



Avadel Pharmaceuticals Reports Second Quarter 2018 Financial Results

August 7, 2018

DUBLIN, Ireland, Aug. 07, 2018 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ: AVDL), a company focused on providing innovative medicines for chronic urological, central nervous system, and sleep disorders, today announced its financial results for the second quarter of 2018.

Mike Anderson, Avadel's Chief Executive Officer, said, "Our second quarter was a period of continued investment and focus on building the foundation that is expected to propel us forward into the future. We came in above consensus with \$29 million in revenues, largely from our generic hospital products, and have transformed our investment focus to growth-oriented products that have the potential to deliver long-term shareholder value. We are adequately capitalized to continue this transformation, and over the next 12 - 18 months we expect to accelerate our two near-term growth catalysts, NOCTIVA™ and FT 218."

Mr. Anderson continued, "We are just a few months into the launch of NOCTIVA, and although net revenue to date is just under one million dollars, we are encouraged with a number of early indicators of positive traction, including prescription demand, active prescribers, and product awareness levels. More than 2,600 prescriptions have been written to date. We have had positive physician reception with more than 1,000 unique prescribers and our unaided brand-awareness level has reached over 60% in just a few short months. Education and increasing the relevance of nocturia as a condition to be treated in and of itself, and improving coverage and patient access, particularly in Part D, are keys to translating this demand into improved revenue numbers and accelerating NOCTIVA's growth over the next 12-18 months."

"Additionally, we continue to improve recruitment efforts for our REST-ON Phase III trial of our investigational FT 218 drug in patients with narcolepsy. As we enter the second half of this year, we are approximately 50% enrolled. With the FDA's recent agreement to allow the inclusion of a select group of former sodium oxybate users, we have initiated a database review program across our clinical sites. We have also implemented a new patient referral program and, over the next few months, we will be adding seven new clinical sites in the U.S., and three in Australia where sodium oxybate is not currently available to patients. We have only been fully operational in our initial U.S. sites for about a year and are confident that these additional measures should continue to improve the enrollment rate for the second half of our study," concluded Mr. Anderson.

Overview of second quarter 2018 financial results:

Revenues:

(\$ in 000s) By Product	Three Months Ended June 30,	
	2018	2017
Bloxiverz	\$ 5,544	\$ 13,719
Vazculep	11,377	10,154
Akovaz	11,875	20,912
Noctiva	289	—
Other	31	2,320
Product sales	29,116	47,105
License revenue	114	(794)
Total revenues	\$ 29,230	\$ 46,311

Revenues for the second quarter 2018 were \$29.2 million, compared to \$46.3 million in the second quarter 2017. The decline on a year-over-year basis was attributed to lower net selling prices and units shipped for Bloxiverz® and Akovaz® due to more competition, slightly offset by higher Vaculep® revenues from increased units shipped during the second quarter 2018. Net sales for NOCTIVA were \$289,000 in the second quarter 2018, down on a quarter-over-quarter basis from \$666,000 due largely to the initial wholesaler stocking that occurred at the end of the first quarter 2018 in anticipation of the May 2018 branded launch.

Operating expenses:

(\$ in 000s) Operating expenses	Three Months Ended June 30,	
	2018	2017
Cost of products	\$ 3,512	\$ 4,561
Research and development expenses (R&D)	11,890	6,792
Selling, general and administrative expenses (SG&A)	27,843	12,429

R&D expense was up 75% in the second quarter 2018 compared to the prior year period, primarily due to increased spend on the Phase III REST-ON trial. The \$15.5 million increase in SG&A in the second quarter 2018 compared to the second quarter 2017 was due to sales and marketing expenses associated with the launch of NOCTIVA.

