Osmotica Pharmaceuticals plc Reports Fourth Quarter and Full Year 2019 Results and Provides Business Updates

March 18, 2020

Fourth quarter and full year 2019 total revenue of $59.9 million and $240.0 million, respectively

New Drug Application accepted by FDA for RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for acquired blepharoptosis, or droopy eyelid; user fee goal date of July 16, 2020

Completed a public offering of 6.9 million common shares at a price of $5 per share

BRIDGEWATER, N.J., March 18, 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 and full year ended December 31, 2019.

"With the completion of our two Phase III trial programs, we continue transitioning our business to a branded specialty pharmaceutical company. Last November, the U.S. Food and Drug Administration (FDA) accepted our new drug application (NDA) for RVL-1201 (RVL), our innovative, once-daily ophthalmic product designed to treat acquired blepharoptosis, or droopy eyelid. We believe RVL represents a significant opportunity to address a sizable unmet need. In the months leading up to our July 16 user fee goal date, we are focused on launch preparation and raising awareness among eye care professionals for a potential first pharmacologic treatment for patients with ptosis," said Brian Markison, Chief Executive Officer.

"Looking ahead, we have a number of exciting milestones in 2020: During the second quarter, we intend to file an amended NDA for arbaclofen ER, a potential treatment for spasticity in patients with Multiple Sclerosis. This summer, we look forward to FDA approval of RVL. Additionally, we expect to provide an update on our RVL partner discussions during the second quarter. If approved, both RVL and arbaclofen ER tablets represent potential significant near-term growth assets, and we look forward to advancing these innovative therapeutics," continued Markison.

Fourth Quarter and Full Year 2019 Financial Highlights

- Total revenues:
  - Fourth quarter 2019 total revenues were $59.9 million, compared to $65.7 million in the fourth quarter of 2018;
  - Full year 2019 total revenues were $240.0 million, compared to $263.7 million in 2018;
- Net loss:
  - Fourth quarter 2019 net loss was $26.6 million, compared to a net loss of $107.0 million in the fourth quarter of 2018. The net losses for the fourth quarters of 2019 and 2018 included $29.9 million and $98 million, respectively, of intangible asset impairment charges;
  - Full year 2019 net loss was $270.9 million, compared to net loss of $109.7 million in 2018. The net losses during 2019 and 2018 included intangible assets impairment charges of $283.7 million and $104.2 million, respectively;
- Adjusted EBITDA[1]
  - Fourth quarter 2019 Adjusted EBITDA was $14.9 million, compared to Adjusted EBITDA of $14.2 million in the fourth quarter of 2018;
  - Full year 2019 Adjusted EBITDA was $68.8 million, compared to Adjusted EBITDA of $95.1 million in 2018; and,
- Cash and cash equivalents were $95.9 million, and debt (net of deferred financing costs) was $268.0 million as of December 31, 2019.

[1]Adjusted 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."

Fourth Quarter 2019 Financial Results

Total revenues for the three months ended December 31, 2019 were $59.9 million, compared to $65.7 million for the three months ended December 31, 2018. The decrease in total revenue in 2019 reflects lower net pricing on sales of methylphenidate hydrochloride ("HCl") extended-release ("ER") tablets, venlafaxine ER tablets ("VERT") and Lorzone (chlorzoxazone scored tablets), partially offset by higher revenues from other non-promoted products. Net sales of methylphenidate ER (including M-72) and VERT decreased 40% and 16%, respectively during the quarter due to additional competitors entering the market resulting in lower net selling prices and volumes partially offset by lower than estimated product returns. Methylphenidate ER and VERT net sales were favorably impacted by approximately $6.8 million in the aggregate, primarily related to adjustments of product returns reserves during the quarter based on actual product return experience.

Selling, general and administrative expenses decreased to $21.1 million in the fourth quarter of 2019, compared to $23.0 million in the fourth quarter of 2018. The decrease was primarily due to the realignment of our field force in the third quarter of 2019, offset by higher general and administrative expenses associated with being a public company.

Research and development expenses decreased to $7.1 million in the fourth quarter of 2019, compared to $14.6 million in the fourth quarter of 2018 primarily due to the completion of the Phase III clinical trials of RVL-1201 and arbaclofen ER.

During the fourth quarter of 2019, we recognized intangible asset impairment charges of $29.9 million, reflecting write downs of developed technology

assets and distribution rights, as compared to $98.0 million for the fourth quarter of 2018, reflecting write downs of goodwill and in-process research and development assets.

