



Osmotica Pharmaceuticals plc Reports Fourth Quarter and Full Year 2018 Financial Results and Highlights Pipeline and Business Progress

March 27, 2019

Reported fourth quarter and full year 2018 total revenue of \$65.7 million and \$263.7 million, respectively

Completed and reported preliminary topline results from second Phase III study of arbaclofen extended-release (ER) tablets for the treatment of spasticity associated with Multiple Sclerosis

Completed enrollment in second Phase III study of RVL-1201 in February 2019; on track for topline results by mid-year

Completed full commercial launch in January 2019 of Osmolex ER™ (amantadine extended-release tablets) for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions in adults

BRIDGEWATER, N.J., March 27, 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 three months and full year ended December 31, 2018.

"This past year was marked by significant progress for Osmotica, including a strong year financially, the completion of our initial public offering (IPO) in the fourth quarter, and our continued transformation towards a Specialty Branded business. During 2018, we launched Methylphenidate 72mg, which continues to gain traction with solid growth in monthly prescriptions, and obtained approval and launched Osmolex ER, which is displaying encouraging early trends. We also continue to maintain strong and growing sales for Divigel® in a highly competitive category. Additionally, we continue to advance our late-stage branded pipeline assets, RVL-1201 and arbaclofen ER," said Brian Markison, Chairman and Chief Executive Officer at Osmotica.

"We completed our second Phase III clinical trial of arbaclofen ER for the treatment of spasticity in Multiple Sclerosis (MS) patients and are reporting preliminary topline results. Arbaclofen did not demonstrate superiority to placebo as measured by the CGIC (Clinical Global Impression of Change); however, a statistically significant improvement in spasticity relative to placebo was demonstrated for the TNmAS (the Total Numeric modified Ashworth Scale) for both 40mg and 80mg doses of arbaclofen. While the results of the study are mixed, we believe that the efficacy signal for the treatment of spasticity identified by the TNmAS endpoint is a positive result and the profile of arbaclofen could offer a meaningful benefit to patients who suffer from spasticity. Based on what we have seen thus far, we intend to continue toward submission of an NDA, although our timeline may now extend past 2019," added Markison.

"We continue to advance RVL-1201, our novel Phase III ophthalmic program for the treatment of blepharoptosis, and remain on track to report topline results from that study by mid-year. Finally, we believe that the transformation and growth of our branded business combined with our strong balance sheet will enable us to continue advancing all of our innovative product candidates and support other strategic business development initiatives," concluded Markison.

Preliminary Topline Results from Study OS440-3004 (arbaclofen extended-release tablets)

Study OS440-3004 was a multicenter, randomized, double-blind placebo-controlled study in which multiple sclerosis patients with documented muscular spasticity in any limb received placebo, 40 mg arbaclofen per day, or 80 mg arbaclofen per day.

The co-primary efficacy measures assessed in this study were CGIC (Clinical Global Impression of Change) and the change from baseline in TNmAS (the Total Numeric modified Ashworth Scale). The CGIC is a generalized global assessment of patient well-being, and TNmAS is a more objective measure of muscular spasticity. The change from baseline through day 84 of treatment was assessed for both endpoints.

Arbaclofen did not demonstrate superiority to placebo as measured by the CGIC; however, a statistically significant improvement in spasticity relative to placebo was demonstrated as measured by the TNmAS ($p=0.0482$ and 0.0118) for 40 mg and 80 mg per day, respectively. Upon preliminary review, it appears that CGIC failed to recognize the improvement demonstrated by the TNmAS. However, the CGIC values indicated both treatment groups improved from baseline.

Further, the preliminary results appear to identify a dose-response relationship between the two strengths with the 80 mg dose exhibiting a stronger signal of efficacy as assessed by the spasticity scale. Though arbaclofen 80 mg per day had a higher discontinuation rate in the study, the safety and tolerability profile was in line with previously reported results, most notably a somnolence incidence of 9.5% and 14.5% for the 40-mg and 80-mg treatment arms, respectively, compared to 9.6% for the placebo treatment arm. Somnolence is one of the most frequently reported dose-limiting adverse events associated with baclofen treatment today. Further evaluation and additional analyses are ongoing, and we anticipate providing a further update once complete.

