Osmotica Pharmaceuticals plc Reports Third Quarter 2018 Results

November 8, 2018

BRIDGEWATER, N.J., Nov. 08, 2018 (GLOBE NEWSWIRE) -- Osmotica Pharmaceuticals plc ("Osmotica" or the "Company") (Nasdaq: OSMT), a fully integrated biopharmaceutical company, today announced financial results for the three and nine months ended September 30, 2018.

Recent Business and Financial Highlights include:

Recent Business Highlights

- Completed an initial public offering ("IPO") and concurrent private placement raising aggregate net proceeds of approximately $58.4 million, including the exercise in full of the underwriter's over-allotment option. $50 million of these proceeds were used to prepay debt;
- Completed enrollment of Osmotica's 510 patient, double-blind, randomized (1:1:1) study to demonstrate the safety and efficacy of arbaclofen ER 40 mg/day and arbaclofen ER 80 mg/day versus placebo for the treatment of spasticity in patients with multiple sclerosis over a 12-week timeframe, and
- Commencing initial commercial launch of Osmolex ER™ (amantadine) extended release tablets ("Osmolex ER") with a full-scale roll out planned for January 2019.

Third Quarter 2018 Financial Highlights

- Total revenues for the third quarter were $66.3 million, compared to $53.7 million in the third quarter of 2017;
- Net loss for the third quarter was $5.0 million compared to a net loss of $12.3 million in the third quarter of 2017;
- Adjusted EBITDA[1] for the third quarter was $25.8 million, compared to Adjusted EBITDA[1] of $24.0 million in the third quarter of 2017; and
- Cash and cash equivalents were $32.2 million, and debt (excluding deferred financing fees) was $321.9 million as of September 30, 2018.

"We are delighted to have completed our IPO, providing us with additional financial flexibility to advance our pipeline programs and explore new product and business development opportunities. We plan to make additional investments in our R&D programs and promotional activities surrounding Osmolex ER in the fourth quarter of 2018," stated Brian Markison, Chief Executive Officer.

"Enrollment in our arbaclofen ER trial for spasticity in multiple sclerosis has been completed. We believe that a positive result from this trial, combined with our existing clinical and pre-clinical data package, would enable us to complete the submission of our NDA during the second half of 2019. We are also concurrently conducting a long-term safety trial for the 80mg/day regimen of arbaclofen ER, which aims to enroll 250 patients. If approved by the FDA, we intend to begin commercialization of arbaclofen ER as early as 2020."

Third Quarter 2018 Financial Results

Total revenues for the three months ended September 30, 2018 was $66.3 million, compared to $53.7 million for the three months ended September 30, 2017.

Net product sales increased to $65.4 million for the three months ended September 30, 2018, compared to $54.7 million for the three months ended September 30, 2017. The increase in product sales was primarily due to methylphenidate hydrochloride ("HCl") extended-release ("ER") tablets, which was approved and launched in the third quarter of 2017, and methylphenidate HCl ER 72 mg tablets ("M-72"), which was launched in the second quarter of 2018, partially offset by lower product sales from venlafaxine ER ("VERT").

Selling, general and administrative expenses increased to $17.5 million in the third quarter of 2018, compared to $13.3 million in the third quarter of 2017. The increase was primarily due to an expansion of our field force in early 2018, expenses associated with the launch of M-72 and pre-launch activities for Osmolex ER, and costs associated with the Company's IPO.

Research and development expenses increased to $13.3 million in the third quarter of 2018, compared to $6.5 million in the third quarter of 2017, largely due to clinical trial costs of arbaclofen ER, as discussed above, and RVL-1201 for the treatment of blepharoptosis, or droopy eyelid, each of which is in Phase III clinical trials, together with additional headcount.

Interest expense and amortization of debt discount decreased to $5.3 million in the third quarter of 2018, compared to $7.3 million in the third quarter of 2017. The decrease in borrowing costs resulted from a refinancing that was completed in December 2017.

Net loss for the third quarter of 2018 was $5.0 million, compared to net loss of $12.3 million in the third quarter of 2017.

Adjusted EBITDA for the third quarter of 2018 was $25.8 million, compared to Adjusted EBITDA of $24.0 million for the third quarter of 2017.

