



Avadel Pharmaceuticals Reports Fourth Quarter and Full Year 2016 Results

March 7, 2017

Strong Fourth Quarter Revenues of \$43.1 Million Drive Full Year Revenues of \$150.2 Million

Reaffirms 2017 Revenue Guidance of \$170 - \$200 Million and Adjusted EPS of \$0.20 - \$0.35

DUBLIN, Ireland, March 07, 2017 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ:AVDL) today announced its financial results for the fourth quarter and full year 2016.

Highlights Include:

- Total revenues for fourth quarter and full year 2016 were \$43.1 million and \$150.2 million, compared to \$44.6 million and \$173.0 million in the prior year periods.
- GAAP net income for the fourth quarter was \$4.7 million, or \$0.11 per diluted share, compared to GAAP net income of \$73.5 million, or \$1.69 per diluted share, during the same period last year. GAAP net loss for the full year 2016 was \$41.3 million or \$1.00 per diluted share compared to GAAP net income of \$41.8 million or \$0.96 per diluted share during the same period last year.
- Adjusted net income for the fourth quarter was \$0.1 million, or \$0.00 per diluted share, compared to an adjusted net income of \$10.8 million, or \$0.25 per diluted share, during the same period last year. ⁽¹⁾
- Cash and marketable securities at December 31, 2016 were \$154.2 million, up from \$149.7 million, at September 30, 2016 and \$144.8 million at December 31, 2015.

Michael Anderson, Avadel's Chief Executive Officer, remarked, "We hit a number of milestones during 2016, including the approval and successful launch of our third hospital product, Akovaz®, and in particular during the fourth quarter, we reached an agreement with the FDA on our special protocol assessment for our REST-ON Phase III clinical trial, began enrollment and dosing of patients, and ended the year by redomiciling from France to Ireland and changing our company name in the process. Although it is still early in the enrollment process, REST-ON remains on track, and the successful completion of our trial continues to be a primary objective in 2017."

Mike Kanan, Avadel's Chief Financial Officer, said, "We are pleased to report strong fourth quarter revenues, which allowed us to finish 2016 above the top end of guidance with \$150.2 million in total revenues. A key contributing factor to our strong financial performance was the ability to maintain stable price and share across our branded hospital products, Bloxiverz® and Vazculep®, while successfully launching our third product Akovaz®. We estimate that we exited the quarter and year with approximately 27% of the 7.5 million vial per year ephedrine market, as was our goal. Despite the recent introduction of a second competitor, as we have demonstrated in the past with our other products, we expect to secure and retain our requisite share of the market."

Kanan continued, "I'm also pleased to report that our cash and marketable securities increased \$9.4 million to \$154.2 million at December 31, 2016 from \$144.8 million at December 31, 2015. We continue to focus on generating cash and have ample liquidity to execute our strategy, including completion of the REST-ON trial and investment in other growth initiatives."

Fourth Quarter 2016 Results

The Company generated revenues during the fourth quarter 2016 of \$43.1 million, compared to \$44.6 million during the same period last year. On a GAAP basis, the Company recorded net income of \$4.7 million during the fourth quarter 2016, or \$0.11 per diluted share, compared to net income of \$73.5 million, or \$1.69 per diluted share, for the same period last year. Included in the net income for the fourth quarter 2016 were \$3.3 million of gains related to changes in the fair value of related party contingent consideration and related party payables compared to \$55.8 million of such gains in the same period last year. Adjusted net income for the fourth quarter was \$0.1 million, or \$0.00 per diluted share, compared to an adjusted net income of \$10.8 million, or \$0.25 per diluted share, during the same period last year.⁽¹⁾ The decline in adjusted net income and adjusted diluted EPS from the previous year was primarily due to lower product sales resulting from increased competition for Bloxiverz®, our neostigmine product, higher SG&A from increased headcount and one-time cross border merger related expenses plus higher R&D spend on the REST-ON Phase III clinical trial. 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.