"This study was the largest MS spasticity clinical trial ever conducted, and we are grateful and committed to the patients and investigators who contributed. We continue to believe that arbaclofen is a promising option for the treatment of spasticity in MS patients. While the topline results are disappointing, spasticity in MS remains an important unmet medical need, and, subject to completion of the data analysis and regulatory considerations we intend to continue to pursue submission of an arbaclofen NDA for review to the FDA although our timeline could now extend past 2019," stated Mr. Markison.

Fourth Quarter and Full Year 2018 Financial Results

- Total revenues:
 - Fourth quarter 2018 total revenues were \$65.7 million, compared to \$76.3 million in the fourth quarter of 2017;

- Full year 2018 total revenues were \$263.7 million, compared to \$245.7 million in 2017;
- Net loss:
 - Fourth quarter 2018 net loss was \$107.2 million, compared to a net income of \$1.8 million in the fourth quarter of 2017. The 2018 net loss included \$98.0 million of intangible asset impairment charges recognized during the fourth quarter;
 - Full year 2018 net loss was \$109.4 million, compared to net loss of \$41.1 million in 2017. The net losses during 2018 and 2017 included intangible assets impairment charges of \$104.2 million and \$73.0 million, respectively;
- Adjusted EBITDA¹
 - Fourth quarter 2018 Adjusted EBITDA was \$14.3 million, compared to Adjusted EBITDA¹ of \$26.5 million in the fourth quarter of 2017;
 - Full year 2018 Adjusted EBITDA was \$95.1 million, compared to Adjusted EBITDA¹ of \$99.1 million in 2017; and,
- Cash and cash equivalents were \$70.8 million, and debt (net of deferred financing costs) was \$268.6 million as of December 31, 2018.

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."

Fourth Quarter 2018 Financial Results

Total revenues for the three months ended December 31, 2018 were \$65.7 million, compared to \$76.3 million for the three months ended December 31, 2017. The decrease in total revenue in 2018 reflects lower net pricing on sales of methylphenidate hydrochloride ("HCl") extended-release ("ER") tablets partially offset by higher sales of venlafaxine ER tablets ("VERT") and Divigel. The decrease also reflects the resolution of disputed gross sales deductions taken by a wholesale customer which favorably impacted sales during the fourth quarter of 2017.

Selling, general and administrative expenses increased to \$22.9 million in the fourth quarter of 2018, compared to \$15.7 million in the fourth quarter of 2017. The increase was primarily due to an expansion of our field force during 2018, expenses associated with the launch of Osmolex ER, and costs associated with the Company's IPO.

Research and development expenses decreased to \$16.3 million in the fourth quarter of 2018, compared to \$24.5 million in the fourth quarter of 2017. In late 2017, the asset acquisition of RevitaLid, Inc. (owner of the rights to RVL-1201) for \$16.4 million was accounted for as a research and development expense. Excluding the acquisition of RevitaLid, research and development expenses increased \$8.2 million during the fourth quarter of 2018 compared to the fourth quarter of 2017, reflecting higher clinical trial costs for arbaclofen ER and RVL-1201, together with additional headcount.

During the fourth quarter of 2018 we recognized intangible asset impairment charges of \$98.0 million reflecting write downs of goodwill, in-process research and development assets and other developed technology assets compared to no charges in the fourth quarter of 2017.

Other non-operating expenses decreased to \$5.6 million in the fourth quarter of 2018, compared to \$14.3 million in the fourth quarter of 2017. The decrease resulted from lower interest expense due to a refinancing transaction that was completed in December 2017 and the prepayment of \$50 million of debt during the fourth quarter of 2018.

Net loss for the fourth quarter of 2018 was \$107.2 million, compared to net income of \$1.8 million in the fourth quarter of 2017.

Adjusted EBITDA for the fourth quarter of 2018 was \$14.3 million, compared to Adjusted EBITDA of \$26.5 million for the fourth quarter of 2017.

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

Full Year 2018 Financial Results

Total revenues increased to \$263.7 million in 2018, compared to \$245.7 million for 2017.

Net product sales increased to \$261.4 million in 2018, compared to \$237.7 million in 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 in 2018.

Selling, general and administrative expenses increased to \$74.2 million in 2018, compared to \$57.0 million in 2017. The increase reflects increased sales force and marketing expenses related to the launches of M-72 and Osmolex ER, and costs incurred for the Company's IPO.

Research and development expenses increased to \$48.8 million in 2018, compared to \$42.7 million in 2017. Excluding the acquisition of RevitaLid, Inc., research and development expenses increased \$22.5 million in 2018 largely due to the clinical trial costs of arbaclofen and RVL-1201.