For a full reconciliation of Adjusted EBITDA to the most comparable GAAP financial measure, please see the tables at the end of this press release.

Nine Month Ended September 30, 2018 Financial Results

Total revenues for the nine months ended September 30, 2018 were $198.0 million, compared to $169.4 million for the nine months ended September

30, 2017.

Net product sales increased to $196.3 million for the nine months ended September 30, 2018, compared to $162.9 million for the nine months ended September 30, 2017, primarily due to methylphenidate HCl ER, which was approved and launched in the third quarter of 2017, and M-72, which was launched in the second quarter of 2018, offset by lower product sales from VERT during the nine months ended September 30, 2018.

Selling, general and administrative expenses increased to $51.3 million for the nine months ended September 30, 2018, compared to $41.3 million in the nine months ended September 30, 2017. The increase reflects costs incurred for the Company's IPO, sales force expenses related to the launch of M-72 and pre-launch activities related to Osmolex ER.

Research and development expenses increased to $32.5 million for the nine months ended September 30, 2018, compared to $18.2 million in the nine months ended September 30, 2017, largely due to clinical trial costs for arbaclofen ER and RVL-1201, as mentioned above.

Net loss for the nine months ended September 30, 2018 was $3.6 million, compared to net loss of $42.3 million for the nine months ended September 30, 2017.

Adjusted EBITDA for the nine months ended September 30, 2018 was $80.9 million, compared to Adjusted EBITDA of $72.1 million for the nine months ended September 30, 2017.

For a full reconciliation of Adjusted EBITDA to the most comparable GAAP financial measure, please see the tables at the end of this press release.

Liquidity

As of September 30, 2018, Osmotica had cash and cash equivalents of $32.2 million and $321.9 million in debt (excluding deferred financing fees). The Company had $50 million of unused borrowing capacity available under its revolving credit facility as of September 30, 2018.

Presentation of Non-GAAP Measures

In addition to the results provided in accordance with GAAP throughout this press release, the Company has provided Adjusted EBITDA, which is a non-GAAP measurement. Adjusted EBITDA represents earnings before interest, taxes, depreciation and amortization adjusted for (i) non-operating income or expense, and (ii) the impact of certain non-cash, nonrecurring or other items that are included in net loss and EBITDA that we do not consider indicative of our ongoing operating performance. Adjusted EBITDA excludes impairments, management fees, IPO expenses, consulting fees, severance expenses, acquired inventory step-up in costs of goods sold, legal and contractual settlements and litigation reserves and write-off of previously acquired balances. We use Adjusted EBITDA for business planning purposes, in assessing our performance and determining the compensation of substantially all of our employees, including our executive officers, and in measuring our performance relative to that of our competitors. We also believe that Adjusted EBITDA provides investors with useful information to understand our operating results and analyze financial and business trends on a period-to-period basis. Adjusted EBITDA has important limitations as an analytical tool and you should not consider it in isolation or as a substitute for analysis of our results as reported under GAAP. Adjusted EBITDA is not intended to replace, and should not be considered superior to, the presentation of our financial results in accordance with GAAP. Our definition of Adjusted EBITDA may differ from similar measures reported by other companies and may not be comparable to other similarly titled measures. Adjusted EBITDA is reconciled from the net loss as determined under GAAP in the attached table "Osmotica Pharmaceuticals plc Non-GAAP Reconciliations."

