



Osmotica Pharmaceuticals plc Reports First Quarter 2020 Results and Provides Business Updates

May 12, 2020

First quarter 2020 total revenue of \$48.6 million

On track to achieve major 2020 milestones

BRIDGEWATER, N.J., May 12, 2020 (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 three months ended March 31, 2020.

"Despite the ongoing COVID-19 pandemic, we have not experienced any impact to our manufacturing and supply chain operations to date, and 2020 is shaping up to be an exciting year for us. Our July 16 user fee goal date remains on track for our innovative product, RVL-1201 ("RVL"), for the treatment of acquired blepharoptosis, or droopy eyelid. As there are currently no non-surgical options or pharmacological treatments for this condition, RVL has garnered a great deal of interest and enthusiasm among eye care professionals and KOLs, who are encouraged both by the results of our clinical development program and by the convenience of this novel treatment option. As we focus on preparing for commercial launch, we are also progressing our RVL strategic partnership discussions," said Brian Markison, Chief Executive Officer.

"We also remain on track to submit an amended New Drug Application ("NDA") for arbaclofen ER for spasticity associated with Multiple Sclerosis in the second quarter of this year. Having completed the long-term safety study, we are now preparing the amended NDA for submission. With these important catalysts in play, we look forward to a productive year as we execute on our strategic objectives," continued Markison.

First Quarter 2020 Financial Highlights

- Total revenues were \$48.6 million, compared to \$57.1 million in the first quarter of 2019;
- Net loss was \$3.1 million, compared to a net loss of \$6.7 million in the first quarter of 2019;
- Adjusted EBITDA¹ was \$11.1 million, compared to Adjusted EBITDA of \$16.6 million in the first quarter of 2019; and
- Cash and cash equivalents were \$125.8 million, and debt (net of deferred financing costs) was \$268.2 million as of March 31, 2020.

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."

First Quarter 2020 Financial Results

Total revenues for the three months ended March 31, 2020 were \$48.6 million, compared to \$57.1 million for the three months ended March 31, 2019. Net product sales decreased by \$9.1 million to \$47.3 million for the three months ended March 31, 2020, as compared to \$56.4 million for the three months ended March 31, 2019. Net sales of methylphenidate ER (including M-72) decreased 60% during the quarter due to existing competitors in the market resulting in significantly lower net selling prices and volumes. Net sales of venlafaxine ER tablets ("VERT") decreased 35% reflecting lower volumes and realized net pricing due to the launch of two additional generic forms of VERT, which had been approved in 2019, but not launched. 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 2020 and in future years. VERT sales were favorably impacted by \$6.5 million in the aggregate primarily related to product returns and other adjustments during the three months ended March 31, 2020 based on actual experience. There can be no assurance that actual product returns experience and other adjustments will continue to favorably impact net sales in 2020 and in future periods.

Selling, general and administrative expenses decreased \$0.5 million during the three months ended March 31, 2020 to \$21.2 million as compared to \$21.7 million in the three months ended March 31, 2019. The decrease in selling, general and administrative expenses reflects expense reductions associated with a salesforce realignment in the third quarter of 2019, which was partially offset by increases in marketing costs associated with the expected launch of RVL, and severance costs associated with the salesforce reduction during the first quarter of 2020.

Research and development expenses decreased by \$4.1 million in the three months ended March 31, 2020 to \$5.7 million as compared to \$9.8 million in the three months ended March 31, 2019. The decrease reflects the completion of the second Phase III clinical trial of arbaclofen ER during the first quarter of 2019, lower clinical trial costs related to RVL and the cost of manufacturing development batches of Osmolex in the three month period ended March 31, 2019, which costs were not present in 2020.

Net loss for the first quarter of 2020 was \$3.1 million, compared to a net loss of \$6.7 million in the first quarter of 2019.

Adjusted EBITDA for the first quarter of 2020 was \$11.1 million, compared to Adjusted EBITDA of \$16.6 million for the first quarter of 2019.

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 March 31, 2020, the Company had cash and cash equivalents of \$125.8 million and borrowing capacity under our revolving credit facility of \$50.0 million. During the quarter the Company raised approximately \$31.8 million in a public offering of its ordinary shares. As of March 31, 2020, the Company also had \$271.4 million aggregate principal amount borrowed under our term loans.

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 measure. 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, as applicable: impairment of intangible assets and fixed assets, impairment of goodwill, share compensation expense, loss on debt extinguishment, management fees, public offering expenses, foreign currency translation, severance expenses and legal and contractual settlements and litigation reserves. 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, 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 business may be adversely affected by the ongoing coronavirus outbreak; 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, 2019 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 first quarter 2020 conference call as follows:

Date	Tuesday, May 12, 2020
Time	4:30 p.m. ET
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	5646947

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. Vertical Pharmaceuticals, LLC represents the Company's diversified branded portfolio and Trigen Laboratories, LLC represents the non-promoted products including complex generic formulations.

