



Osmotica Pharmaceuticals plc Reports Second Quarter 2019 Results

August 8, 2019

Second quarter 2019 total revenue of \$57.5 million

On track to submit NDA for RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for acquired blepharoptosis, or droopy eyelid, by end of Q3 2019

BRIDGEWATER, N.J., Aug. 08, 2019 (GLOBE NEWSWIRE) -- Osmotica Pharmaceuticals plc ("Osmotica" or the "Company") (Nasdaq: OSMT), a fully integrated biopharmaceutical company, today announced business highlights and financial results for the quarter ended June 30, 2019.

"During the second quarter, we continued to make meaningful progress in our ongoing transition towards becoming a specialty branded pharmaceutical company. We once again saw prescription growth from key promoted brands – Divige[®], methylphenidate hydrochloride ER 72 mg (M-72), and Osmolex ER[™] (amantadine extended-release tablets) – as well as the previously announced successful completion of our clinical program for RVL-1201, our potential first-in-class ophthalmic solution in development for the treatment of droopy eyelid. We remain on track to submit our NDA for RVL-1201 by the end of the third quarter of 2019. We are also in dialogue with the FDA to discuss the potential resubmission of our NDA for arbaclofen ER, and remain optimistic based on the strength of our clinical efficacy and safety data in M.S. spasticity," stated Brian Markison, Chief Executive Officer.

"Combined with the significant and compelling opportunity we have with RVL-1201, our late-stage pipeline represents a tremendous opportunity," added Markison.

Second Quarter 2019 Financial Results

- Total revenues were \$57.5 million, compared to \$71.9 million in the second quarter of 2018;
- Net loss was \$124.7 million, including an impairment charge of \$125.8 million, compared to net income of \$5.9 million in the second quarter of 2018;
- Adjusted EBITDA¹ was \$14.5 million, compared to Adjusted EBITDA of \$34.6 million in the second quarter of 2018; and
- Cash and cash equivalents were \$63.7 million and debt (net of deferred financing costs) was \$267.4 million as of June 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."

Second Quarter 2019 Financial Results

Total revenues decreased by \$14.3 million to \$57.5 million for the three months ended June 30, 2019, as compared to \$71.9 million for the three months ended June 30, 2018, primarily due to a decrease in net product sales.

Net product sales decreased by \$15.8 million to \$56.2 million for the three months ended June 30, 2019, as compared to \$72.0 million for the three months ended June 30, 2018, largely due to declines in sales of methylphenidate ER and venlafaxine ER tablets (VERT). Net sales of methylphenidate ER (including M-72 which was launched in the second quarter of 2018) decreased by 56% during the quarter due to additional competitors entering the market resulting in significantly lower net selling prices. VERT net sales decreased 7%, reflecting lower sales volumes following the launch of a competing product in the largest dosage strength during the quarter, partially offset by higher realized net selling prices due to lower than estimated product returns.

Selling, general and administrative expenses increased \$8.8 million during the three months ended June 30, 2019 to \$25.5 million as compared to \$16.7 million in the three months ended June 30, 2018. The increase reflects additions to salesforce headcount and marketing costs associated with the launch of Osmolex ER, together with share compensation expense and higher costs associated with being a public company.

Research and development expenses decreased by \$3.5 million in the three months ended June 30, 2019 to \$5.4 million as compared to \$8.9 million in the three months ended June 30, 2018. The decrease reflects the completion of Phase III clinical trials of both arbaclofen ER and RVL-1201 during the first and second quarters of 2019, respectively, partially offset by share compensation expense.

The Company incurred an impairment of intangible assets charge of \$125.8 million during the three months ended June 30, 2019, primarily related to the write down to fair value of VERT due to price and volume decreases resulting from competing generic products, a slower sales uptake of Osmolex ER and the decision to discontinue selling a formulation of Corvite

Net loss for the second quarter of 2019 was \$124.7 million, compared to net income of \$5.9 million in the second quarter of 2018.

Adjusted EBITDA for the second quarter of 2019 was \$14.5 million, compared to Adjusted EBITDA of \$34.6 million in the second 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 June 30, 2019, Osmotica had cash and cash equivalents of \$63.7 million and \$267.4 million in debt (net of deferred financing costs). The

Company had \$50.0 million of unused borrowing capacity available under its revolving credit facility as of June 30, 2019

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 second quarter 2019 conference call as follows:

Date	Thursday, August 8, 2019
Time	4:30 p.m. EDT
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	2989975

