



Avadel Pharmaceuticals Reports Third Quarter 2017 Results

November 8, 2017

Total Revenues for the Third Quarter Were \$39.7 Million

Full Year Revenue Guidance of \$165-\$175 Million Unchanged

Acquired License for Noctiva™

DUBLIN, Ireland, Nov. 08, 2017 (GLOBE NEWSWIRE) -- Avadel Pharmaceuticals plc (NASDAQ:AVDL) today announced its financial results for the third quarter ended September 30, 2017.

Highlights Include:

- Total revenues for the third quarter 2017 were \$39.7 million, compared to \$32.1 million in the third quarter 2016.
- GAAP net income for the third quarter of 2017 was \$21.7 million, or \$0.52 per diluted share, compared to GAAP net loss of \$20.0 million, or \$0.48 per diluted share, in the third quarter of 2016.
- Adjusted net income for the third quarter of 2017 was \$3.7 million, or \$0.09 per diluted share, compared to an adjusted net loss of \$3.5 million, or \$0.08 per diluted share, in the third quarter of 2016. ⁽¹⁾
- On September 1, 2017, the Company acquired the commercial license for Noctiva™, the first and only product approved by the U.S. Food & Drug Administration (FDA) for the treatment of nocturia due to nocturnal polyuria in adults.
- Cash and marketable securities at September 30, 2017 were \$115.6 million, down from \$173.8 million at June 30, 2017, largely as a result of cash used for the Noctiva license acquisition.
- Cash used for share repurchases totaled \$16.7 million for the nine months ended September 30, 2017.

Mike Anderson, Avadel's Chief Executive Officer, said, "The third quarter of 2017 was another strong quarter for Avadel. Operationally, the Company continues to execute. We have generated \$30 million in operating cash flow year-to-date, and we have maintained our full year revenue guidance of \$165-\$175 million. Our strong financial performance over the last few years has allowed us to invest in the development and acquisition of proprietary specialty products that will provide the Company with long-term growth opportunities."

Mr. Anderson continued, "In early September, we took another step forward in the continued pursuit of becoming a fully integrated specialty pharmaceutical company when we acquired the license to commercialize Noctiva. Noctiva is the first and only product approved by the FDA for the treatment of nocturia, and aligns with our mission to offer patients differentiated specialty products that are safe and effective. We also believe Noctiva is an excellent strategic growth opportunity for Avadel, as it is the only available FDA approved product for this indication and has excellent patent protection through 2030 with the potential to deliver meaningful shareholder value."

Third Quarter 2017 Results

Revenues during the third quarter of 2017 were \$39.7 million, compared to \$32.1 million during the same period last year. The increase in revenues was due to Akovaz®, which was not fully launched in the third quarter of 2016. However, this increase was partially offset by a decline in Bloxivert® revenues, primarily as a result of additional competition to neostigmine in the form of an alternative molecule, sugammadex, and continued pricing pressure due to four competing neostigmine products. On a GAAP basis, net income was \$21.7 million during the third quarter of 2017, or \$0.52 per diluted share, compared to a net loss of \$20.0 million, or \$0.48 per diluted share, for the same period last year. This increase in net income on a year-over-year basis was attributed to \$9.9 million of gains related to changes in the fair value of related party contingent consideration for the third of quarter 2017, compared to \$20.8 million of expense 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.

Research and development expenses totaled \$8.1 million for the third quarter of 2017, flat compared to the same period last year. Sequentially, research and development expenses were up from \$6.8 million in the second quarter of 2017 as a result of increased spend on the REST-ON clinical trial. Research and development expenses are expected to increase in the fourth quarter of 2017 as the Company continues to open clinical sites in the United States and looks to add sites in new countries.

Selling, general and administrative expenses were \$11.6 million in the third quarter of 2017, compared to \$12.7 million in the same period last year. This decrease was largely due to a lower in stock based compensation expense period over period, partially offset by higher payroll and benefit costs as the Company continues to hire new employees to support future growth of the business.

