Avadel Pharmaceuticals Reports Second Quarter 2019 Financial Results and Provides Company Update

August 9, 2019

- *Better-than-expected Hospital Product revenue improves liquidity position*
- *Restructuring and other cost reduction actions on track to realize $80 to $90 million in annualized cost savings*
- *REST-ON 69% enrolled; 81 patients remain to be enrolled*

DUBLIN, Ireland, Aug. 09, 2019 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (Nasdaq: AVDL), a company focused on developing FT218 for narcolepsy, today announced its financial results for the second quarter of 2019 and provided a company update.

“During the second quarter, we made meaningful progress against our key strategic objectives,” said Greg Divis, Chief Executive Officer of Avadel. “Our top priority is the continued advancement of FT218, our proprietary once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy associated with narcolepsy. Recent additions to our clinical and medical team, including the appointment of Jordan Dubow as Chief Medical Officer, have enhanced our capabilities with respect to the ongoing development of FT218, which is currently being studied in our pivotal Phase 3 REST-ON trial. In addition, we believe the PK data that were presented at the SLEEP 2019 conference further demonstrates the potential benefits of FT218, which reinforces our belief in its potential for success in addressing patient needs. Looking ahead for this program, we expect to complete enrollment for the Phase 3 REST-ON trial in the second half of 2020.

“I am pleased to announce that the benefits from our restructuring initiatives are being realized, as evidenced by approximately $40 million of year-over-year cost reductions. In addition, our Hospital Products business continues to perform beyond our expectations, providing added liquidity to support the development of FT218. We look forward to continuing to drive this positive momentum in the business through the remainder of 2019 and beyond.”

Second quarter and recent company highlights

- The REST-ON clinical trial has enrolled 183 patients, which is 69% of the total 264 target enrollment for the study; based on current trends, the Company remains on-track to complete enrollment in the second half of 2020;
- Data were presented in two posters at the SLEEP 2019 conference, highlighting the pharmacokinetic (PK) profile of FT218, including a head-to-head comparison to twice-nightly sodium oxybate and a dose proportionality study demonstrating linearity across three doses;
- Gregory J. Divis was appointed Chief Executive Officer;
- The Company has significantly strengthened its scientific, clinical and regulatory capabilities with the appointments of Jordan Dubow, M.D., as Chief Medical Officer; Courtney Wells as Vice President, Clinical Operations, and David Seiden, M.D., as Senior Medical Director;
- The U.S. Food and Drug Administration accepted the New Drug Application for AV001, the Company’s fourth hospital product with an updated Prescription Drug User Fee Act (PDUFA) target action date of December 15, 2019;
- Cost reductions and restructuring actions to date have resulted in approximately $40 million of lower SG&A and R&D spending; the Company is on track to realize the full $80 to $90 million of cost reductions before December 31, 2019, as previously announced;
- Cash and cash equivalents as of June 30, 2019 totaled $79.3 million compared to $79.9 million as of March 31, 2019, and compared to $99.9 million as of December 31, 2018 and;
- Reported revenues of $17.6 million in the second quarter of 2019; annual revenue is now expected to be in excess of $45 million for 2019.

Overview of second quarter 2019 financial results

Revenues for the second quarter of 2019 were $17.6 million, compared to $29.2 million in the second quarter of 2018. The decline on a year-over-year basis was primarily attributed to lower net selling prices across all of the Company’s hospital products as a result of increased market competition.

Revenues by Product:	Three Months Ended June 30, 2019	2018	Six Months Ended June 30, 2019	2018
Bloxiverz	$ 2,358	$ 5,544	$ 4,926	$ 13,035
Vazculep	9,410	11,377	18,883	24,338
Akovaz	5,946	11,875	9,738	22,092
Other	(160)	320	444	2,812
Total product sales	17,554	29,116	33,991	62,277
License revenue	—	114	—	246
Total revenues	$ 17,554	$ 29,230	$ 33,991	$ 62,523

Research and development (R&D) expenses were $10.3 million in the second quarter of 2019 compared to $11.9 million in the second quarter of 2018. The Company continues to invest a substantial portion of R&D in its FT218 development program.