2017 Guidance

"We are reaffirming the guidance we issued in January 2017 of full year 2017 revenue in the range of \$170 to \$200 million and adjusted EPS of between \$0.20 and \$0.35 per diluted share. Although a second Akovaz® competitor has recently launched, we feel at this time it is premature to modify our full year 2017 guidance. We expect R&D spending be in the range of \$40 and \$50 million and our full year adjusted tax rate to fall in the range of 70% -

80%," commented Mike Kanan.

Conference Call

A conference call to discuss these results has been scheduled for Tuesday, March 7, 2017 at 10:00 a.m. ET. 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 69283135. A live audio webcast and accompanying slides can be accessed by visiting the "News & Events" page of the Company's Investors website at www.avadel.com. A replay of the webcast will be archived on Avadel's website for 90 days following the event.

About REST-ON Phase III Clinical Trial

REST-ON is a double-blind, randomized, placebo controlled study of 264 patients to assess the efficacy and safety of a once nightly formulation of sodium oxybate for extended-release oral suspension for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. For more information, please visit clinicaltrial.avadel.com.

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 in-licensing / acquiring new products; ultimately, helping patients adhere to their prescribed medical treatment and see better results. Avadel currently markets products in the hospital and primary care spaces. The Company is headquartered in Dublin, Ireland with operations in St. Louis, Missouri, United States and Lyon, France. For more information, please visit www.avadel.com.

Safe Harbor: *This release may include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements herein that are not clearly historical in nature are forward-looking, and the words "anticipate," "assume," "believe," "expect," "estimate," "plan," "will," "may," and the negative of these and similar expressions generally identify forward-looking statements. All forward-looking statements involve risks, uncertainties and contingencies, many of which are beyond Avadel's control and could cause actual results to differ materially from the results contemplated in such forward-looking statements. These risks, uncertainties and contingencies include the risks relating to: 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 product and apply for FDA approval of such product before us; our dependence on the performance of third parties in partnerships or strategic alliances for the commercialization of some of our products; 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; our dependence on key personnel to execute our business plan; the amount of additional costs we will incur to comply with U.S. securities laws as a result of our ceasing to qualify as a foreign private issuer; and 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, 2015, all of which filings are also available on the Company's website. Avadel undertakes no obligation to update its forward-looking statements as a result of new information, future events or otherwise, except as required by law.*

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 a comparison of its current and historical results would be difficult if the disclosures were limited to financial measures prepared only 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, impairment of intangible assets, amortization of intangible assets, foreign exchange gains and losses on assets and liabilities denominated in foreign currency, but includes the operating cash flows plus any unpaid accrued amounts associated with the contingent consideration, in order to supplement investors' and other readers' understanding and assessment of the Company's financial performance. 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 applicable 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.

¹Non-GAAP financial measure. 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.

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

Three-Months Ended		Twelve-Months Ended	
December 31,		December 31,	
2016	2015	2016	2015

Revenues:				
Product sales and services	\$ 42,364	\$ 43,847	\$ 147,222	\$ 172,288
License and research revenue	721	721	3,024	721
Total	43,085	44,568	150,246	173,009
Operating expenses:				
Cost of products and services sold	2,591	2,937	13,248	11,410
Research and development	13,476	5,161	34,611	25,608
Selling, general and administrative	10,688	6,808	44,179	21,712
Intangible asset amortization	2,970	3,141	13,888	12,564
Changes in fair value of related party contingent consideration	(3,704)	(51,079)	49,285	30,957
Total	26,021	(33,032)	155,211	102,251
Operating income (loss)	17,064	77,600	(4,965)	70,758
Investment and other income	555	65	1,635	1,236
Interest expense	(261)	—	(963)	—
Other income (expense) - changes in fair value of related party payable	(413)	4,746	(6,548)	(4,883)
Foreign exchange gain	1,135	2,498	1,123	10,594
Income (loss) before income taxes	18,080	84,909	(9,718)	77,705
Income tax provision	13,346	11,391	31,558	35,907
Net income (loss)	\$ 4,734	\$ 73,518	\$ (41,276)	\$ 41,798
Earnings (loss) per share - basic:	\$ 0.11	\$ 1.79	\$ (1.00)	\$ 1.03
Earnings (loss) per share - diluted:	\$ 0.11	\$ 1.69	\$ (1.00)	\$ 0.96
Weighted average number of shares outstanding - basic	41,269	41,125	41,248	40,580
Weighted average number of shares outstanding - diluted	42,808	43,430	41,248	43,619