Forward Looking Statements

This press release includes statements that express the Company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements." The Company's actual results may vary significantly from the results anticipated in these forward-looking statements, which can generally be identified by the use of forward-looking terminology, including the terms "believes," "expects," "may," "will," "should," "seeks," "projects," "approximately," "intends," "plans," "estimates" or "anticipates," or, in each case, their negatives or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They include statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, our results of operations, financial condition, liquidity, prospects, financial guidance, growth plan, strategies, trends and events, particularly relating to sales of current products and the development, approval and introduction of new products, FDA and other regulatory applications, approvals and actions, the continuation of historical trends, our ability to operate our business under our new capital and operating structure, and the sufficiency of our cash balances and cash generated from operating and financing activities for future liquidity and capital resource needs. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place significant reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Important factors that could cause actual results and events to differ materially from those indicated in the forward-looking statements include the following: our ability to successfully develop or commercialize new products, or do so on a timely or cost effective basis; our dependence on a limited number of products; failures of or delays in clinical trials or other delays in obtaining regulatory approval or commencing product sales for new products; the impact of legal proceedings; our ability to service our substantial debt; our ability to raise additional capital; the impact of competition from both brand and generic companies; any interruption at our manufacturing facility, our warehouses or at facilities operated by third parties that we rely on for our products; our dependence on our major customers; our ability to develop and maintain our sales capabilities; the impact of any litigation related to allegations of infringement of intellectual property; any changes to the coverage and reimbursement levels for our products by governmental authorities and other third-party payors as a result of healthcare reform or otherwise; the impact of any changes in the extensive governmental regulation that we face; manufacturing or quality control issues that we may face; and other risks and uncertainties more fully described in the "Risk Factors" section of the prospectus dated October 17, 2018 related to the Company's IPO and other filings that the Company makes with the Securities and Exchange Commission. These forward-looking statements speak only as of the time of this release and we do not undertake to publicly update or revise them, whether as a result of new information, future events or otherwise, except as required by law.

Conference Call

As previously announced, Osmotica management will host its third quarter 2018 conference call as follows:

Date	Thursday, November 8, 2018

Time	4:30 p.m. EST
Toll free (U.S.)	(866) 672-5029
International	(409) 217-8312
Webcast (live and replay)	www.osmotica.com, under the “Investor & News” section

A replay of the conference call will be available for one week after the call's completion by dialing (855) 859-2056 (US) or 404-537-3406 (International) and entering conference call ID 1018838. The webcast will be archived for 30 days at the aforementioned URL.

About Osmotica Pharmaceuticals plc
Osmotica Pharmaceuticals plc is a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations. Our diversified product portfolio in the specialty neurology and women's health therapeutic areas, together with our non-promoted complex formulations of generic drugs, form the foundation of our unwavering commitment to improve patients' lives.

Osmotica has a late-stage development pipeline highlighted by two NDA candidates in Phase III clinical trials: arbaclofen extended-release tablets for muscle spasticity in multiple sclerosis patients and RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for the treatment of blepharoptosis, or droopy eyelid.

Osmotica has operations in the United States, Argentina, and Hungary.

Investor and Media Relations for Osmotica Pharmaceuticals plc
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

-Financial tables follow-

Osmotica Pharmaceuticals plc
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2018 (Unaudited)	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 32,203	$ 34,743
Trade accounts receivable, net	72,718	37,638
Inventories, net	25,594	16,947
Prepaid expenses and other current assets	18,802	25,814
Total current assets	149,317	115,142
Property, plant and equipment, net	31,301	31,410
Intangibles, net	521,239	585,389
Goodwill	152,816	152,816
Other non-current assets	799	942
Total assets	$ 855,472	$ 885,699
Liabilities and Partners' Capital		
Current liabilities:		
Trade accounts payable	$ 27,861	$ 36,070
Accrued liabilities	81,576	81,926
Current portion of long-term debt, net of deferred financing costs	6,066	6,656
Current portion of obligation under capital leases	111	24
Total current liabilities	115,614	124,676
Long-term debt, net of non-current deferred financing costs	310,009	313,950
Long-term portion of obligation under capital leases	149	57
Income taxes payable	1,073	1,335
Deferred taxes	13,125	25,364
Other long-term liabilities	-	1,047
Total liabilities	439,970	466,429
Commitments and contingencies		
Partners' capital		
Partners' capital	417,374	419,903

Accumulated other comprehensive loss	(1,872)	(633)
Total partners' capital	415,502	419,270
Total liabilities and partners' capital	$ 855,472	$ 885,699