Selling, general and administrative (SG&A) expenses were $6.8 million in the second quarter of 2019 compared to $27.8 million for the second quarter of 2018 and $10.4 million for the first 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 restructuring actions.

Net loss for the second quarter of 2019 was $8.6 million or $0.23 per share compared to a net loss of $3.4 million or $0.09 per share for the same period in 2018.

Cash, cash equivalents and marketable securities were $79.3 million as of June 30, 2019, compared to $79.9 million as of March 31, 2019 and $99.9 million as of December 31, 2018. Based on our current FT218 clinical development plan, anticipated cost structure and hospital products revenue projections, cash is expected to be sufficient to fund operations into 2021. This includes completion of the REST-ON study and disclosure of top-line results. The Company has convertible debt of $144 million due in 2023.

2019 Guidance:
Based on recent hospital products sales performance and continuing to factor in increased competition from products launched and products expected to be launched in 2019, and possible market price actions, which have not yet occurred, hospital product revenue for 2019 is now expected to be in excess of $45 million. The U.S. Food and Drug Administration (FDA) is reviewing an NDA for a fourth Hospital Product, AV001, with a recently updated PDUFA target action date of December 15, 2019. If approved, AV001 could be launched in the first quarter of 2020 and contribute revenues to Avadel in 2020.

Conference Call:
A conference call to discuss these results has been scheduled for Friday, August 9, 2019 at 8:30 a.m. EDT. To access the conference call, investors are invited to dial (844) 388-0559 (U.S. and Canada) or (216) 562-0393 (International). The conference ID number is 4290467. 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 a branded specialty pharmaceutical company. The Company's primary focus is on the development and potential FDA approval for 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," "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 dependent upon 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;
- the Chapter 11 bankruptcy filing by our subsidiary Avadel Specialty Pharmaceuticals LLC may have unexpected adverse results; and

- Patient enrollment for our FT 218 clinical trial is not expected to be complete until the second half of 2020. As a result, we do not expect to submit an application for FDA approval of FT218 until sometime during 2021, Our financial resources are currently anticipated to be sufficient to finance our operations into 2021. Accordingly, 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; or 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, 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 one or 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 face challenges in protecting intellectual property underlying 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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product sales	$ 17,554	$ 29,116	$ 33,991	$ 62,277
License revenue	—	114	—	246
Total revenues	17,554	29,230	33,991	62,523
Operating expenses:				
Cost of products	3,622	3,512	6,888	10,104
Research and development expenses	10,292	11,890	17,621	21,841
Selling, general and administrative expenses	6,758	27,843	17,204	52,330
Intangible asset amortization	204	1,609	405	3,376
Changes in fair value of related party contingent consideration	(377)	(12,889)	1,757	(9,921)
Restructuring costs	1,506	50	2,734	203
Total operating expenses	22,005	32,015	46,609	77,933
Operating loss	(4,451)	(2,785)	(12,618)	(15,410)
Investment and other income, net	950	583	1,767	637
Interest expense	(3,106)	(2,980)	(6,168)	(4,577)

Loss on deconsolidation of subsidiary	(167)	—	(2,840)	—
Other (expense) income - changes in fair value of related party payable	(50)	1,402	(357)	1,007
Loss before income taxes	(6,824)	(3,780)	(20,216)	(18,343)
Income tax provision (benefit)	1,781	(342)	1,407	(2,669)
Net loss	$ (8,605)	$ (3,438)	$ (21,623)	$ (15,674)
Net loss per share - basic	$ (0.23)	$ (0.09)	$ (0.58)	$ (0.42)
Net loss per share - diluted	(0.23)	(0.09)	(0.58)	(0.42)
Weighted average number of shares outstanding - basic	37,356	36,772	37,355	37,666
Weighted average number of shares outstanding - diluted	37,356	36,772	37,355	37,666

