



Osmotica Pharmaceuticals plc Reports Third Quarter 2019 Results

November 14, 2019

Third quarter 2019 total revenue of \$65.5 million

Submitted NDA for RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for acquired blepharoptosis, or droopy eyelid, to FDA

BRIDGEWATER, N.J., Nov. 14, 2019 (GLOBE NEWSWIRE) -- Osmotica Pharmaceuticals plc (Nasdaq: OSMT) ("Osmotica" or the "Company"), a fully integrated biopharmaceutical company, today announced business highlights and financial results for the quarter ended September 30, 2019.

"We are pleased with the progress we made on many fronts during the third quarter, beginning with the submission of our new drug application (NDA) for RVL-1201 (RVL) in September. We are currently engaged in productive follow-up discussions with the U.S. Food and Drug Administration (FDA) and believe we are on track for an acceptance to file during the fourth quarter. RVL, with its once-a-day ophthalmic formulation, has the potential to be a first-in-class pharmacologic treatment for acquired blepharoptosis, and a meaningful solution to patients with mild-to-moderate ptosis. In recent weeks, we presented Phase III efficacy and safety trial data for RVL at several global eye care conferences, where we received positive feedback from key opinion leaders. As we build out our medical education strategy for RVL, we are also turning our focus to messaging and pre-launch activities," stated Brian Markison, Chief Executive Officer.

"We are also in communication with the FDA regarding arbaclofen ER, a treatment for spasticity in Multiple Sclerosis patients, with a potential NDA amendment submission in the first half of 2020. These advancements in our late-stage pipeline are encouraging as we continue to transition our business to a branded specialty pharmaceuticals company," added Markison.

Third Quarter 2019 Financial Highlights

- Total revenues were \$65.5 million, compared to \$66.3 million in the third quarter of 2018;
- Net loss was \$112.7 million, reflecting an impairment charge of \$128.1 million, compared to net loss of \$3.6 million in the third quarter of 2018;
- Adjusted EBITDA¹ was \$22.9 million, compared to Adjusted EBITDA of \$25.8 million in the third quarter of 2018; and
- Cash and cash equivalents were \$98.0 million and debt (net of deferred financing costs) was \$268.1 million as of September 30, 2019.

¹Adjusted EBITDA is a non-GAAP measure. Adjusted EBITDA is more fully described and reconciled from net loss determined under U.S. generally accepted accounting principles ("GAAP") in "Presentation of Non-GAAP Measures" and the attached table "Osmotica Pharmaceuticals plc GAAP to Non-GAAP Reconciliations."

Third Quarter 2019 Financial Results

Total revenues decreased by \$0.9 million to \$65.5 million for the three months ended September 30, 2019, as compared to \$66.3 million for the three months ended September 30, 2018 primarily due to a decrease in net product sales.

Net product sales decreased by \$1.4 million to \$64.0 million for the three months ended September 30, 2019, as compared to \$65.4 million for the three months ended September 30, 2018. Net sales of methylphenidate ER (including M-72) decreased 46% during the quarter due to additional competitors entering the market resulting in significantly lower net selling prices and volumes, partially offset by lower than estimated product returns. Net sales of venlafaxine extended release tablets (VERT) increased 41% during the quarter compared to the prior year period as a result of higher realized net selling prices due to lower than estimated product returns combined with higher volumes. We expect that additional competition for both methylphenidate ER and VERT from current competitors, as well as additional generic product approvals and launches in the future, if any, will continue to negatively affect our sales of these products during the remainder of 2019 and in future years. Methylphenidate and VERT net sales were favorably impacted by adjustments of approximately \$11.6 million in the aggregate, primarily related to product returns reserves during the quarter based on actual product returns experience. There can be no assurance that actual product returns experience and other adjustments will continue to favorably impact net sales in the remainder of 2019 and future years.

Selling, general and administrative expenses increased \$7.3 million during the three months ended September 30, 2019 to \$24.8 million as compared to \$17.5 million in the three months ended September 30, 2018. The increase in our selling, general and administrative expenses reflects additions to salesforce headcount and marketing costs following the launch of Osmolex ER in the first quarter of 2019, severance costs associated with the salesforce realignment during the third quarter of 2019, and increased share compensation expense and higher costs associated with being a public company.