**AVADEL PHARMACEUTICALS PLC
CONSOLIDATED BALANCE SHEETS**

(In thousands, except per share data)

	As of December 31,	
	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 39,215	\$ 65,064
Marketable securities	114,980	79,738
Accounts receivable	17,839	7,487
Inventories	3,258	3,666
Research and development tax credit receivable	—	2,382
Prepaid expenses and other current assets	5,894	8,064
Total current assets	181,186	166,401
Property and equipment, net	3,320	2,616
Goodwill	18,491	18,491
Intangible assets, net	22,837	15,825
Research and development tax credit receivable	1,775	—
Income tax deferred charge	10,342	11,581
Other	7,531	167
Total assets	\$ 245,482	\$ 215,081
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 268	\$ 434
Current portion of long-term related party payable	34,177	25,204

Accounts payable	7,105	5,048
Deferred revenue	2,223	5,121
Accrued expenses	17,222	9,308
Income taxes	1,200	—
Other	226	133
Total current liabilities	62,421	45,248
Long-term debt	547	684
Long-term related party payable	135,170	97,489
Other	5,275	2,526
Total liabilities	203,413	145,947
Shareholders' equity:		
Preferred shares, \$0.01 nominal value; 50,000 shares authorized at December 31, 2016, none authorized at December 31, 2015; none issued or outstanding at December 31, 2016 and December 31, 2015, respectively	—	—
Ordinary shares, nominal value of \$0.01 and €0.122; 500,000 and 53,178 shares authorized; 41,371 and 41,241 issued and outstanding at December 31, 2016 and 2015, respectively	414	6,331
Additional paid-in capital	385,020	363,984
Accumulated deficit	(319,800)	(278,524)
Accumulated other comprehensive loss	(23,565)	(22,657)
Total shareholders' equity	42,069	69,134
Total liabilities and shareholders' equity	\$ 245,482	\$ 215,081

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

	Twelve-Months Ended December 31,	
	2016	2015
Cash flows from operating activities:		
Net income (loss)	\$ (41,276)	\$ 41,798
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	14,489	13,132
Loss on disposal of property and equipment	110	—
Loss on sale of marketable securities	826	779
Unrealized foreign currency exchange gain	(349)	(8,969)
Gains on waiver of research and development grants and other	—	(1,498)
Remeasurement of related party acquisition-related contingent consideration	49,285	30,957
Remeasurement of related party financing-related royalty agreements	6,548	4,883
Change in deferred tax and income tax deferred charge	(4,000)	69
Stock-based compensation expense	14,679	7,741
Increase (decrease) in cash from:		
Accounts receivable	(10,050)	(8,440)
Inventories	1,831	3,036
Prepaid expenses and other current assets	3,412	(684)
Research and development tax credit receivable	397	2,975
Accounts payable & other current liabilities	(434)	(8,533)
Deferred revenue	(2,923)	3,815
Accrued expenses	6,764	3,376
Accrued income taxes	1,778	(393)
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(20,252)	—
Royalty payments for related party payable in excess of original fair value	(2,469)	—
Other long-term assets and liabilities	535	249
Net cash provided by operating activities	18,901	84,293
Cash flows from investing activities:		