Other non-operating expenses decreased to $4.5 million in the fourth quarter of 2019, compared to $5.6 million in the fourth quarter of 2018. The decrease resulted from lower interest expense due to the prepayment of $50 million of debt during the fourth quarter of 2018.

Net loss for the fourth quarter of 2019 was $26.6 million, compared to a net loss of $107.0 million in the fourth quarter of 2018 primarily due to lower impairment charges during the quarter.

Adjusted EBITDA for the fourth quarter of 2019 was $14.9 million, compared to Adjusted EBITDA of $14.2 million for the fourth 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.

Full Year 2019 Financial Results

Total revenues decreased by $23.7 million to $240.0 million in 2019, compared to $263.7 million in 2018.

Net product sales decreased by $25.9 million to $235.5 million for the year ended December 31, 2019, as compared to $261.4 million for the year ended December 31, 2018. Net product sales of methylphenidate ER (including M-72, which was launched in the second quarter of 2018) decreased 43% due to additional competitors entering the market, resulting in significantly lower net selling prices, partially offset by lower than estimated product returns. Product sales from VERT increased by 14% for the year ended December 31, 2019. During 2019 a competing dosage strength was launched which negatively affected sales volumes, however volume decreases were more than offset by lower than estimated product returns and government rebates resulting in higher realized net selling prices in the period. Additionally, during the third and fourth quarter of 2019, two additional generic forms of VERT from competitors were approved but not launched. We expect that the additional competition for both methylphenidate ER and VERT from these 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 in 2020 and future years. Methylphenidate ER and VERT net sales were favorably impacted by adjustments of approximately $25.3 million in the aggregate primarily related to product returns reserves during the year ended December 31, 2019 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 2020 and in future years.

Selling, general and administrative expenses increased by $18.8 million in 2019 to $93.0 million as compared to $74.2 million in 2018. The increase reflects additions to salesforce headcount and marketing costs associated with the launch of Osmolex ER in the first quarter of 2019, severance expenses associated with a 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 $11.4 million in 2019 to $32.3 million as compared to $43.7 million in 2018. The decrease primarily reflects the completion of the Phase III clinical trials of arbaclofen ER during the first quarter of 2019, partially offset by increased share compensation expense during 2019 and the cost of manufacturing development batches of Osmolex ER during 2018, which were costs not present in 2019.

The Company incurred an impairment of intangible assets charge of $283.7 million during the twelve months ended December 31, 2019, primarily related to the write down to fair value of methylphenidate ER, venlafaxine ER tablets due to price and volume decreases resulting from competing generic products.

Net loss in 2019 was $270.9 million, compared to net loss of $109.7 million in 2018.

Adjusted EBITDA in 2019 was $68.8 million, compared to Adjusted EBITDA of $95.1 million in 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 December 31, 2019, we had cash and cash equivalents of $95.9 million and borrowing availability under our revolving credit facility of $50.0 million. The Company also had debt of $268.0 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 and fixed assets, impairment of goodwill, share compensation expense, loss on debt extinguishment, management fees, IPO 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, 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 fourth quarter 2019 conference call as follows:

Date	Wednesday, March 18, 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	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. 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.

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-Financial tables follow-

Osmotica Pharmaceuticals plc
Consolidated Balance Sheets
(in thousands)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 95,865	$ 70,834
Trade accounts receivable, net	43,914	56,424
Inventories, net	21,305	24,383
Prepaid expenses and other current assets	11,546	20,723
Total current assets	172,630	172,364

Property, plant and equipment, net	30,238	31,263
Operating lease assets	4,983	-
Intangibles, net	153,986	490,390
Goodwill	100,855	100,855
Other non-current assets	563	752
Total assets	$ 463,255	$ 795,624
Liabilities and Shareholders' Equity/Partners' Capital		
Current liabilities:		
Trade accounts payable	$ 8,495	$ 24,871
Accrued liabilities	65,253	87,237
Current portion of long-term debt, net of deferred financing costs	-	1,774
Current portion of obligation under finance leases	127	119
Current portion of lease liability	2,062	-
Total current liabilities	75,937	114,001
Long-term debt, net of non-current deferred financing costs	267,950	266,803
Long-term portion of obligation under finance leases	44	138
Long-term portion of lease liability	3,116	-
Income taxes payable - long term portion	-	2,541
Deferred taxes	1,500	28,294
Total liabilities	348,547	411,777
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares	518	525
Additional paid in capital	489,440	487,288
Accumulated deficit	(373,021)	(102,120)
Accumulated other comprehensive loss	(2,229)	(1,846)
Total shareholders' equity	114,708	383,847
Total liabilities and shareholders' equity	$ 463,255	$ 795,624