Adjusted net income for the third quarter of 2017 was \$3.7 million, or \$0.09 per diluted share, compared to an adjusted net loss of \$3.5 million, or \$0.08 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 58% compared to 283% 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 reiterated its full year revenue guidance of between \$165 and \$175 million. During the fourth quarter of 2017, the Company expects to spend approximately \$15 million on launch preparation costs for Noctiva, and between \$8 to \$10 million in research and development costs, principally associated with the REST-ON clinical trial. For the full year, research and development costs are now expected to be in the range of \$30 to \$35 million and selling, general & administrative costs are expected to be in the range of \$60 to \$65 million, inclusive of the Noctiva launch preparation costs. As a result of the Noctiva costs, the Company slightly lowered its full year adjusted diluted EPS guidance to \$0.25 to \$0.35, down from \$0.30 to \$0.45.

Conference Call

A conference call to discuss these results has been scheduled for Wednesday, November 8, 2017 at 10:00 a.m. EST. 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 6289129. 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 in-licensing / acquiring new products; ultimately, helping patients adhere to their prescribed medical treatment and see better results. 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.

About Noctiva™

Noctiva is the first and only formulation of desmopressin acetate, a vasopressin analog, approved by the FDA for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least two times per night to void. It is a proprietary low-dose formulation of desmopressin acetate administered through a patent-protected preservative-free intranasal delivery system. Noctiva is dosed as a single spray in one nostril 30 minutes before bedtime, and is approved in two dosage forms of 0.83 mcg and 1.66 mcg. Noctiva is expected to become available to patients in the second quarter of 2018. (Full Prescribing Information available here).

Important Safety Information and Indication for Noctiva (desmopressin acetate)

WARNING: HYPONATREMIA

- **NOCTIVA can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death.**
- **NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids.**
- **Ensure serum sodium concentrations are normal before starting or resuming NOCTIVA. Measure serum sodium within seven days and approximately one month after initiating therapy or increasing the dose, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.**
- **If hyponatremia occurs, NOCTIVA may need to be temporarily or permanently discontinued.**

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 license agreement with Serenity Pharmaceuticals, LLC including that our internal analyses may overstate the market opportunity in the United States for the drug desmopressin acetate (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 (ii) 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, 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. Except as may be required by law, we disclaim any obligation to publicly update any forward-looking statements to reflect events after the date of this press release.

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.

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.

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AVADEL PHARMACEUTICALS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)

(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Revenues:				
Product sales and services	\$ 39,147	\$ 31,340	\$ 138,009	\$ 104,858
License and research revenue	528	747	484	2,303
Total	39,675	32,087	138,493	107,161
Operating expenses:				
Cost of products and services sold	3,790	2,844	12,253	10,657
Research and development expenses	8,095	8,143	22,093	21,135
Selling, general and administrative expenses	11,563	12,740	35,804	33,491
Intangible asset amortization	564	3,702	1,692	10,918
(Gain)/loss - changes in fair value of related party contingent consideration	(9,906)) 20,848	(30,107)) 52,989
Restructuring (income) costs	(549)) —	3,173) —
Total operating expenses	13,557	48,277	44,908	129,190
Operating income (loss)	26,118	(16,190)) 93,585	(22,029)
Investment income, net	1,110	490	2,689	1,080
Interest expense, net	(263)) (264)) (789)) (702)
Other income (expense) - changes in fair value of related party payable	768	(1,828)) 2,988	(6,135)
Foreign exchange gain (loss)	(133)) 1,249	(127)) (12)
Income (loss) before income taxes	27,600	(16,543)) 98,346	(27,798)
Income tax provision	5,921	3,451	21,830	18,212
Net income (loss)	\$ 21,679	\$ (19,994)) \$ 76,516	\$ (46,010)
Net income (loss) per share - basic	\$ 0.54	\$ (0.48)) \$ 1.87	\$ (1.12)
Net income (loss) per share - diluted	0.52	(0.48)) 1.81	(1.12)
Weighted average number of shares outstanding - basic	40,061	41,241	40,839	41,241
Weighted average number of shares outstanding - diluted	41,339	41,241	42,194	41,241

AVADEL PHARMACEUTICALS PLC

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except per share data)

	September 30, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 37,449	\$ 39,215
Marketable securities	78,161	114,980
Accounts receivable	24,080	17,839

Inventories, net	5,870	3,258
Prepaid expenses and other current assets	3,373	5,894
Total current assets	148,933	181,186
Property and equipment, net	3,180	3,320
Goodwill	18,491	18,491
Intangible assets, net	94,256	22,837
Research and development tax credit receivable	3,547	1,775
Income tax deferred charge	—	10,342
Other	9,020	7,531
Total assets	\$ 277,427	\$ 245,482

LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities:

Current portion of long-term debt	\$ 301	\$ 268
Current portion of long-term related party payable	30,986	34,177
Accounts payable	8,564	7,105
Deferred revenue	1,927	2,223
Accrued expenses	47,997	17,222
Income taxes	7,026	1,200
Other	507	226
Total current liabilities	97,308	62,421
Long-term debt, less current portion	614	547
Long-term related party payable, less current portion	76,131	135,170
Other	6,911	5,275
Total liabilities	180,964	203,413

Shareholders' equity:

Preferred shares, \$0.01 nominal value; 50,000 shares authorized; none issued or outstanding at September 30, 2017 and December 31, 2016, respectively	—	—
Ordinary shares, nominal value of \$0.01; 500,000 shares authorized; 41,435 and 41,371 issued and outstanding at September 30, 2017 and December 31, 2016, respectively	414	414
Treasury shares, at cost, 1,673 and 0 shares held at September 30, 2017 and December 31, 2016, respectively	(17,506)	—
Additional paid-in capital	391,416	385,020
Accumulated deficit	(254,440)	(319,800)
Accumulated other comprehensive loss	(23,421)	(23,565)
Total shareholders' equity	96,463	42,069
Total liabilities and shareholders' equity	\$ 277,427	\$ 245,482

AVADEL PHARMACEUTICALS PLC

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Nine Months Ended September 30,	
	2017	2016
Cash flows from operating activities:		
Net income (loss)	76,516	(46,010)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	2,664	11,555
Loss on disposal of property and equipment	—	110
Loss (gain) on sale of marketable securities	(550)	666
Foreign exchange loss	127	12
Grants recognized in research and development expenses	—	(70)
Remeasurement of related party acquisition-related contingent consideration	(30,107)	52,989
Remeasurement of related party financing-related contingent consideration	(2,988)	6,135
Change in deferred tax and income tax deferred charge	322	(5,680)
Stock-based compensation expense	6,019	10,541
Increase (decrease) in cash from:		
Accounts receivable	(6,240)	(7,594)
Inventories	(2,612)	2,080

License and research revenue	528	—	—	—	—	—	—	528				
Total	39,675	—	—	—	—	—	—	39,675				
Operating expenses:												
Cost of products and services sold	3,790	—	—	—	—	—	—	3,790				
Research and development	8,095	—	—	—	—	—	—	8,095				
Selling, general and administrative	11,563	—	—	—	—	—	—	11,563				
Intangible asset amortization	564	(564)	—	—	—	(564) —				
Changes in fair value of related party contingent consideration	(9,906)	—	—	9,906	7,264	17,170	7,264				
Restructuring costs	(549)	—	549	—	—	549	—				
Total	13,557	(564)	549	9,906	7,264	17,155	30,712				
Operating income (loss)	26,118	564	—	(549)	(9,906) (7,264) (17,155) 8,963			
Investment and other income	1,110	—	—	—	—	—	—	1,110				
Interest expense	(263)	—	—	—	—	—	(263)			
Other expense - changes in fair value of related party payable	768	—	—	—	(768)	(963) (1,731) (963)		
Foreign exchange gain	(133)	—	133	—	—	—	133	—			
Income (loss) before income taxes	27,600	564	133	(549)	(10,674) (8,227) (18,753) 8,847			
Income tax provision (benefit)	5,921	201	—	—	(507)	(515) (821) 5,100			
Net income (loss)	\$ 21,679	\$ 363	\$ 133	\$ (549)	\$ (10,167)	\$ (7,712)	\$ (17,932)	\$ 3,747
Net income (loss) per share - diluted ⁽¹⁾	0.52	\$ 0.01	\$ —	\$ (0.01)	\$ (0.25)	\$ (0.19)	\$ (0.43)	\$ 0.09
Weighted average number of shares outstanding - diluted	41,339	41,339	41,339	41,339	41,339	41,339	41,339	41,339	41,339	41,339		