Research and development expenses decreased by \$3.7 million in the three months ended September 30, 2019 to \$8.3 million as compared to \$12.0 million in the three months ended September 30, 2018. The decrease reflects the completion of the Phase III clinical trial for arbaclofen ER during the first quarter of 2019, partially offset by increased share compensation expense, and the cost of manufacturing development batches of Osmolex ER in the three month period ended September 30, 2018, which costs did not reoccur in 2019.

The Company incurred an impairment of intangible assets charge of \$128.1 during the three months ended September 30, 2019, primarily related to the write down to fair value of methylphenidate due to price and volume decreases resulting from competing generic products.

Net loss for the third quarter of 2019 was \$112.7 million, compared to net loss of \$3.6 million in the third quarter of 2018.

Adjusted EBITDA for the third quarter of 2019 was \$22.9 million, compared to Adjusted EBITDA of \$25.8 million in the third quarter of 2018.

For a reconciliation of Adjusted EBITDA to net loss (income), the most comparable GAAP financial measure, please see the “Osmotica Pharmaceuticals plc GAAP to Non-GAAP Reconciliations” table at the end of this press release.

Liquidity

As of September 30, 2019, we had cash and cash equivalents of \$98.0 million and borrowing availability under our revolving credit facility of \$50.0 million. The Company also had debt of \$268.1 million (net of deferred financing costs).

Presentation of Non-GAAP Measures

In addition to the results provided in accordance with GAAP throughout this press release, the Company has presented Adjusted EBITDA, which is a non-GAAP measurement. Adjusted EBITDA represents earnings before interest, taxes, depreciation and amortization (“EBITDA”) 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. In particular, Adjusted EBITDA excludes the following from EBITDA: impairment of intangible assets, management fees, IPO expenses, severance expenses, foreign currency translation, legal settlements and share-based compensation expense. 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, however, 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 GAAP to 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 other 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 our Annual Report on Form 10-K for the year ended December 31, 2018 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 2019 conference call as follows:

Date	Friday, November 15, 2019
Time	8:30 a.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
Conference call ID	8189498

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 that recently completed Phase III clinical trials: arbaclofen ER for spasticity in multiple sclerosis patients and RVL-1201 for the treatment of acquired blepharoptosis, or droopy eyelid.

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

Investor and Media Relations for Osmotica Pharmaceuticals plc

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-Financial tables follow-

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Net loss	\$ (112,704) \$ (3,606) \$ (244,260) \$ (2,675
Interest expense and amortization of debt discount	4,504	5,311	13,555	15,396
Income tax benefit	(14,623) (3,872) (26,824) (2,898
Depreciation and amortization expense	14,614	20,457	50,605	61,323
EBITDA	(108,209) 18,290	(206,924) 71,146
Impairment of intangibles	128,113	6,173	253,879	6,173
Management fees	-	250	(43) 770
IPO expenses	-	1,038	-	1,982
Consulting Fees	-	-	-	-
Severance expenses	1,275	-	1,638	484
FX translation	363	-	575	-
Legal settlements	-	-	1,002	333
Share compensation expense	1,335	-	3,831	-
Adjusted EBITDA	\$ 22,877	\$ 25,751	\$ 53,958	\$ 80,888

Osmotica Pharmaceuticals plc Condensed Consolidated Balance Sheets (in thousands)

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 98,014	\$ 70,834
Trade accounts receivable, net	33,862	56,424
Inventories, net	27,240	24,383
Prepaid expenses and other current assets	8,186	20,723
Total current assets	167,302	172,364
Property, plant and equipment, net	30,325	31,263
Operating lease assets	5,558	-
Intangibles, net	189,324	490,390
Goodwill	100,855	100,855