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

	Year Ended December 31,		Three Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Net product sales	$ 235,472	$ 261,398	$ 58,815	$ 65,134
Royalty revenue	3,641	1,959	815	303
Licensing and contract revenue	918	344	281	259
Total revenues	240,031	263,701	59,911	65,696
Cost of good sold (inclusive of amortization of intangibles)	111,630	140,082	24,241	37,587
Gross profit	128,401	123,619	35,670	28,109
Selling, general and administrative expenses	93,030	74,243	21,111	22,954
Research and development expenses	32,319	43,693	7,138	14,588
Impairment of intangibles and fixed assets	283,747	17,903	29,868	11,730
Impairment of goodwill	-	86,318	-	86,318
Total operating expenses	409,096	222,157	58,117	135,590
Operating loss	(280,695)	(98,538)	(22,447)	(107,481)
Interest expense and amortization of debt discount	18,211	20,790	4,655	5,394
Other non-operating (income) loss, net	(884)	(664)	(165)	217
Total other non-operating expense, net	17,327	20,126	4,490	5,611
Loss before income taxes	(298,022)	(118,664)	(26,937)	(113,092)
Income tax benefit	27,121	8,983	297	6,085
Net loss	$ (270,901)	$ (109,681)	$ (26,640)	$ (107,007)
Loss per share attributable to shareholders				
Basic	$ (5.17)	$ (2.42)	$ (0.51)	$ (2.36)
Diluted	$ (5.17)	$ (2.42)	$ (0.51)	$ (2.36)
Weighted average share basic and diluted				

Basic and diluted	52,367,444	45,276,268	51,960,082	45,276,268

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

	Year Ended December 31, 2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (270,901)	$ (109,681)
Adjustments to reconcile net loss to cash provided by operating activities		
Depreciation and amortization	57,015	81,573
Share compensation	4,932	1,965
Impairment of goodwill	-	86,318
Impairment of intangibles	283,747	17,903
Deferred income tax benefit	(26,794)	(15,513)
Loss on sale of fixed and leased assets	173	93
Bad debt provision	(164)	(1,771)
Non-cash interest expenses and amortization of deferred financing and loan origination fees	1,337	1,652
Write off of deferred financing fees in connection with loan prepayment	-	876
Change in operating assets and liabilities		
Trade accounts receivable, net	12,674	(17,041)
Inventories, net	3,078	(7,436)
Prepaid expenses and other current assets	9,177	4,549
Trade accounts payable	(16,375)	(11,326)
Accrued and other current liabilities	(24,332)	5,397
Net cash provided by operating activities	33,567	37,558
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed and leased assets	17	10
Payment on disposal of leased assets	(74)	-
Purchase of property, plant and equipment	(3,963)	(4,144)
Net cash used in investing activities	(4,020)	(4,134)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments to affiliates	-	(2)
Payments on finance lease obligations	(130)	(112)
Proceeds from insurance financing loan	1,314	2,745
Repayment of insurance financing loan	(3,088)	(971)
Proceeds from initial public offering and private placement, net of issuance costs	-	58,084
Debt repayment	-	(56,140)
Repurchase of ordinary shares	(2,787)	-
Net cash provided by (used in) financing activities	(4,691)	3,604
Net change in cash and cash equivalents	24,856	37,028
Effect on cash of change in exchange rate	175	(938)
Cash and cash equivalents, beginning of period	70,834	34,744
Cash and cash equivalents, end of period	$ 95,865	$ 70,834

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

	Year Ended December 31, 2019	2018	Three Months Ended December 31, 2019	2018
Net Loss	$ (270,901)	$ (109,681)	$ (26,640)	$ (107,007)
Interest expense and amortization of debt discount	18,211	20,790	4,655	5,394
Income tax benefit	(27,121)	(8,983)	(297)	(6,085)
Depreciation and Amortization Expense	57,015	81,573	6,410	20,249

EBITDA	(222,796)	(16,301)	(15,872)	(87,449)
Impairment of intangible and fixed assets	283,747	17,903	29,868	11,730
Impairment of goodwill	-	86,318	-	86,318
Share compensation expense	4,932	1,965	1,101	1,965
Loss on debt extinguishment	-	876	-	876
Management Fees	(42)	921	-	151
IPO expenses	-	2,442	-	460
FX Translation	655	-	80	-
Severance expenses	1,802	679	164	195
Legal and contractual settlements and litigation reserves	526	332	(477)	-
Adjusted EBITDA	$ 68,824	$ 95,135	$ 14,864	$ 14,246

Source: Osmotica Holdings US LLC