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
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 63,737	\$ 70,834
Trade accounts receivable, net	68,142	56,424
Inventories, net	27,875	24,383
Prepaid expenses and other current assets	14,221	20,744
Total current assets	173,975	172,385
Property, plant and equipment, net	31,084	31,263
Operating lease assets	6,375	-
Intangibles, net	330,888	490,390
Goodwill	100,855	100,855
Other non-current assets	658	752
Total assets	\$ 643,835	\$ 795,645
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	\$ 18,917	\$ 24,870
Accrued liabilities	75,525	87,236
Current portion of long-term debt, net of deferred financing costs	991	1,774
Current portion of lease liability	2,206	-
Current portion of obligation under finance leases	131	119
Income taxes payable - current portion	134	394
Total current liabilities	97,904	114,393
Long-term debt, net of non-current deferred financing costs	267,366	266,803
Long-term portion of obligation under finance leases	101	138
Long-term portion of lease liability	4,383	-
Income taxes payable-long term portion	1,803	1,804
Deferred taxes	14,367	26,238
Total liabilities	385,924	409,376
Commitments and contingencies		
Shareholders' equity		
Ordinary shares	525	525
Additional paid in capital	492,446	489,950
Accumulated deficit	(233,214)	(102,360)
Accumulated other comprehensive loss	(1,846)	(1,846)
Total shareholders' equity	257,911	386,269
Total liabilities and shareholders' equity	\$ 643,835	\$ 795,645

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Net product sales	\$ 56,215	\$ 71,986	\$ 112,615	\$ 130,820
Royalty revenue	780	(211)	1,501	752
Licensing and contract revenue	537	84	543	88
Total revenues	57,532	71,859	114,659	131,660
Cost of goods sold (inclusive of amortization of intangibles)	32,644	33,677	61,847	67,338
Gross profit	24,888	38,182	52,812	64,322
Selling, general and administrative expenses	25,511	16,676	47,168	33,838
Research and development expenses	5,360	8,867	15,125	18,941
Impairment of intangibles	125,766	-	125,766	-
Total operating expenses	156,637	25,543	188,059	52,779
Operating income (loss)	(131,749)	12,639	(135,247)	11,543
Interest expense and amortization of debt discount	4,552	5,241	9,052	10,084
Other non-operating expense (gain)	15	(309)	(542)	(446)
Total other non-operating expense (gain)	4,567	4,932	8,510	9,638
Income (loss) before income taxes	(136,316)	7,707	(143,757)	1,905
Income tax benefit (expense)	11,662	(1,819)	12,902	(624)
Net income (loss)	\$ (124,654)	\$ 5,888	\$ (130,855)	\$ 1,281
Other comprehensive loss, net				
Change in foreign currency translation adjustments	-	(722)	-	(1,090)
Comprehensive income (loss)	\$ (124,654)	\$ 5,166	\$ (130,855)	\$ 191
Income (loss) per share attributable to shareholders				
Basic and Diluted	\$ (2.37)	\$ 0.14	\$ (2.49)	\$ 0.03
Weighted average shares basic and diluted				
Basic and Diluted	52,519	42,856	52,519	42,856

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

	Six Months Ended June 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	\$ (130,854)	\$ 1,281
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	35,992	40,867
Share compensation	2,496	-
Loss on sale of fixed assets	53	-
Impairment of intangibles	125,766	-
Deferred income tax benefit	(11,870)	(4,310)
Bad debt provision	(157)	(240)
Amortization of deferred financing and loan origination fees	657	839
Change in operating assets and liabilities:		
Trade accounts receivable, net	(11,561)	(23,112)
Inventories, net	(3,492)	(9,079)
Prepaid expenses and other current assets	6,524	5,800
Trade accounts payable	(5,953)	(5,420)
Accrued and other current liabilities	(11,760)	(6,680)
Net cash used in operating activities	(4,159)	(54)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(2,091)	(2,181)
Net cash used in investing activities	(2,091)	(2,181)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments to affiliates	-	(2)
Payments on finance lease obligations	(64)	(54)
Proceeds from insurance financing loan	1,314	975
Repayment of insurance financing loan	(2,097)	(195)

Repayment of debt	-	(4,094)
Net cash used in financing activities	(847)	(3,370
Net change in cash and cash equivalents	(7,097)	(5,605
Effect on cash of changes in exchange rate	-	(730)
Cash and cash equivalents, beginning of period	70,834		34,743
Cash and cash equivalents, end of period	\$ 63,737		\$ 28,408

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

	Three Months Ended		Six Months Ended	
	June 30, 2019	2018	June 30, 2019	2018
Net income (loss)	\$ (124,654) \$ 5,888	\$ (130,855) \$ 1,281
Interest expense and amortization of debt discount	4,552	5,241	9,052	10,084
Income tax (benefit) expense	(11,662) 1,819	(12,902) 624
Depreciation and amortization expense	17,999	20,452	35,992	40,867
EBITDA	(113,765) 33,400	(98,713) 52,856
Impairment of intangibles	125,766	-	125,766	-
Management fees	-	270	(43) 520
IPO expenses	-	548	-	944
Severance expenses	181	40	362	484
FX translation	(11) -	211	-
Legal settlements	1,002	332	1,002	332
Share compensation expense	1,327	-	2,496	-
Adjusted EBITDA	\$ 14,500	\$ 34,590	\$ 31,081	\$ 55,136



Source: Osmotica Holdings US LLC