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

	June 30, 2019 *(unaudited)*	**December 31, 2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,111	$ 9,325
Marketable securities	62,151	90,590
Accounts receivable	10,172	11,330
Inventories	2,601	4,770
Prepaid expenses and other current assets	5,165	8,836
Total current assets	97,200	124,851
Property and equipment, net	934	1,911
Operating lease right-of-use assets	5,454	—
Goodwill	18,491	18,491
Intangible assets, net	1,224	1,629
Research and development tax credit receivable	7,833	7,272
Other non-current assets	34,573	36,146
Total assets	$ 165,709	$ 190,300
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 105	$ 106
Current portion of long-term related party payable	8,264	9,439
Current portion of operating lease liability	999	—
Accounts payable	4,798	3,503
Accrued expenses	15,737	21,695
Other current liabilities	3,677	3,640
Total current liabilities	33,580	38,383
Long-term debt, less current portion	118,631	115,734
Long-term related party payable, less current portion	15,983	19,401
Long-term operating lease liability	3,617	—
Other non-current liabilities	11,675	14,002
Total liabilities	183,486	187,520
Shareholders' (deficit) equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; none issued or outstanding at June 30, 2019 and December 31, 2018, respectively	—	—
Ordinary shares, nominal value of $0.01 per share; 500,000 shares authorized; 42,763 issued and 37,356 outstanding at June 30, 2019 and 42,720 issued and 37,313 outstanding at December 31, 2018	427	427
Treasury shares, at cost, 5,407 shares held at June 30, 2019 and December 31, 2018, respectively	(49,998)	(49,998)
Additional paid-in capital	434,254	433,756
Accumulated deficit	(379,612)	(357,989)
Accumulated other comprehensive loss	(22,848)	(23,416)
Total shareholders' (deficit) equity	(17,777)	2,780

Total liabilities and shareholders' (deficit) equity	$ 165,709	$ 190,300

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

	Six Months Ended June 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (21,623)	$ (15,674)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	1,064	3,810
Loss on disposal of property and equipment	478	—
Amortization of premiums on marketable securities	17	1,693
Remeasurement of related party acquisition-related contingent consideration	1,757	(9,921)
Remeasurement of related party financing-related contingent consideration	357	(1,007)
Amortization of debt discount and debt issuance costs	2,918	2,019
Change in deferred tax and income tax deferred charge	1,900	(3,247)
Stock-based compensation expense	406	4,358
Loss on deconsolidation of subsidiary	1,750	—
Other adjustments	(1,012)	91
Net changes in assets and liabilities		
Accounts receivable	579	(157)
Inventories	2,124	(242)
Prepaid expenses and other current assets	(1,829)	1,587
Research and development tax credit receivable	(593)	(1,003)
Accounts payable & other current liabilities	3,127	5,206
Accrued expenses	(3,737)	(9,831)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(5,790)	(11,113)
Royalty payments for related party payable in excess of original fair value	(917)	(1,618)
Other assets and liabilities	(3,629)	(2,893)
Net cash used in operating activities	(22,653)	(37,942)
Cash flows from investing activities:		
Purchases of property and equipment	(29)	(99)
Proceeds from the disposal of property and equipment	154	—
Purchase of intangible asset	—	(20,000)
Proceeds from sales of marketable securities	52,202	253,525
Purchases of marketable securities	(21,991)	(312,638)
Net cash provided by (used in) investing activities	30,336	(79,212)
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	—	(5,760)
Share repurchases	—	(27,637)
Proceeds from issuance of ordinary shares and warrants	92	3,446
Other financing activities, net	(37)	6
Net cash provided by financing activities	55	113,160
Effect of foreign currency exchange rate changes on cash and cash equivalents	48	(93)
Net change in cash and cash equivalents	7,786	(4,087)
Cash and cash equivalents at January 1,	9,325	16,564
Cash and cash equivalents at June 30,	$ 17,111	$ 12,477

Source: Avadel Pharmaceuticals plc