Avadel Pharmaceuticals Reports First Quarter 2017 Results

May 9, 2017

Total Revenues of $52.5 million, Highest Quarterly Revenue in Company History

DUBLIN, Ireland, May 09, 2017 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ:AVDL) today announced its financial results for the first quarter of 2017.

Highlights Include:

- Total revenues for the first quarter 2017 were $52.5 million, compared to $43.1 million in the fourth quarter 2016 and $36.2 million in the first quarter 2016.
- GAAP net income for the first quarter 2017 was $25.4 million, or $0.59 per diluted share, compared to GAAP net income of $4.7 million, or $0.11 per diluted share, in the fourth quarter 2016 and a GAAP net loss of $6.1 million, or $0.15 per diluted share, in the first quarter 2016.
- Adjusted net income for the first quarter 2017 was $11.3 million, or $0.26 per diluted share, compared to an adjusted net income of $0.1 million, or $0.00 per diluted share, in the fourth quarter 2016 and $1.8 million, or $0.04 per diluted share, in the first quarter 2016. (1)
- Cash and marketable securities at March 31, 2017 were $179.2 million, up from $154.2 million at December 31, 2016.

Michael Anderson, Avadel's Chief Executive Officer, remarked, “This was a strong start to the year for us, producing record quarterly revenues of $52.5 million, driven largely by the continued durability of our hospital products. We saw strong performance from Akovaz® and continued to maintain stable share and pricing for our other two hospital products, Bloxiverz® and Vazculep®. In addition, we began site initiations for our REST-ON Phase III clinical trial of once nightly sodium oxybate in the United States, where we expect to enroll a large portion of patients."

First Quarter 2017 Results

Revenues during the first quarter 2017 of $52.5 million, compared to $36.2 million during the same period last year. The increase in revenues is due to Akovaz, which was not yet in the market during the first quarter of 2016. On a GAAP basis, net income was $25.4 million during the first quarter 2016, or $0.59 per diluted share, compared to a net loss of $6.1 million, or $0.15 per diluted share, for the same period last year. Included in GAAP net income for the first quarter 2017 were $7.0 million of gains related to changes in the fair value of related party contingent consideration, compared to charges of $8.2 million in the same period last year. Changes in the fair value of related party contingent consideration are non-cash items, and do not reflect the cash amount paid to related parties. Cash payments can be found in the Consolidated Statement of Cash Flows. Also, included in GAAP net income in the first quarter 2017 are $2.7 million in restructuring costs related to the reduction of the Company's workforce in France, which consist of employee severance, benefits and other costs.

Research and Development expenses totaled $7.2 million for the first quarter, compared to $5.4 million for the same period last year. The increase in spending is due to the Company's Phase III REST-ON trial to assess the safety and efficacy of a once-nightly version of sodium oxybate for the treatment of excessive daytime sleepiness and cataplexy in patients suffering from narcolepsy. The Company expects spending on Research and Development to increase in the coming quarters and remain in line with initial expectations of total spend between $40 and $50 million for the full year 2017. Selling, General and Administrative expenses were $11.8 million in the first quarter 2017, compared to $9.5 million in the same period last year. This increase was primarily due to higher sales and marketing expenses resulting from the acquisition of FSC Pediatrics, which incurred three months of expenses during the three months ended March 31, 2017 compared to only two months in the prior year due to the February 2016 acquisition.

Adjusted net income for the first quarter 2017 was $11.3 million, or $0.26 per diluted share, compared to $1.8 million, or $0.04 per diluted share, in the same period last year.(1) The increase in adjusted net income is largely attributable to an increase in revenues from Akovaz and a lower adjusted effective tax rate of 41% compared to 83% in the prior year period. 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

The Company is increasing its full year adjusted EPS guidance to a range of $0.30 to $0.45 per diluted share, up from its previous range of between $0.20 and $0.35 per diluted share, on stronger than anticipated first quarter results. The Company is narrowing its full year revenue guidance to be in the range of $170 - $185 million as a result of a second competitor for Akovaz entering the market earlier than anticipated and a shift in market conditions for neostigmine. R&D spend is expected to be in the range of $40 to $50 million, and the full year adjusted tax rate is now expected to be in the range of 60% to 70%, down from previous guidance of 70% - 80%.

Conference Call

A conference call to discuss these results has been scheduled for Tuesday, May 9, 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 9368017. 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 www.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, 2016, 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, restructuring costs, foreign exchange gains and losses on assets and liabilities denominated in foreign currencies, 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.