Osmotica Pharmaceuticals plc
Condensed Consolidated Statements of Operations
(Unaudited)
(in thousands, except unit and per unit data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net product sales	$ 65,444	$ 54,678	$ 196,264	$ 162,903
Royalty revenue	903	(1,085)	1,656	5,122
Licensing and contract revenue	(2)	148	85	1,392
Total revenues	66,345	53,741	198,005	169,417
Cost of good sold (inclusive of amortization of intangibles)	32,012	21,464	99,150	77,364
Gross profit	34,333	32,277	98,855	92,053
Selling, general and administrative expenses	17,451	13,258	51,289	41,301
Research and development expenses	13,309	6,492	32,451	18,187
Impairment of intangible assets	6,173	30,748	6,173	72,448
Total operating expenses	36,933	50,498	89,913	131,936
Operating (loss) income	(2,600)	(18,221)	8,942	(39,883)
Interest expense and amortization of debt discount	5,311	7,301	15,396	21,721
Other non-operating income, net	(434)	(1,202)	(881)	(2,485)
Total other non-operating expense, net	4,877	6,099	14,515	19,236
Loss before income taxes	(7,477)	(24,320)	(5,573)	(59,119)
Income tax benefit	2,489	12,047	1,999	16,786
Net loss	$ (4,988)	$ (12,273)	$ (3,574)	$ (42,333)
Loss per unit attributable to unitholders				
Basic	$ (4.99)	$ (12.27)	$ (3.57)	$ (42.31)
Diluted	$ (4.99)	$ (12.27)	$ (3.57)	$ (42.31)
Weighted average units basic and diluted				
Basic and diluted	1,000,515	1,000,515	1,000,515	1,000,515

Osmotica Pharmaceuticals plc
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (3,574)	$ (42,333)
Adjustments to reconcile net loss to cash provided by operating activities		
Depreciation and amortization	61,323	24,939
Loss on sale of fixed assets	13	-
Impairment of intangible assets	6,173	72,448
Deferred income tax benefit	(12,240)	(32,786)
Bad debt provision	(1,293)	(1,052)
Change in fair value of contingent consideration	-	182
Payment for contingent consideration	-	(1,991)
Amortization of deferred financing and loan origination fees	1,261	1,645

Non-cash interest expense	-	3,961
Change in operating assets and liabilities		
Trade accounts receivable, net	(33,821)	18,809
Inventories, net	(8,647)	(133)
Prepaid expenses and other current assets	6,442	3,878
Other non-current assets	(2)	-
Trade accounts payable	(9,063)	(21,849)
Accrued and other current liabilities	602	10,289
Net cash provided by operating activities	7,174	36,007
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	10	-
Purchase of property, plant and equipment	(2,998)	(7,126)
Net cash used in investing activities	(2,988)	(7,126)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Distributions to partners	(2)	(2,545)
Contributions from partners	-	128
Payments on capital lease obligations	(82)	(108)
Proceeds from insurance financing loan	975	-
Repayment of insurance financing loan	(484)	-
Debt repayment	(6,140)	(5,252)
Payment for contingent consideration	-	(8,509)
Net cash used in financing activitIes	(5,733)	(16,286)
Net change in cash and cash equivalents	(1,547)	12,595
Effect on cash of change in exchange rate	(993)	524
Cash and cash equivalents, beginning of period	34,743	19,559
Cash and cash equivalents, end of period	$ 32,203	$ 32,678

Osmotica Pharmaceuticals plc
GAAP to Non-GAAP Reconciliations
Adjusted EBITDA (Unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net Loss	$ (4,988)	$ (12,273)	$ (3,574)	$ (42,333)
Interest expense and amortization of debt discount	5,311	7,301	15,396	21,721
Income tax benefit	(2,489)	(12,047)	(1,999)	(16,786)
Depreciation and Amortization Expense	20,457	9,769	61,323	24,939
EBITDA	18,291	(7,250)	71,146	(12,459)
Impairment of intangible assets	6,173	30,748	6,173	72,448
Management Fees	250	250	770	750
IPO expenses	1,038	-	1,982	-
Consulting Fees	-	138	-	414
Severance expenses	-	42	484	123
Acquired Inventory Step-up in cost of goods sold	-	-	-	9,175
Legal and contractual settlements and litigation reserves	-	-	332	1,052
Write off of previously acquired balances	-	-	-	578
Adjusted EBITDA	$ 25,752	$ 23,928	$ 80,887	$ 72,081

Source: Osmotica Holdings US LLC