For 2018 and 2017 intangible asset impairment charges were \$104.2 million and \$73.0 million, respectively, reflecting write downs of goodwill, in-process research and development assets and other developed technology assets.

Other non-operating expenses decreased to \$20.1 million in 2018 compared to \$33.6 million in 2017 due to the prepayment of debt in the fourth quarter of 2018, and lower borrowing costs associated with debt refinancing which was completed at the end of 2017.

Net loss in 2018 was \$109.4 million, compared to net loss of \$41.1 million in 2017.

Adjusted EBITDA in 2018 was \$95.1 million, compared to Adjusted EBITDA of \$99.1 million in 2017.

For a reconciliation of Adjusted EBITDA to net loss, the most directly comparable GAAP financial measure, please see the table "Osmotica

Pharmaceuticals plc GAAP to Non-GAAP Reconciliations” at the end of this press release.

Liquidity

As of December 31, 2018, Osmotica had cash and cash equivalents of \$70.8 million and \$268.6 million in debt (net of deferred financing costs). The Company had \$50 million of unused borrowing capacity available under its revolving credit facility as of December 31, 2018.

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 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, share based compensation expense, write-off of acquired IPR&D, loss on debt extinguishment, management fees, IPO expenses, consulting fees, severance expenses, acquired inventory step-up in costs of goods sold, legal and contractual settlements and litigation reserves, API inventory disposal and write-off of previously acquired balances. We use Adjusted EBITDA for business planning purposes, in assessing our performance and determining the incentive 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 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 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 fourth quarter 2018 conference call as follows:

Date	Wednesday, March 27, 2019
Time	5:00 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

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 2286829. 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 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

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-Financial tables follow-

Osmotica Pharmaceuticals plc

Consolidated Balance Sheets

(in thousands)

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 70,834	\$ 34,743
Trade accounts receivable, net	56,424	37,638
Inventories, net	24,383	16,947
Prepaid expenses and other current assets	20,744	25,498
Total current assets	172,385	114,826
Property, plant and equipment, net	31,263	31,410
Intangibles, net	490,390	585,389
Goodwill	100,855	187,173
Other non-current assets	752	942
Total assets	\$ 795,645	\$ 919,740
Liabilities and Shareholders' Equity/Partners' Capital		
Current liabilities:		
Trade accounts payable	\$ 24,870	\$ 36,070
Accrued liabilities	87,237	81,926
Current portion of long-term debt, net of deferred financing costs	1,774	6,656
Current portion of obligation under capital leases	119	24
Income taxes payable - current portion	394	-
Total current liabilities	114,394	124,676
Long-term debt, net of non-current deferred financing costs	266,803	313,950
Long-term portion of obligation under capital leases	138	57
Income taxes payable	1,804	1,335
Deferred taxes	26,237	42,891
Other long-term liabilities	-	1,047
Total liabilities	409,376	483,956
Commitments and contingencies		
Shareholders' equity/partners' capital:		
Ordinary shares	525	
Additional paid in capital	489,950	
Accumulated deficit	(102,360)	
Partners' capital		436,417
Accumulated other comprehensive loss	(1,846)	(633)
Total shareholders' equity/partners' capital	386,269	435,784
Total liabilities and shareholders' equity/partners' capital	\$ 795,645	\$ 919,740

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,	
	2018	2017
Net product sales	\$ 261,398	\$ 237,671
Royalty revenue	1,959	6,449
Licensing and contract revenue	344	1,629
Total revenues	263,701	245,749
Cost of good sold (inclusive of amortization of intangibles)	135,014	125,188
Gross profit	128,687	120,561
Selling, general and administrative expenses	74,244	56,955
Research and development expenses	48,761	42,688
Impairment of intangibles and fixed assets	17,903	72,986
Impairment of goodwill	86,318	-
Total operating expenses	227,226	172,629
Operating loss	(98,539)	(52,068)
Interest expense and amortization of debt discount	20,790	29,052
Other non-operating (income) loss, net	(664)	4,522
Total other non-operating expense, net	20,126	33,574
Loss before income taxes	(118,665)	(85,642)
Income tax benefit	9,268	44,500
Net Loss	\$ (109,397)	\$ (41,142)
Income (loss) per share attributable to shareholders		
Basic	\$ (2.42)	\$ (0.96)
Diluted	\$ (2.42)	\$ (0.96)
Weighted average shares basic and diluted		
Basic and diluted	45,276,278	42,855,722

