



Osmotica Pharmaceuticals plc Reports Fourth Quarter and Full Year 2020 Results and Provides Business Update

March 30, 2021

Fourth quarter and full year 2020 total revenue of \$34.5 million and \$177.9 million, respectively

Received FDA approval and subsequently introduced Upneeq® (oxymetazoline hydrochloride ophthalmic solution, 0.1%), the first therapeutic for treatment of acquired ptosis in adults

Established Upneeq as a global brand with the execution of the license with Santen Pharmaceuticals, a leading eye-care company for the development and commercialization of Upneeq in Asia and the EU

Strengthened balance sheet by reducing \$50 million in debt and increasing cash

Initiated strategic review in fourth quarter; robust process centered on non-core asset divestitures

BRIDGEWATER, N.J., March 30, 2021 (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, 2020.

"Throughout the past year, we have made meaningful progress on transforming our business, as highlighted by the approval and launch of Upneeq, the first FDA-approved therapeutic treatment for acquired ptosis in adults. In addition to this important accomplishment, we also expanded the international reach of Upneeq through our licensing transaction with Santen Pharmaceuticals – an exceptional partner – covering the EU and Asia, which we see as a major milestone toward establishing Upneeq as a global brand," stated Brian Markison, Chief Executive Officer.

Key Upneeq launch highlights include:

- Established RVL Pharmaceuticals the Company's new operating subsidiary dedicated to Ocular Aesthetics, for the launch of Upneeq;
- Successfully executed an early experience program to a select group of eye-care professionals through a defined sampling and field force effort;
- Reached over 4,000 prescribers through the end of 2020, with consistent and robust new prescriber growth; and
- Seeing consistent growth in new and filled prescriptions through the Company's pharmacy, RVL Pharmacy.

"This initial roll-out of Upneeq has been met with a high degree of patient and physician satisfaction, validating what we believe is a significant commercial market opportunity. Based on the excellent responses from our KOLs and targeted physicians, we recently accelerated the commercial launch in the first quarter of this year.

"We remain highly encouraged by the positive feedback on Upneeq from physicians and patients, especially during a period of constrained physician access and tightly controlled resources.

"Regarding Arbaclofen ER, we had a constructive Type A meeting with the FDA, and we are exploring a number of options as we work together to define a path forward, which will most likely include another clinical trial.

"We have taken steps in 2020 to strengthen our balance sheet by reducing debt, increasing cash and expanding our equity base. Finally, the strategic review process we disclosed last November, now centered on the Company's legacy portfolio, is well underway and robust. We look forward to providing more details regarding this in the months to come," concluded Markison.

Fourth Quarter and Full Year 2020 Financial Highlights

- Total revenues:
 - Fourth quarter 2020 total revenues were \$34.5 million, compared to \$59.9 million in the fourth quarter of 2019;
 - Full year 2020 total revenues were \$177.9 million, compared to \$240.0 million in 2019;
- Net loss:
 - Fourth quarter 2020 net loss was \$54.9 million, compared to a net loss of \$26.6 million in the fourth quarter of 2019. The net losses for the fourth quarters of 2020 and 2019 included \$49.0 million and \$29.9 million, respectively, of intangible asset impairment charges;
 - Full year 2020 net loss was \$79.6 million, compared to net loss of \$270.9 million in 2019. The net losses during 2020 and 2019 included intangible assets impairment charges of \$72.2 million and \$283.7 million, respectively;
- Adjusted EBITDA¹

- Fourth quarter 2020 Adjusted EBITDA was \$1.2 million, compared to Adjusted EBITDA of \$14.9 million in the fourth quarter of 2019;
- Full year 2020 Adjusted EBITDA was \$40.6 million, compared to Adjusted EBITDA of \$68.8 million in 2019; and,
- Cash and cash equivalents were \$114.1 million, and debt (net of deferred financing costs) was \$219.5 million as of December 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.”

Fourth Quarter 2020 Financial Results

Total revenues for the three months ended December 31, 2020 were \$34.5 million, compared to \$59.9 million for the three months ended December 31, 2019. The decrease in total revenue in 2020 largely reflects a decline in net product sales, partially offset by higher licensing and contract revenue and royalty revenue.

Net product sales decreased by \$26.7 million to \$32.1 million for the three months ended December 31, 2020, as compared \$58.8 million for the three months ended December 31, 2019. Approximately \$13.4 million of this decrease was attributable to lower realized pricing and \$13.4 million of this decrease was due to lower volumes of products sold. Lower net pricing and volumes primarily on sales of methylphenidate hydrochloride extended-release (“ER”) tablets, venlafaxine ER tablets (“VERT”), Nitrofurantoin and Lorzone® (chlorzoxazone scored tablets) were partially offset by higher revenues from Divigel® and sales of Upneeq. During the fourth quarter of 2020, net product sales of methylphenidate ER tablets (including M-72) and VERT decreased 55% and 73% 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. VERT sales were favorably impacted by \$0.7 million, in the aggregate, related to product returns during the three months ended December 31, 2020 based on actual experience.