GAAP earnings:

(\$ in 000s except for per share)	Three Months Ended June 30,	
	2018	2017

Net (loss) income	\$ (3,438)	\$ 28,927
Net (loss) income per share - diluted	(0.09)	0.68

Included in GAAP net loss for the second quarter 2018 were gains of \$12.9 million related to changes in the fair value of related party contingent consideration, compared to gains of \$13.2 million in the same period last year. These non-cash gains were recorded as a result of reducing the fair value of related party contingent consideration due to changing market conditions across the Company's three hospital products.

Adjusted earnings (1):

(\$ in 000s except for per share)	Three Months Ended June 30,	
	2018	2017
Net (loss) income	\$ (20,261) \$ 8,165
Net (loss) income per share - diluted	(0.55) 0.19

(1) Descriptions of Avadel's non-GAAP financial measures are included under the caption Non-GAAP Disclosures and Adjustments included within this press release and reconciliations of such non-GAAP financial measures to their most closely applicable GAAP financial measures are found in the Supplemental Information section herein.

The decrease in adjusted net income is largely attributable to lower revenues from the Company's hospital products and higher SG&A due to the 2018 launch of Noctiva. Please see the Supplemental Information section within this document for a reconciliation of adjusted net income and adjusted diluted EPS to the respective GAAP amounts.

2018 Guidance:

The Company maintained its full year 2018 spend guidance for R&D of between \$40 to \$50 million, and SG&A of between \$80 to \$90 million. Cash interest expense as a result of the Company's convertible notes offering in February 2018 is expected to be approximately \$6 million, and a non-GAAP tax benefit of 0% to 10% of loss before tax is anticipated for the full year 2018. During the second quarter competing products were approved for Vazculep, Bloxiverz and NOCTIVA; as such, the Company is lowering its full year revenue guidance to a range of \$90 to \$105 million from \$105 to \$125 million. Included in this range is an estimated \$5 to \$10 million in revenue from NOCTIVA, down from previous guidance of \$10 to \$20 million, in part due to a lower than expected net-realized selling price from a less favorable mix of commercially insured to Medicare Part D prescriptions in the initial launch period. The Company expects an increase in net-selling price as it continues to improve script volume and market access throughout the course of the next 12 to 18 months.

Conference Call:

A conference call to discuss these results has been scheduled for Tuesday, August 7, 2018 at 10:00 a.m. EDT. A question and answer period will follow management's prepared remarks. 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 7367859. A live audio webcast can be accessed by visiting the Investors 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 specialty pharmaceutical company that seeks to develop differentiated pharmaceutical products that are safe, effective and easy to take through formulation development, by utilizing its proprietary drug delivery technology and through in-licensing / acquiring new products; ultimately, helping patients adhere to their prescribed medical treatment and see better results. Avadel's current portfolio of products and product candidates focuses on the urology, central nervous system (CNS) / sleep, and hospital markets. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri and Lyon, France. For more information, please visit www.avadel.com.