Osmotica Pharmaceuticals plc**Condensed Consolidated Statements of Operations****(Unaudited)**

(in thousands)

	Three Months Ended December 31,	
	2018	2017
Total revenues	65,697	76,332
Cost of good sold (inclusive of amortization of intangibles)	35,864	47,825
Gross profit	29,833	28,507
Selling, general and administrative expenses	22,953	15,654
Research and development expenses	16,311	24,501
Impairment of intangibles and fixed assets	11,730	539
Impairment of goodwill	86,318	-
Total operating expenses	137,312	40,694
Operating loss	(107,479)	(12,187)
Total other non-operating expense, net	5,611	14,338
Loss before income taxes	(113,090)	(26,525)
Net income (loss)	\$ (107,244)	\$ 1,835

Osmotica Pharmaceuticals plc**Consolidated Statements of Cash Flows**

(in thousands)

	Year Ended December 31,	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (109,397)	\$ (41,142)
Adjustments to reconcile net loss to cash provided by operating activities	-	-
Depreciation and amortization	81,573	46,450
Share compensation	1,965	-
Impairment of goodwill	86,318	-
Impairment of intangibles and fixed assets	17,903	72,986
Deferred income tax benefit	(16,654)	(48,506)
Loss on sale of fixed assets	94	-
Bad debt provision	(1,772)	832
Non-cash interest expenses and amortization of deferred financing and loan origination fees	1,652	7,506
Write off of deferred financing fees in connection with loan prepayment	876	4,982
Expensed IPR&D	-	16,373
Change in fair value of contingent consideration	-	182
Payment for contingent consideration	-	(1,991)
Payment of In-kind interest	-	(9,321)
Change in operating assets and liabilities		
Trade accounts receivable, net	(17,041)	5,269
Inventories, net	(7,436)	2,892
Prepaid expenses and other current assets	4,686	(14,570)
Other non-current assets	-	1,512
Trade accounts payable	(11,326)	588
Accrued and other current liabilities	6,117	13,795
Net cash provided by operating activities	37,558	57,837
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed assets	10	-
Payment for asset acquisition	-	(12,500)
Purchase of property, plant and equipment	(4,143)	(6,895)
Net cash used in investing activities	(4,133)	(19,395)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments to affiliates	(2)	-
Contributions from partners	-	128
Payments on capital lease obligations	(111)	(114)
Proceeds from issuance of debt	-	327,500
Debt financing costs	-	(3,564)
Proceeds from insurance financing loan	2,744	-
Repayment of insurance financing loan	(971)	-
Proceeds from initial public offering and private placement, net of issuance costs	58,084	-
Debt repayment	(56,140)	(338,756)
Payment for contingent consideration	-	(8,509)
Net cash provided by (used in) financing activities	3,604	(23,315)
Net change in cash and cash equivalents	37,029	15,127
Effect on cash of change in exchange rate	(938)	57
Cash and cash equivalents, beginning of period	34,743	19,559
Cash and cash equivalents, end of period	\$ 70,834	\$ 34,743

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

	Year Ended		Three Months Ended	
	December 31,		December 31,	
	2018	2017	2018	2017
Net Loss	\$ (109,397)	\$ (41,142)	\$ (107,244)	\$ 1,835
Interest expense and amortization of debt discount	20,790	29,052	5,395	7,332

Income tax benefit	(9,268)	(44,500)	(5,846)	(28,360)
Depreciation and Amortization Expense	81,573	46,450	20,250	21,511
EBITDA	(16,302)	(10,140)	(87,445)	2,318
Impairment of intangible and fixed assets	17,903	72,986	11,730	-
Impairment of goodwill	86,318		86,318	
Share compensation expense	1,965	-	1,965	
Write off of acquired IPR&D	-	16,372		16,372
Loss on debt extinguishment	876	5,371	876	5,371
Management fees	921	1,000	151	250
IPO expenses	2,442	-	460	-
Consulting Fees	-	552	-	138
Severance expenses	679	589	195	466
Acquired Inventory step-up in cost of goods sold	-	9,175	-	-
Legal and contractual settlements and litigation reserves	332	1,550	-	498
API inventory disposal	-	468	-	468
Write off of previously acquired balances	-	1,209	-	631
Adjusted EBITDA	\$ 95,134	\$ 99,132	\$ 14,250	\$ 26,512



Source: Osmotica Pharmaceuticals plc