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[1]Non-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

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)

(In thousands, except per share data)

	Three Months Ended March 31,	
	2017	**2016**
Revenues:		
Product sales and services	$ 51,757	$ 35,353
License and research revenue	750	863
Total	52,507	36,216
Operating expenses:		

Cost of products and services sold	3,902	3,906
Research and development expenses	7,206	5,388
Selling, general and administrative expenses	11,812	9,461
Intangible asset amortization	564	3,514
Changes in fair value of related party contingent consideration	(6,971)	8,243
Restructuring costs	2,653	—
Total operating expenses	19,166	30,512
Operating income	33,341	5,704
Investment income, net	529	200
Interest expense, net	(263)	(175)
Other income (expense) - changes in fair value of related party payable	550	(1,534)
Foreign exchange loss	(231)	(2,941)
Income before income taxes	33,926	1,254
Income tax provision	8,525	7,312
Net income (loss)	$ 25,401	$ (6,058)
Net income (loss) per share - basic	$ 0.61	$ (0.15)
Net income (loss) per share - diluted	0.59	(0.15)
Weighted average number of shares outstanding - basic	41,374	41,241
Weighted average number of shares outstanding - diluted	42,810	41,241

AVADEL PHARMACEUTICALS PLC

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	March 31, 2017	**December 31, 2016**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,236	$ 39,215
Marketable securities	146,978	114,980
Accounts receivable	13,463	17,839
Inventories	5,406	3,258
Prepaid expenses and other current assets	6,529	5,894
Total current assets	204,612	181,186
Property and equipment, net	3,382	3,320
Goodwill	18,491	18,491
Intangible assets, net	22,274	22,837
Research and development tax credit receivable	2,396	1,775
Income tax deferred charge	—	10,342
Other	7,533	7,531
Total assets	$ 258,688	$ 245,482
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 272	$ 268
Current portion of long-term related party payable	43,699	34,177
Accounts payable	7,962	7,105
Deferred revenue	1,617	2,223
Accrued expenses	19,936	17,222
Income taxes	9,723	1,200
Other	825	226

Total current liabilities	84,034	62,421
Long-term debt, less current portion	555	547
Long-term related party payable, less current portion	109,514	135,170
Other	5,488	5,275
Total liabilities	199,591	203,413
Shareholders' equity:		
Preferred shares, $0.01 nominal value; 50,000 shares authorized at March 31, 2017 and December 31, 2016,respectively; none issued or outstanding at March 31, 2017 and December 31, 2016, respectively	—	—
Ordinary shares, nominal value of $0.01; 500,000 shares authorized; 41,380 and 41,371 issued and outstanding at March 31, 2017 and December 31, 2016, respectively	414	414
Additional paid-in capital	387,105	385,020
Accumulated deficit	(305,555)	(319,800)
Accumulated other comprehensive loss	(22,867)	(23,565)
Total shareholders' equity	59,097	42,069
Total liabilities and shareholders' equity	$ 258,688	$ 245,482

AVADEL PHARMACEUTICALS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Three Months Ended March 31,	
	2017	**2016**
Cash flows from operating activities:		
Net income (loss)	25,401	(6,058)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	837	3,754
Loss on disposal of property and equipment	—	102
Loss on sale of marketable securities	236	285
Foreign exchange loss	—	2,941
Grants recognized in research and development expenses	—	(2)
Remeasurement of related party acquisition-related contingent consideration	(6,971)	8,243
Remeasurement of related party financing-related contingent consideration	(550)	1,534
Change in deferred tax and income tax deferred charge	—	(1,682)
Stock-based compensation expense	2,047	2,475
Increase (decrease) in cash from:		
Accounts receivable	4,376	2,093
Inventories	(2,148)	723
Prepaid expenses and other current assets	(1,354)	(131)
Research and development tax credit receivable	(716)	(363)
Accounts payable & other current liabilities	1,456	6,119
Deferred revenue	(606)	(758)
Accrued expenses	2,714	(2,888)
Accrued income taxes	8,523	5,616
Earn-out payments for related party contingent consideration in excess of acquisition-date fair value	(7,166)	(1,566)
Royalty payments for related party payable in excess of original fair value	(1,003)	(561)
Other long-term assets and liabilities	232	493
Net cash provided by operating activities	25,308	20,369
Cash flows from investing activities:		
Purchases of property and equipment	(334)	(460)
Acquisitions of businesses	—	161
Proceeds from sales of marketable securities	14,419	9,766

Purchase of marketable securities	(46,074)	(50,454)
Net cash used in investing activities	(31,989)	(40,987)
Cash flows from financing activities:		
Earn-out payments for related party contingent consideration	(444)	(6,448)
Royalty payments for related party payable	—	(531)
Cash proceeds from issuance of ordinary shares and warrants	38	—
Net cash used in financing activities	(406)	(6,979)
Effect of exchange rate changes on cash and cash equivalents	108	403
Net decrease in cash and cash equivalents	(6,979)	(27,194)
Cash and cash equivalents at January 1,	39,215	65,064
Cash and cash equivalents at March 31,	$ 32,236	$ 37,870

AVADEL PHARMACEUTICALS PLC

UNAUDITED SUPPLEMENTAL INFORMATION

(In thousands, except per share data)

	Three Months Ended March 31,	
Revenues by Product:	**2017**	**2016**
Bloxiverz	$ 13,902	$ 24,747
Vazculep	10,179	9,406
Akovaz	25,638	—
Other	2,038	1,200
Total product sales and services	51,757	35,353
License and research revenue	750	863
Total revenues	$ 52,507	$ 36,216