Purchases of property and equipment	(1,201))	(1,629))
Acquisitions of businesses, including cash acquired and other adjustments	628		—	
Proceeds from sales of marketable securities	71,546		48,308	
Purchases of marketable securities	(107,603))	(78,409))
Net cash used in investing activities	(36,630))	(31,730))
Cash flows from financing activities:				
Reimbursement of loans	—		(4,911))
Reimbursement of conditional R&D grants	(277))	(747))
Earn-out payments for related party contingent consideration	(6,892))	(24,526))
Royalty payments for related party payable	(1,225))	(3,371))
Excess tax benefit from stock-based compensation	—		2,814	
Cash proceeds from issuance of ordinary shares and warrants	440		6,990	
Net cash used in financing activities	(7,954))	(23,751))
Effect of exchange rate changes on cash and cash equivalents	(166))	(3,508))
Net increase (decrease) in cash and cash equivalents	(25,849))	25,304)
Cash and cash equivalents - beginning balance	65,064		39,760	
Cash and cash equivalents - ending balance	\$ 39,215		\$ 65,064	
Supplemental disclosures of cash flow information:				
Income tax paid	\$ 27,180		\$ 42,121	
Interest paid	788		4,738	

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

Revenues	Three-Months Ended December 31,		Twelve-Months Ended December 31,	
	2016	2015	2016	2015
Bloxiverz	\$ 16,938	\$ 36,009	\$ 82,896	\$ 150,083
Vazculep	10,629	7,394	39,796	20,151
Akovaz	11,263	—	16,831	—
Other	3,534	444	7,699	2,054
Total product sales and services	42,364	43,847	147,222	172,288
License and research revenue	721	721	3,024	721
Total revenues	\$ 43,085	\$ 44,568	\$ 150,246	\$ 173,009

GAAP to Non-GAAP adjustments for the three-months ended December 31, 2016

	GAAP	Exclude					Include		Adjusted GAAP
		Intangible asset amortization	Foreign exchange (gain)/loss	Cross-border merger impacts	Purchase accounting adjustments - FSC	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued	Total adjustments	
Revenues:									
Product sales and services	\$ 42,364	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 42,364
License and research revenue	721	—	—	—	—	—	—	—	721
Total	43,085	—	—	—	—	—	—	—	43,085
Operating expenses:									
Cost of products and services sold	2,591	—	—	—	1,019	—	—	1,019	3,610

Research and development	13,476	—	—	—	—	—	—	—	—	13,476
Selling, general and administrative	10,688	—	—	—	—	—	—	—	—	10,688
Intangible asset amortization	2,970	(2,970)	—	—	—	—	—	—	(2,970)	—
Changes in fair value of related party contingent consideration	(3,704)	—	—	—	—	3,704	7,645	11,349	7,645	
Total	26,021	(2,970)	—	—	1,019	3,704	7,645	9,398	35,419	
Operating income (loss)	17,064	2,970	—	—	(1,019)	(3,704)	(7,645)	(9,398)	7,666	
Investment and other income	555	—	—	—	—	—	—	—	555	
Interest expense	(261)	—	—	—	—	—	—	—	(261)	
Other expense - changes in fair value of related party payable	(413)	—	—	—	—	413	(1,018)	(605)	(1,018)	
Foreign exchange gain	1,135	—	(1,135)	—	—	—	—	(1,135)	—	
Income (loss) before income taxes	18,080	2,970	(1,135)	—	(1,019)	(3,291)	(8,663)	(11,138)	6,942	
Income tax provision (benefit)	13,346	1,066	—	(6,754)	(366)	82	(499)	(6,471)	6,875	
Net income (loss)	\$ 4,734	\$ 1,904	\$ (1,135)	\$ 6,754	\$ (653)	\$ (3,373)	\$ (8,164)	\$ (4,667)	\$ 67	
Net income (loss) per share - diluted ⁽¹⁾	\$ 0.11	\$ 0.04	\$ (0.03)	\$ 0.16	\$ (0.02)	\$ (0.08)	\$ (0.19)	\$ (0.11)	\$ —	
Weighted average number of shares outstanding - diluted	42,808	42,808	42,808	42,808	42,808	42,808	42,808	42,808	42,808	

(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 December 31, 2015

	GAAP	Exclude	Exclude	Exclude	Include	Total adjustments	Adjusted GAAP
		Intangible asset amortization	Foreign exchange (gain)/loss	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued		

Revenues:

Operating expenses:										
Cost of products and services sold	13,248	—	—	—	(506)	—	—	(506)	12,742	
Research and development	34,611	—	—	—	—	—	—	—	34,611	
Selling, general and administrative	44,179	—	—	—	—	—	—	—	44,179	
Intangible asset amortization	13,888	(13,888)	—	—	—	—	—	(13,888)	—	
Changes in fair value of related party contingent consideration	49,285	—	—	—	—	(49,285)	26,966	(22,319)	26,966	
Total	155,211	(13,888)	—	—	(506)	(49,285)	26,966	(36,713)	118,498	
Operating income (loss)	(4,965)	13,888	—	—	506	49,285	(26,966)	36,713	31,748	
Investment and other income	1,635	—	—	—	—	—	—	—	1,635	
Interest expense	(963)	—	—	—	—	—	—	—	(963)	
Other expense - changes in fair value of related party payable	(6,548)	—	—	—	—	6,548	(3,636)	2,912	(3,636)	
Foreign exchange gain	1,123	—	(1,123)	—	—	—	—	(1,123)	—	
Income (loss) before income taxes	(9,718)	13,888	(1,123)	—	506	55,833	(30,602)	38,502	28,784	
Income tax provision (benefit)	31,558	4,986	—	(6,754)	182	3,068	(1,667)	(185)	31,373	
Net income (loss)	\$ (41,276)	\$ 8,902	\$ (1,123)	\$ 6,754	\$ 324	\$ 52,765	\$ (28,935)	\$ 38,687	\$ (2,589)	
Net (loss) income per share - diluted ⁽¹⁾	\$ (1.00)	\$ 0.22	\$ (0.03)	\$ 0.16	\$ 0.01	\$ 1.28	\$ (0.70)	\$ 0.94	\$ (0.06)	
Weighted average number of shares outstanding - diluted	41,248	41,248	41,248	41,248	41,248	41,248	41,248	41,248	41,248	

(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 twelve-months ended December 31, 2015

Exclude

Include

	GAAP	Intangible asset amortization	Foreign exchange (gain)/loss	Contingent related party payable fair value remeasurements	Contingent related party payable paid/accrued	Total adjustments	Adjusted GAAP
Revenues:							
Product sales and services	\$ 172,288	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 172,288
License and research revenue	721	—	—	—	—	—	721
Total	173,009	—	—	—	—	—	173,009
Operating expenses:							
Cost of products and services sold	11,410	—	—	—	—	—	11,410
Research and development	25,608	—	—	—	—	—	25,608
Selling, general and administrative	21,712	—	—	—	—	—	21,712
Intangible asset amortization	12,564	(12,564)	—	—	—	(12,564)	—
Changes in fair value of related party contingent consideration	30,957	—	—	(30,957)	32,081	1,124	32,081
Total	102,251	(12,564)	—	(30,957)	32,081	(11,440)	90,811
Operating income (loss)	70,758	12,564	—	30,957	(32,081)	11,440	82,198
Investment and other income	1,236	—	—	—	—	—	1,236
Interest expense	—	—	—	—	—	—	—
Other expense - changes in fair value of related party payable	(4,883)	—	—	4,883	(4,414)	469	(4,414)
Foreign exchange gain	10,594	—	(10,594)	—	—	(10,594)	—
Income (loss) before income taxes	77,705	12,564	(10,594)	35,840	(36,495)	1,315	79,020
Income tax provision (benefit)	35,907	4,397	(3,178)	1,709	(1,545)	1,383	37,290
Net income (loss)	\$ 41,798	\$ 8,167	\$ (7,416)	\$ 34,131	\$ (34,950)	\$ (68)	\$ 41,730
Net (loss) income per share - diluted (1)	\$ 0.96	\$ 0.19	\$ (0.17)	\$ 0.78	\$ (0.80)	\$ —	\$ 0.96
Weighted average number of shares outstanding - diluted	43,619	43,619	43,619	43,619	43,619	43,619	43,619

(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.

Contacts:

Michael F. Kanan
Chief Financial Officer
Phone: (636) 449-1844
Email : mkanan@avadel.com

Lauren Stival
Sr. Director, Investor Relations & Corporate Communications
Phone: (636) 449-5866
Email: lstival@avadel.com

 Primary Logo

Avadel Pharmaceuticals plc