Selling, general and administrative expenses decreased to \$20.7 million in the fourth quarter of 2020, compared to \$21.1 million in the fourth quarter of 2019. The slight decrease largely reflects lower selling expenses due to sales force realignments in 2019 and early 2020, offset by higher marketing spend and higher legal expenses.

Research and development expenses decreased to \$4.5 million in the fourth quarter of 2020, compared to \$8.9 million in the fourth quarter of 2019, primarily due to the completion of the Phase III clinical trials of RVL-1201 and arbaclofen ER.

During the fourth quarter of 2020, we recognized intangible asset impairment charges of \$49.0 million, reflecting write downs of developed technology assets, distribution rights and in-process research and development, as compared to \$29.9 million for the fourth quarter of 2019, reflecting write downs of developed technology assets and distribution rights.

Other non-operating expenses decreased to \$2.7 million in the fourth quarter of 2020, compared to \$4.5 million in the fourth quarter of 2019. The decrease resulted from lower interest expense due to the prepayment of \$50 million of debt during the third quarter of 2020.

Net loss for the fourth quarter of 2020 was \$54.9 million, compared to a net loss of \$26.6 million in the fourth quarter of 2019 primarily due to a decrease in total revenues and higher impairment charges during the quarter.

Adjusted EBITDA for the fourth quarter of 2020 was \$1.2 million, compared to Adjusted EBITDA of \$14.9 million for the fourth 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.

Full Year 2020 Financial Results

Total revenues decreased by \$62.1 million to \$177.9 million in 2020, as compared to \$240.0 million in 2019, primarily due to a decrease in net product sales, partially offset by higher licensing and contract revenue.

Net product sales decreased by \$89.6 million to \$145.9 million for the year ended December 31, 2020, as compared to \$235.5 million for the year ended December 31, 2019. Approximately \$52.2 million of this decrease was attributable to lower realized prices, and approximately \$37.4 million was due to lower volumes of products sold. Net product sales of methylphenidate ER (including M-72), decreased 57% due to price erosion from generic competitors resulting in significantly lower net selling prices and lower volumes. Product sales from VERT decreased by 66% for the year ended December 31, 2020 due to additional generic competition resulting in lower volumes and net realized selling prices. During the first quarter of 2020, two competitors launched competing dosage strengths of VERT, which negatively affected selling prices and volumes. The Company expects 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 2021 and future years. VERT sales were favorably impacted by \$6.4 million, in the aggregate related to product returns during the 12 months ended December 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 2021 and in future years.

Selling, general and administrative expenses decreased by \$11.0 million in 2020 to \$82.0 million as compared to \$93.0 million in 2019. The decrease reflects salesforce reductions in the third quarter of 2019 and in the first quarter of 2020, partially offset by higher marketing expenses associated with the launch of Upneeq and higher general and administrative expenses largely due to costs associated with the Santen license transaction and legal expenses during the year.

Research and development expenses decreased by \$12.6 million in 2020 to \$19.7 million as compared to \$32.3 million in 2019. The decrease primarily reflects the completion of the Phase III clinical trials of both arbaclofen ER and RVL-1201 during the first and second quarters of 2019, respectively, and the NDA filing fees for RVL-1201 incurred in the third quarter of 2019.

The Company incurred an impairment of intangible assets charge of \$72.2 million during the 12 months ended December 31, 2020, primarily related to the write down to fair value of methylphenidate ER, VERT, Oxybutynin and arbaclofen ER due to price and volume decreases resulting from competing

generic products, and delays associated with the anticipated commercialization of arbaclofen, if approved.

Net loss in 2020 was \$79.6 million, compared to net loss of \$270.9 million in 2019.

Adjusted EBITDA in 2020 was \$40.6 million, compared to Adjusted EBITDA of \$68.8 million in 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 December 31, 2020, the Company had cash and cash equivalents of \$114.1 million and borrowing availability under our revolving credit facility of \$50.0 million. The Company also had debt of \$219.5 million (net of deferred financing costs).

Process Update and Responsibility Statement Required by the Irish Takeover Rules

The directors of the Company accept responsibility for the information contained in this announcement. To the best of the knowledge and belief of the directors (who have taken all reasonable care to ensure that such is the case) the information contained in this announcement is in accordance with the facts and does not omit anything likely to affect the import of such information.

As referenced above, the strategic review process is now focused on the Company's legacy portfolio. The Company is not in discussions with any party regarding the sale of the entire Company. As such, the sales process under the Irish Takeover Rules is no longer in place.

A copy of this announcement will be available on the Company's website at www.osmotica.com by no later than noon (Irish time) on the business day following this announcement. The content of the Company's website is not incorporated into, and does not form part of, this announcement.

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, 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 review of strategic alternatives, 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 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, 2020 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 2020 conference call as follows:

Date: Tuesday, March 30, 2021
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: 5056728

The webcast will be archived for 30 days at the aforementioned URL.