GAAP to Non-GAAP adjustments for the three-months ended March 31, 2017

		Exclude					***Include***		
	GAAP	**Intangible asset amortization**	**Foreign exchange (gain)/loss**	**Restructuring impacts**	**Purchase accounting adjustments - FSC**	**Contingent related party payable fair value remeasurements**	**Contingent related party payable paid/accrued**	**Total adjustments**	**Adjusted GAAP**
Revenues:									
Product sales and services	$ 51,757	$ —	$ —	$ —	$ —	$ —	$ —	$ —	$ 51,757
License and research revenue	750	—	—	—	—	—	—	—	750
Total	52,507	—	—	—	—	—	—	—	52,507
Operating expenses:									
Cost of products and services sold	3,902	—	—	—	(46)	—	—	(46)	3,856
Research and development	7,206	—	—	—	—	—	—	—	7,206

Selling, general and administrative	11,812	—	—	—	—	—	—	—	11,812
Intangible asset amortization	564	(564)	—	—	—	—	—	(564)	—
Changes in fair value of related party contingent consideration	(6,971)	—	—	—	—	6,971	9,616	16,587	9,616
Restructuring costs	2,653	—	—	(2,653)	—	—	—	(2,653)	—
Total	19,166	(564)	—	(2,653)	(46)	6,971	9,616	13,324	32,490
Operating income (loss)	33,341	564	—	2,653	46	(6,971)	(9,616)	(13,324)	20,017
Investment and other income	529	—	—	—	—	—	—	—	529
Interest expense	(263)	—	—	—	—	—	—	—	(263)
Other expense - changes in fair value of related party payable	550	—	—	—	—	(550)	(1,299)	(1,849)	(1,299)
Foreign exchange gain	(231)	—	231	—	—	—	—	231	—
Income (loss) before income taxes	33,926	564	231	2,653	46	(7,521)	(10,915)	(14,942)	18,984
Income tax provision (benefit)	8,525	201	—	—	17	(360)	(691)	(833)	7,692
Net income (loss)	$ 25,401	$ 363	$ 231	$ 2,653	$ 29	$ (7,161)	$ (10,224)	$ (14,109)	$ 11,292
Net income (loss) per share - diluted[(1)]	$ 0.59	$ 0.01	$ 0.01	$ 0.06	$ —	$ (0.17)	$ (0.24)	$ (0.33)	$ 0.26
Weighted average number of shares outstanding - diluted	42,810	42,810	42,810	42,810	42,810	42,810	42,810	42,810	42,810

(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, 2016							
	Exclude					***Include***		
	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**	**Adjusted GAAP**
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 March 31, 2016							
		Exclude				***Include***		
	GAAP	**Intangible asset amortization**	**Foreign exchange (gain)/loss**	**Purchase accounting adjustments - FSC**	**Contingent related party payable fair value remeasurements**	**Contingent related party payable paid/accrued**	**Total adjustments**	**Adjusted GAAP**
Revenues:								
Product sales and services	$ 35,353	$ —	$ —	$ —	$ —	$ —	$ —	$ 35,353
License and research revenue	863	—	—	—	—	—	—	863

Total	36,216	—	—	—	—	—	—	36,216
Operating expenses:								
Cost of products and services sold	3,906	—	—	(763)	—	—	(763)	3,143
Research and development	5,388	—	—	—	—	—	—	5,388
Selling, general and administrative	9,461	—	—	—	—	—	—	9,461
Intangible asset amortization	3,514	(3,514)	—	—	—	—	(3,514)	—
Changes in fair value of related party contingent consideration	8,243	—	—	—	(8,243)	6,445	(1,798)	6,445
Total	30,512	(3,514)	—	(763)	(8,243)	6,445	(6,075)	24,437
Operating income (loss)	5,704	3,514	—	763	8,243	(6,445)	6,075	11,779
Investment and other income	200	—	—	—	—	—	—	200
Interest expense	(175)	—	—	—	—	—	—	(175)
Other expense - changes in fair value of related party payable	(1,534)	—	—	—	1,534	(892)	642	(892)
Foreign exchange gain	(2,941)	—	2,941	—	—	—	2,941	—
Income (loss) before income taxes	1,254	3,514	2,941	763	9,777	(7,337)	9,658	10,912
Income tax provision (benefit)	7,312	1,262	—	274	551	(321)	1,766	9,078
Net income (loss)	$ (6,058)	$ 2,252	$ 2,941	$ 489	$ 9,226	$ (7,016)	$ 7,892	$ 1,834
Net income (loss) per share - diluted[(1)]	$ (0.15)	$ 0.05	$ 0.07	$ 0.01	$ 0.22	$ (0.17)	$ 0.19	$ 0.04
Weighted average number of shares outstanding - diluted	41,241	41,241	41,241	41,241	41,241	41,241	41,241	41,241

[(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

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