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)

	March 31, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 125,830	\$ 95,865
Trade accounts receivable, net	32,644	43,914
Inventories, net	20,536	21,305
Prepaid expenses and other current assets	10,654	11,546
Total current assets	189,664	172,630
Property, plant and equipment, net	29,987	30,238
Operating lease assets	4,471	4,983
Intangibles, net	149,624	153,986
Goodwill	100,855	100,855
Other non-current assets	533	563
Total assets	\$ 475,134	\$ 463,255
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	\$ 8,784	\$ 8,495
Accrued liabilities	47,256	65,253
Current portion of lease liability	110	127
Current portion of obligation under finance leases	2,004	2,062
Total current liabilities	58,154	75,937
Long-term debt, net of non-current deferred financing costs	268,236	267,950
Long-term portion of obligation under finance leases	29	44
Long-term portion of lease liability	2,646	3,116
Deferred taxes	2,329	1,500
Total liabilities	331,394	348,547
Commitments and contingencies		
Shareholders' equity		
Ordinary shares	589	518
Additional paid in capital	521,484	489,440
Accumulated deficit	(376,104)	(373,021)
Accumulated other comprehensive loss	(2,229)	(2,229)
Total shareholders' equity	143,740	114,708
Total liabilities and shareholders' equity	\$ 475,134	\$ 463,255

Osmotica Pharmaceuticals plc
Condensed Consolidated Statements of Operations
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2020	2019
Net product sales	\$ 47,308	\$ 56,400
Royalty revenue	869	721
Licensing and contract revenue	472	5
Total revenues	48,649	57,126
Cost of goods sold (inclusive of amortization of intangibles)	20,590	29,203
Gross profit	28,059	27,923

Selling, general and administrative expenses	21,176	21,656	
Research and development expenses	5,688	9,764	
Total operating expenses	26,864	31,420	
Operating income (loss)	1,195	(3,497))
Interest expense and amortization of debt discount	4,064	4,501	
Other non-operating gain	(746)	(557))
Total other non-operating expense	3,318	3,944	
Loss before income taxes	(2,123)	(7,441))
Income tax benefit (expense)	(960)	754)
Net and comprehensive loss	\$ (3,083)) \$ (6,687))
Loss per share attributable to shareholders			
Basic and Diluted	\$ (0.05)) \$ (0.13))
Weighted average shares basic and diluted			
Basic and Diluted	58,257,191	52,518,924	

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

	Three Months Ended March 31,		
	2020	2019	
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (3,083)) \$ (6,687))
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,562	17,993	
Share compensation	1,107	1,169	
Loss on sale of fixed and leased assets	(3)) 53	
Deferred income tax benefit	829	(1,060))
Bad debt provision	29	(84))
Amortization of deferred financing and loan origination fees	333	323	
Change in operating assets and liabilities:			
Trade accounts receivable, net	11,242	(378))
Inventories, net	769	(3,432))
Prepaid expenses and other current assets	891	4,691	
Other non-current assets	(18)) -	
Trade accounts payable	289	(4,279))
Accrued and other current liabilities	(18,011)) (14,436))
Net cash used in operating activities	(64)) (6,127))
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from sale of fixed and leased assets	4	-	
Payments on disposal of leased assets	(1)) -	
Purchase of property, plant and equipment	(949)) (635))
Net cash used in investing activities	(946)) (635))
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payments on finance lease obligations	(33)) (31))
Proceeds from public offering, net of issuance costs	31,791	-	
Repurchases of ordinary shares	(167)) -	
Payments for taxes related to net share settlement of equity awards	(616)) -	
Proceeds from insurance financing loan	-	(979))
Net cash provided by (used in) financing activities	30,975	(1,010))
Net change in cash and cash equivalents	29,965	(7,772))
Cash and cash equivalents, beginning of period	95,865	70,834	
Cash and cash equivalents, end of period	\$ 125,830	\$ 63,062	

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

	Three Months Ended	
	March 31,	2019
	2020	
Net loss	\$ (3,083) \$ (6,687
Interest expense and amortization of debt discount	4,064	4,501
Income tax benefit	960	(754
Depreciation and amortization expense	5,562	17,993
EBITDA	7,503	15,053
Management fees	-	(43
Severance expenses	1,965	182
FX translation	59	222
Public offering expenses	528	-
Share compensation expense	1,016	1,169
Adjusted EBITDA	\$ 11,071	\$ 16,583



Source: Osmotica Holdings US LLC