Safe Harbor: This press release may include 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. The words "will," "may," "believe," "expect," "anticipate," "estimate," "project" and similar expressions, and the negatives thereof, identify forward-looking statements, each of which speaks only as of the date the statement is made. Although we believe that our forward-looking statements are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and as a result there can be no assurance that actual results of our research, development and commercialization activities and our results of operations will not differ materially from the results contemplated in such forward-looking statements. These risks include: (i) risks relating to our exchangeable senior notes including use of the net proceeds from the offering of the notes and other future events related to the notes; (ii) risks relating to the divestiture of our former pediatric business including whether such divestiture will be accretive to our operating income and cash flow; (iii) risks relating to our license agreement with Serenity Pharmaceuticals, LLC including that a potential competitive product, and patent litigation with the manufacturer of that product, could have a material adverse impact on our ability to successfully exploit any market opportunity for the drug desmopressin acetate (the "Drug") which we are marketing under the brand name Noctivatm, our internal analyses may overstate the market opportunity in the United States for the Drug or we may not effectively exploit such market opportunity, that significant safety or drug interaction problems could arise with respect to the Drug, that we may not successfully increase awareness of nocturia and the potential benefits of the Drug, and that the need for management to focus attention on the development and commercialization of the Drug could cause our ongoing business operations to suffer; and (iv) the other risks, uncertainties and contingencies described in the Company's filings with the U.S. Securities and Exchange Commission, including our annual report on Form 10-K for the year ended December 31, 2017, in particular disclosures that may be set forth in particular under the captions "Forward-Looking Statements" and "Risk Factors," including without limitation: our dependence on a small number of products and customers for the majority of our revenues; the possibility that our Bloxiverz®, Vazculep® and Akovaz® products, which are not patent protected, could face substantial competition resulting in a loss of market share or forcing us to reduce the prices we charge for those products; the possibility that we could fail to successfully complete the research and development for pipeline products we are evaluating for potential application to the FDA pursuant to our "unapproved-to-approved" strategy, or that competitors could complete the development of such products and apply for FDA approval of such products before us; the possibility that our products may not reach the commercial market or gain market acceptance; our need to invest substantial sums in research and development in order to remain competitive; our dependence on certain single providers for development of several of our drug delivery platforms and products; our dependence on a limited number of suppliers to manufacture our products and to deliver certain raw materials used in our products; the possibility that 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; the challenges in protecting the intellectual property underlying our drug delivery platforms and other products; and our dependence on key personnel to execute our business plan.

Non-GAAP Disclosures and Adjustments

Avadel discloses certain non-GAAP financial measures, including adjusted net income and loss and adjusted net income and loss per diluted share, as management believes that such non-GAAP financial measures can enhance an overall understanding of the Company's financial performance when considered together with financial measures prepared in accordance with generally accepted accounting principles (GAAP) in the U.S. In addition to reporting its financial results in accordance with GAAP, Avadel reports certain non-GAAP results that exclude, if any, fair value remeasurements of its contingent consideration, amortization of debt discount and debt issuance costs attributable to our exchangeable notes, impairment of intangible assets, if any, amortization of intangible assets, restructuring costs, if any, foreign exchange gains and losses on assets and liabilities denominated in foreign currencies, unrealized gains/losses on marketable equity securities, but includes the cash payments plus any unpaid accrued cash payments associated with the contingent consideration and cash interest payments or related accruals on the exchangeable notes. The Company's management uses these non-GAAP measures internally for forecasting, budgeting and measuring its operating performance. Investors and other readers should review the related GAAP financial measures and the reconciliation of non-GAAP measures to their most closely comparable GAAP measure set forth below and should consider non-GAAP measures only as a supplement to, not as a substitute for or as a superior measure to, measures of financial performance prepared in accordance with GAAP. The table provided within the following "Supplemental Information" section reconciles GAAP net income and loss and diluted earnings or loss per share to the corresponding adjusted amounts.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
Product sales	\$ 29,116	\$ 47,105	\$ 62,277	\$ 98,862
License revenue	114	(794)	246	(44)
Total revenues	29,230	46,311	62,523	98,818
Operating expenses:				
Cost of products	3,512	4,561	10,104	8,463
Research and development expenses	11,890	6,792	21,841	13,998
Selling, general and administrative expenses	27,843	12,429	52,330	24,241
Intangible asset amortization	1,609	564	3,376	1,128
Gain - changes in fair value of related party contingent consideration	(12,889)	(13,230)	(9,921)	(20,201)
Restructuring costs	50	1,069	203	3,722
Total operating expenses	32,015	12,185	77,933	31,351
Operating (loss) income	(2,785)	34,126	(15,410)	67,467
Investment and other income (expense), net	583	764	637	1,585
Interest expense, net	(2,980)	(263)	(4,577)	(526)
Other income - changes in fair value of related party payable	1,402	1,670	1,007	2,220
(Loss) income before income taxes	(3,780)	36,297	(18,343)	70,746
Income tax (benefit) provision	(342)	7,370	(2,669)	15,909
Net (loss) income	\$ (3,438)	\$ 28,927	\$ (15,674)	\$ 54,837
Net (loss) income per share - basic	\$ (0.09)	\$ 0.70	\$ (0.42)	\$ 1.33
Net (loss) income per share - diluted	(0.09)	0.68	(0.42)	1.29
Weighted average number of shares outstanding - basic	36,772	41,091	37,666	41,233
Weighted average number of shares outstanding - diluted	36,772	42,487	37,666	42,625