(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 September 30, 2016

	GAAP	Exclude			Include		
		Intangible asset amortization	Foreign exchange (gain)/loss	Contingent related party payable fair value adjustment	Contingent related party payable paid/accrued	Total adjustments	Adjusted GAAP
Revenues:							
Product sales and services	\$ 31,340	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 31,340
License and research revenue	747	—	—	—	—	—	747
Total	32,087	—	—	—	—	—	32,087
Operating expenses:							
Cost of products and services sold	2,844	—	—	—	—	—	2,844
Research and development	8,143	—	—	—	—	—	8,143
Selling, general and administrative	12,740	—	—	—	—	—	12,740
Intangible asset amortization	3,702	(3,702)	—	—	(3,702) —

Changes in fair value of related party contingent consideration	20,848	—	—	(20,848)	5,884	(14,964)	5,884		
Restructuring costs	—	—	—	—	—	—	—	—	—		
Total	48,277	(3,702)	—	(20,848)	5,884	(18,666)	29,611	
Operating income (loss)	(16,190)	3,702	—	20,848	(5,884)	18,666	2,476		
Investment and other income	490	—	—	—	—	—	—	490			
Interest expense	(264)	—	—	—	—	—	(264)		
Other expense - changes in fair value of related party payable	(1,828)	—	—	1,828	(785)	1,043	(785)	
Foreign exchange gain	1,249	—	(1,249)	—	—	(1,249)	—		
Income (loss) before income taxes	(16,543)	3,702	(1,249)	22,676	(6,669)	18,460	1,917	
Income tax provision (benefit)	3,451	1,329	—	1,021	(385)	1,965	5,416			
Net income (loss)	\$ (19,994)	\$ 2,373	\$ (1,249)	\$ 21,655	\$ (6,284)	\$ 16,495	\$ (3,499)
Net income (loss) per share - diluted ⁽¹⁾	(0.48)	\$ 0.06	\$ (0.03)	\$ 0.53	\$ (0.15)	\$ 0.40	\$ (0.08)
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.

GAAP to Non-GAAP adjustments for the nine-months ended September 30, 2017

		Exclude					Include				
	GAAP	Intangible asset amortization	Foreign exchange (gain)/loss	Restructuring impacts	Purchase accounting adjustment - FSC	License revenue adjustment	Contingent related party payable fair value adjustment	Contingent related party payable paid/accrued	Total adjustments	Adjusted GAAP	
Revenues:											
Product sales and services	\$ 138,009	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 138,009	
License and research revenue	484	—	—	—	—	1,100	—	—	1,100	1,584	
Total	138,493	—	—	—	—	1,100	—	—	1,100	139,593	
Operating expenses:											
Cost of products and services sold	12,253	—	—	—	(46)	—	—	—	(46)	12,207	
Research and development	22,093	—	—	—	—	—	—	—	—	22,093	
Selling, general and administrative	35,804	—	—	—	—	—	—	—	—	35,804	
Intangible asset amortization	1,692	(1,692)	—	—	—	—	—	—	(1,692)	—	
Changes in fair value of related party contingent consideration	(30,107)	—	—	—	—	—	30,107	25,396	55,503	25,396	
Restructuring charges	3,173	—	—	(3,173)	—	—	—	—	(3,173)	—	
Total	44,908	(1,692)	—	(3,173)	(46)	—	30,107	25,396	50,592	95,500	
Operating income (loss)	93,585	1,692	—	3,173	46	1,100	(30,107)	(25,396)	(49,492)	44,093	

(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.

Investment and other income	1,080	—	—	—	—	—	—	1,080
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Interest expense	(702)	—	—	—	—	—	—	(702)	
Other expense - changes in fair value of related party payable	(6,135)	—	—	—	6,135	(2,618)	3,517	(2,618)
Foreign exchange gain	(12)	—	12	—	—	—	12	—		
Income (loss) before income taxes	(27,798)	10,918	12	1,525	59,124	(21,939)	49,640	21,842	
Income tax provision (benefit)	18,212		3,920	—	533	2,986	(1,165)	6,274	24,486	
Net income (loss)	\$ (46,010)	\$ 6,998	\$ 12	\$ 992	\$ 56,138	\$ (20,774)	\$ 43,366	\$ (2,644)
Net income (loss) per share - diluted ⁽¹⁾	(1.12)	\$ 0.17	\$ —	\$ 0.02	\$ 1.36	\$ (0.50)	\$ 1.05	\$ (0.07)
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.

Avadel Pharmaceuticals plc