization	205	1,620	610	4,996
Changes in fair value of related party contingent consideration	627	(7,115)	2,384	(17,036)
Restructuring costs	1,866	65	4,600	268
Total operating expenses	18,376	33,921	64,985	111,854
Operating loss	(4,147)	(14,095)	(16,765)	(29,505)
Investment and other income, net	781	208	2,548	845
Interest expense	(3,125)	(3,000)	(9,293)	(7,577)
Loss on deconsolidation of subsidiary	—	—	(2,840)	—
Other (expense) income - changes in fair value of related party payable	(139)	425	(496)	1,432
Loss before income taxes	(6,630)	(16,462)	(26,846)	(34,805)
Income tax provision (benefit)	2,234	(691)	3,641	(3,360)
Net loss	$ (8,864)	$ (15,771)	$ (30,487)	$ (31,445)

Net loss per share - basic	$ (0.24)	$ (0.43)	$ (0.82)	$ (0.84)
Net loss per share - diluted	(0.24)	(0.43)	(0.82)	(0.84)
Weighted average number of shares outstanding - basic	37,436	36,904	37,382	37,410
Weighted average number of shares outstanding - diluted	37,436	36,904	37,382	37,410

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

	September 30, 2019	December 31, 2018
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,867	$ 9,325
Marketable securities	59,587	90,590
Accounts receivable	8,725	11,330
Inventories	2,260	4,770
Prepaid expenses and other current assets	5,163	8,836
Total current assets	88,602	124,851
Property and equipment, net	770	1,911
Operating lease right-of-use assets	4,385	—
Goodwill	18,491	18,491
Intangible assets, net	1,019	1,629
Research and development tax credit receivable	7,694	7,272
Other non-current assets	34,927	36,146
Total assets	$ 155,888	$ 190,300
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 35	$ 106
Current portion of long-term related party payable	7,588	9,439
Current portion of operating lease liability	1,596	—
Accounts payable	3,538	3,503
Accrued expenses	17,017	21,695
Other current liabilities	1,989	3,640
Total current liabilities	31,763	38,383
Long-term debt, less current portion	120,132	115,734
Long-term related party payable, less current portion	14,118	19,401
Long-term operating lease liability	2,866	—
Other non-current liabilities	13,972	14,002
Total liabilities	182,851	187,520
Shareholders' (deficit) equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; none issued or outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 42,857 issued and 37,450 outstanding at September 30, 2019 and 42,720 issued and 37,313 outstanding at December 31, 2018	428	427
Treasury shares, at cost, 5,407 shares held at September 30, 2019 and December 31, 2018, respectively	(49,998)	(49,998)
Additional paid-in capital	434,055	433,756
Accumulated deficit	(388,476)	(357,989)
Accumulated other comprehensive loss	(22,972)	(23,416)
Total shareholders' (deficit) equity	(26,963)	2,780
Total liabilities and shareholders' (deficit) equity	$ 155,888	$ 190,300

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

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (30,487)	$ (31,445)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	1,690	5,625
Loss on disposal of property and equipment	478	—
Amortization of premiums on marketable securities	(275)	2,889
Remeasurement of related party acquisition-related contingent consideration	2,384	(17,036)
Remeasurement of related party financing-related contingent consideration	496	(1,432)
Amortization of debt discount and debt issuance costs	4,424	3,402
Change in deferred tax and income tax deferred charge	1,333	(4,675)
Stock-based compensation expense	177	7,190
Loss on deconsolidation of subsidiary	1,750	—
Other adjustments	(392)	117
Net changes in assets and liabilities		
Accounts receivable	2,026	5,059
Inventories	2,465	(548)
Prepaid expenses and other current assets	(1,859)	2,194
Research and development tax credit receivable	(749)	(1,350)
Accounts payable & other current liabilities	259	4,312
Accrued expenses	(2,379)	(11,660)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(8,640)	(16,254)
Royalty payments for related party payable in excess of original fair value	(1,374)	(2,362)
Other assets and liabilities	(1,399)	(2,216)
Net cash used in operating activities	(30,072)	(58,190)
Cash flows from investing activities:		
Purchases of property and equipment	(29)	(167)
Proceeds from the disposal of property and equipment	154	—
Purchase of intangible asset	—	(20,000)
Proceeds from sales of marketable securities	57,242	308,015
Purchases of marketable securities	(23,814)	(341,036)
Net cash provided by (used in) investing activities	33,553	(53,188)
Cash flows from financing activities:		
Earn-out payments for related party contingent consideration	—	(645)
Proceeds from debt issuance	—	143,750
Payments for debt issuance costs	—	(6,190)
Share repurchases	—	(27,637)
Proceeds from issuance of ordinary shares and warrants	123	3,488
Other financing activities, net	(109)	(31)
Net cash provided by financing activities	14	112,735
Effect of foreign currency exchange rate changes on cash and cash equivalents	47	(84)
Net change in cash and cash equivalents	3,542	1,273
Cash and cash equivalents at January 1,	9,325	16,564
Cash and cash equivalents at September 30,	$ 12,867	$ 17,837

Source: Avadel Pharmaceuticals plc