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

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,477	\$ 16,564
Marketable securities	134,629	77,511
Accounts receivable	14,940	14,785
Inventories	5,724	6,157
Prepaid expenses and other current assets	7,206	8,958
Total current assets	174,976	123,975
Property and equipment, net	2,439	3,001
Goodwill	18,491	18,491
Intangible assets, net	70,962	92,289
Research and development tax credit receivable	6,124	5,272
Other non-current assets	22,244	10,249
Total assets	\$ 295,236	\$ 253,277
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 108	\$ 111
Current portion of long-term related party payable	14,067	25,007
Accounts payable	11,169	7,477
Deferred revenue	1,724	2,007
Accrued expenses	21,493	50,926
Other current liabilities	3,052	1,011
Total current liabilities	51,613	86,539
Long-term debt, less current portion	113,038	156
Long-term related party payable, less current portion	38,050	73,918
Other non-current liabilities	13,989	7,084
Total liabilities	216,690	167,697
Shareholders' equity:		
Preferred shares, \$0.01 nominal value; 50,000 shares authorized at June 30, 2018 and December 31, 2017, respectively; none issued or outstanding at June 30, 2018 and December 31, 2017, respectively	—	—
Ordinary shares, nominal value of \$0.01; 500,000 shares authorized; 42,148 issued and 36,740 outstanding at June 30, 2018 and 41,463 issued and 39,346 outstanding at December 31, 2017	421	414
Treasury shares, at cost, 5,408 and 2,117 shares held at June 30, 2018 and December 31, 2017, respectively	(49,998) (22,361
Additional paid-in capital	430,141	393,478
Accumulated deficit	(278,359) (262,685
Accumulated other comprehensive loss	(23,659) (23,266
Total shareholders' equity	78,546	85,580
Total liabilities and shareholders' equity	\$ 295,236	\$ 253,277

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

	Six Months Ended June 30, 2018	2017
Cash flows from operating activities:		
Net (loss) income	\$ (15,674) \$ 54,837
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	3,810	1,611
Amortization of premiums on marketable securities	1,693	34
Foreign exchange loss	(160) 1,304
Remeasurement of related party acquisition-related contingent consideration	(9,921) (20,201
Remeasurement of related party financing-related contingent consideration	(1,007) (2,220
Amortization of debt discount and debt issuance costs	2,019	—
Change in deferred tax and income tax deferred charge	(3,247) 322
Stock-based compensation expense	4,358	4,055