Deferred taxes	198	-
Other non-current assets	611	752
Total assets	\$ 494,173	\$ 795,624
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	\$ 9,905	\$ 24,870
Accrued liabilities	66,076	87,238
Current portion of long-term debt, net of deferred financing costs	398	1,774
Current portion of lease liability	2,082	-
Current portion of obligation under finance leases	130	119
Total current liabilities	78,591	114,001
Long-term debt, net of non-current deferred financing costs	267,661	266,803
Long-term portion of obligation under finance leases	68	138
Long-term portion of lease liability	3,677	-
Income taxes payable-long term portion	2,479	2,541
Deferred taxes	-	28,294
Total liabilities	352,476	411,777
Commitments and contingencies		
Shareholders' equity		
Ordinary shares	522	525
Additional paid in capital	489,784	487,288
Accumulated deficit	(346,380)	(102,120)
Accumulated other comprehensive loss	(2,229)	(1,846)
Total shareholders' equity	141,697	383,847
Total liabilities and shareholders' equity	\$ 494,173	\$ 795,624

Osmotica Pharmaceuticals plc
Condensed Consolidated Statements of Operations
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September		Nine Months Ended September	
	30, 2019	2018	30, 2019	2018
Net product sales	\$ 64,041	\$ 65,444	\$ 176,657	\$ 196,264
Royalty revenue	1,325	903	2,826	1,656
Licensing and contract revenue	95	(2)	637	85
Total revenues	65,461	66,345	180,120	198,005
Cost of goods sold (inclusive of amortization of intangibles)	27,312	33,356	89,160	102,495
Gross profit	38,149	32,989	90,960	95,510
Selling, general and administrative expenses	24,751	17,452	71,919	51,290
Research and development expenses	8,285	11,965	23,410	29,105
Impairment of intangibles	128,113	6,173	253,879	6,173
Total operating expenses	161,149	35,590	349,208	86,568
Operating income (loss)	(123,000)	(2,601)	(258,248)	8,942
Interest expense and amortization of debt discount	4,504	5,311	13,555	15,396
Other non-operating gain	(177)	(434)	(719)	(881)
Total other non-operating expense	4,327	4,877	12,836	14,515
Loss before income taxes	(127,327)	(7,478)	(271,084)	(5,573)
Income tax benefit	14,623	3,872	26,824	2,898
Net loss	\$(112,704)	\$(3,606)	\$(244,260)	\$(2,675)
Other comprehensive loss, net				
Change in foreign currency translation adjustments	(383)	(148)	(383)	(1,239)
Comprehensive loss	\$(113,087)	\$(3,754)	\$(244,643)	\$(3,914)
Loss per share attributable to shareholders				

Basic and Diluted	\$ (2.15)	\$ (0.08)	\$ (4.65)	\$ (0.06)
Weighted average shares basic and diluted								
Basic and Diluted	52,477		42,862		52,505		42,862	

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

	Nine Months Ended September 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (244,260) \$ (2,675
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	50,605	61,323
Share compensation	3,831	-
Loss on sale of fixed and leased assets	75	13
Impairment of intangibles	253,879	6,173
Deferred income tax benefit	(28,493) (7,508
Bad debt provision	(160) (1,293
Amortization of deferred financing and loan origination fees	1,000	1,261
Change in operating assets and liabilities:		
Trade accounts receivable, net	22,722	(33,821
Inventories, net	(2,857) (8,647
Prepaid expenses and other current assets	12,536	811
Trade accounts payable	(14,964) (9,063
Accrued and other current liabilities	(21,022) 600
Net cash provided by operating activities	32,892	7,174
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed and leased assets	12	10
Payments on disposal of leased assets	(34) -
Purchase of property, plant and equipment	(3,042) (2,998
Net cash used in investing activities	(3,064) (2,988
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments to affiliates	-	(2
Repurchases of ordinary shares	(1,338) -
Payments on finance lease obligations	(97) (82
Proceeds from insurance financing loan	1,314	975
Repayment of insurance financing loan	(2,691) (484
Repayment of debt	-	(6,140
Net cash used in financing activities	(2,812) (5,733
Net change in cash and cash equivalents	27,016	(1,547
Effect on cash of changes in exchange rate	164	(993
Cash and cash equivalents, beginning of period	70,834	34,743
Cash and cash equivalents, end of period	\$ 98,014	\$ 32,203



Source: Osmotica Holdings US LLC