Revenues:										
Product sales	\$ 29,116	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 29,116
License revenue	114	—	—	—	—	—	—	—	—	114
Total revenues	29,230	—	—	—	—	—	—	—	—	29,230
Operating expenses:										
Cost of products	3,512	—	—	—	—	—	—	—	—	3,512
Research and development expenses	11,890	—	—	—	—	—	—	—	—	11,890
Selling, general and administrative expenses	27,843	—	—	—	—	—	—	—	—	27,843
Intangible asset amortization	1,609	(1,609)	—	—	—	—	—	—	(1,609)	—
Loss (gain) - changes in fair value of related party contingent consideration	(12,889)	—	—	—	—	—	12,889	5,060	17,949	5,060
Restructuring costs	50	—	—	(50)	—	—	—	—	(50)	—
Total operating expenses	32,015	(1,609)	—	(50)	—	—	12,889	5,060	16,290	48,305
Operating (loss) income	(2,785)	1,609	—	50	—	—	(12,889)	(5,060)	(16,290)	(19,075)
Investment and other income (expense), net	583	—	7	—	(112)	—	—	—	(105)	478
Interest expense, net	(2,980)	—	—	—	—	1,363	—	—	1,363	(1,617)
Other expense (income) - changes in fair value of related party payable	1,402	—	—	—	—	—	(1,402)	(751)	(2,153)	(751)
(Loss) income before income taxes	(3,780)	1,609	7	50	(112)	1,363	(14,291)	(5,811)	(17,185)	(20,965)
Income tax (benefit) provision	(342)	338	—	—	(2)	—	(471)	(227)	(362)	(704)
Net (loss) income	\$ (3,438)	\$ 1,271	\$ 7	\$ 50	\$ (110)	\$ 1,363	\$ (13,820)	\$ (5,584)	\$ (16,823)	\$ (20,261)
Net income (loss) per share - diluted ⁽¹⁾	\$ (0.09)	\$ 0.03	\$ —	\$ —	\$ —	\$ 0.04	\$ (0.38)	\$ (0.15)	\$ (0.46)	\$ (0.55)
Weighted average number of shares outstanding - diluted	36,772	36,772	36,772	36,772	36,772	36,772	36,772	36,772	36,772	36,772

(1) Net income (loss) per share - diluted is calculated by dividing Net income (loss) by the Weighted average number of shares outstanding - diluted. Note, when recalculated using this method, the balances in the Total adjustment and Adjusted GAAP columns may not cross-foot as a result of rounding to full

precision.

GAAP to Non-GAAP adjustments for the three-months ended June 30, 2017

	<i>Exclude</i>					<i>Include</i>		Total adjustments	Adjusted GAAP
	GAAP	Intangible asset amortization	Foreign exchange (gain)/loss	Restructuring impacts	License revenue adjustment	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued		
Revenues:									
Product sales	\$ 47,105	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 47,105
License revenue	(794)	—	—	—	1,100	—	—	1,100	306
Total revenues	46,311	—	—	—	1,100	—	—	1,100	47,411
Operating expenses:									
Cost of products	4,561	—	—	—	—	—	—	—	4,561
Research and development expenses	6,792	—	—	—	—	—	—	—	6,792
Selling, general and administrative expenses	12,429	—	—	—	—	—	—	—	12,429
Intangible asset amortization	564	(564)	—	—	—	—	—	(564)	—
Loss (gain) - changes in fair value of related party contingent consideration	(13,230)	—	—	—	—	13,230	8,516	21,746	8,516
Restructuring costs	1,069	—	—	(1,069)	—	—	—	(1,069)	—
Total operating expenses	12,185	(564)	—	(1,069)	—	13,230	8,516	20,113	32,298
Operating (loss) income	34,126	564	—	1,069	1,100	(13,230)	(8,516)	(19,013)	15,113
Investment and other income (expense), net	764	—	(237)	—	—	—	—	(237)	527
Interest expense, net	(263)	—	—	—	—	—	—	—	(263)
Other expense (income) - changes in fair value of related party payable	1,670	—	—	—	—	(1,670)	(1,166)	(2,836)	(1,166)
(Loss) income before income taxes	36,297	564	(237)	1,069	1,100	(14,900)	(9,682)	(22,086)	14,211
Income tax (benefit) provision	7,370	201	—	—	—	(909)	(616)	(1,324)	6,046
Net (loss) income	\$ 28,927	\$ 363	\$ (237)	\$ 1,069	\$ 1,100	\$ (13,991)	\$ (9,066)	\$ (20,762)	\$ 8,165
Net income (loss) per share - diluted ⁽¹⁾	\$ 0.68	\$ 0.01	\$ (0.01)	\$ 0.03	\$ 0.03	\$ (0.33)	\$ (0.21)	\$ (0.49)	\$ 0.19
Weighted average number of shares outstanding - diluted	42,487	42,487	42,487	42,487	42,487	42,487	42,487	42,487	42,487

(1) Net income (loss) per share - diluted is calculated by dividing Net income (loss) by the Weighted average number of shares outstanding - diluted. Note, when recalculated using this method, the balances in the Total adjustment and Adjusted GAAP columns may not cross-foot as a result of rounding to full precision.

GAAP to Non-GAAP adjustments for the six-months ended June 30, 2018

	<i>Exclude</i>					<i>Include</i>		Total adjustments	Adjusted GAAP
	GAAP	Intangible asset amortization	Foreign exchange (gain)/loss	Restructuring impacts	Equity securities unrealized (gain)/loss impact	Amortization of debt discount and debt issuance costs	Contingent related party payable fair value remeasurements		

Revenues:

GAAP to Non-GAAP adjustments for the six-months ended June 30, 2017

	<i>Exclude</i>						<i>Include</i>			
GAAP	Intangible asset amortization	Foreign exchange (gain)/loss	Restructuring impacts	Purchase accounting adjustments - FSC	License revenue adjustment	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued	Total adjustments	Adjusted GAAP	
Revenues:										
Product sales	\$ 98,862	\$ —	\$ —	—	\$ —	\$ —	\$ —	\$ —	\$ 98,862	
License revenue	(44)	—	—	—	1,100	—	—	1,100	1,056	
Total revenues	98,818	—	—	—	1,100	—	—	1,100	99,918	
Operating expenses:										
Cost of products	8,463	—	—	—	(46)	—	—	(46)	8,417	
Research and development expenses	13,998	—	—	—	—	—	—	—	13,998	
Selling, general and administrative expenses	24,241	—	—	—	—	—	—	—	24,241	
Intangible asset amortization	1,128	(1,128)	—	—	—	—	—	(1,128)	—	
Loss (gain) - changes in fair value of related party contingent consideration	(20,201)	—	—	—	—	20,201	18,132	38,333	18,132	
Restructuring costs	3,722	—	—	(3,722)	—	—	—	(3,722)	—	
Total operating expenses	31,351	(1,128)	—	(3,722)	(46)	20,201	18,132	33,437	64,788	
Operating (loss) income	67,467	1,128	—	3,722	46	1,100	(20,201)	(18,132)	(32,337)	35,130
Investment and other income (expense), net	1,585	—	(6)	—	—	—	—	(6)	1,579	
Interest expense, net	(526)	—	—	—	—	—	—	—	(526)	
Other expense (income) - changes in fair value of related party payable	2,220	—	—	—	—	(2,220)	(2,465)	(4,685)	(2,465)	
(Loss) income before income taxes	70,746	1,128	(6)	3,722	46	1,100	(22,421)	(20,597)	(37,028)	33,718
Income tax (benefit) provision	15,909	402	—	—	17	—	(1,269)	(1,307)	(2,157)	13,752
Net (loss) income	\$ 54,837	\$ 726	\$ (6)	3,722	\$ 29	\$ 1,100	\$ (21,152)	\$ (19,290)	\$ (34,871)	\$ 19,966
Net income (loss) per share - diluted ⁽¹⁾	\$ 1.29	\$ 0.02	\$ —	0.09	\$ —	\$ 0.03	\$ (0.50)	\$ (0.45)	\$ (0.82)	\$ 0.47

Weighted average number of shares outstanding - diluted	42,625	42,625	42,625	42,625	42,625	42,625	42,625	42,625	42,625	42,625
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(1) Net income (loss) per share - diluted is calculated by dividing Net income (loss) by the Weighted average number of shares outstanding - diluted. Note, when recalculated using this method, the balances in the Total adjustment and Adjusted GAAP columns may not cross-foot as a result of rounding to full precision.



Avadel Pharmaceuticals plc