About Osmotica Pharmaceuticals plc

Osmotica Pharmaceuticals plc (Nasdaq: OSMT) is a fully integrated biopharmaceutical company focused on the development and commercialization of specialty products that target markets with underserved patient populations. The company has a diverse portfolio consisting of promoted and non-promoted products, several of which incorporate Osmotica's proprietary Osmodex® drug delivery system. RVL Pharmaceuticals, Inc. is the Company's ophthalmic subsidiary supporting Upneeq®. Vertical Pharmaceuticals, LLC represents the Company's diversified branded portfolio and Trigen Laboratories, LLC represents the Company's 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

Consolidated Balance Sheets

(in thousands)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 114,053	\$ 95,865
Trade accounts receivable, net	26,412	43,914
Inventories, net	17,934	21,305
Prepaid expenses and other current assets	14,755	11,546
Total current assets	173,154	172,630
Property, plant and equipment, net	28,054	30,238
Operating lease assets	2,755	4,983
Intangibles, net	65,758	153,986
Goodwill	100,855	100,855
Other non-current assets	373	563
Total assets	\$ 370,949	\$ 463,255
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	\$ 6,768	\$ 8,495
Accrued liabilities	47,517	65,253
Current portion of obligation under finance leases	40	127
Current portion of lease liability	1,457	2,062
Income taxes payable - current portion	2	-
Total current liabilities	55,784	75,937
Long-term debt, net of non-current deferred financing costs	219,525	267,950
Long-term portion of obligation under finance leases	4	44
Long-term portion of lease liability	1,436	3,116
Deferred taxes	344	1,500
Total liabilities	277,093	348,547
Commitments and contingencies		
Shareholders' equity:		
Ordinary shares	625	518
Additional paid in capital	548,070	489,440
Accumulated deficit	(452,610)	(373,021)

Accumulated other comprehensive loss		(2,229)	(2,229)
Total shareholders' equity		93,856	114,708
Total liabilities and shareholders' equity	\$	370,949	\$ 463,255

Osmotica Pharmaceuticals plc

Consolidated Statements of Operations

(in thousands, except share and per share data)

	Year Ended December 31,		Three Months Ended December 31,	
	2020	2019	2020	2019
Net product sales	\$ 145,850	\$ 235,472	\$ 32,067	\$ 58,815
Royalty revenue	4,107	3,641	1,232	815
Licensing and contract revenue	27,927	918	1,233	281
Total revenues	177,884	240,031	34,532	59,911
Cost of good sold (inclusive of amortization of intangibles)	74,480	111,630	17,179	22,470
Gross profit	103,404	128,401	17,353	37,441
Selling, general and administrative expenses	81,961	93,030	20,685	21,111
Research and development expenses	19,696	32,319	4,511	8,909
Impairment of intangibles	72,183	283,747	49,026	29,868
Total operating expenses	173,840	409,096	74,222	59,888
Operating loss	(70,436)	(280,695)	(56,869)	(22,447)
Interest expense and amortization of debt discount	14,396	18,211	3,028	4,656
Other non-operating gain	(546)	(884)	(305)	(165)
Total other non-operating expense	13,850	17,327	2,723	4,491
Loss before income taxes	(84,286)	(298,022)	(59,592)	(26,938)
Income tax benefit	4,697	27,121	4,718	297
Net loss	\$ (79,589)	\$ (270,901)	\$ (54,874)	\$ (26,641)
Loss per share attributable to shareholders				
Basic and diluted	\$ (1.31)	\$ (5.17)	\$ (0.88)	\$ (0.51)
Weighted average share basic and diluted				
Basic and diluted	60,652,999	52,367,444	62,663,913	51,960,082

Osmotica Pharmaceuticals plc

Consolidated Statements of Cash Flows

(in thousands)

	Year Ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (79,589)	\$ (270,901)
Adjustments to reconcile net loss to cash provided by operating activities:		
Depreciation and amortization	21,026	57,015
Share compensation	4,925	4,932
Impairment of intangibles	72,183	283,747
Deferred income tax benefit	(1,156)	(26,794)
Loss on sale of fixed and leased assets	287	173
Bad debt provision	6	(164)
Amortization of deferred financing and loan origination fees	1,269	1,337
Write off of deferred financing fees in connection with loan prepayment	496	-
Change in operating assets and liabilities		
Trade accounts receivable, net	17,496	12,674
Inventories, net	3,371	3,078
Prepaid expenses and other current assets	(3,209)	9,177
Trade accounts payable	(1,723)	(16,375)
Accrued and other current liabilities	(17,792)	(24,332)

Net cash provided by operating activities	17,590	33,567
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed and leased assets	50	17
Payments on disposal of leased assets	(214)	(74)
Purchase of property, plant and equipment	(2,920)	(3,963)
Net cash used in investing activities	(3,084)	(4,020)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on finance lease obligations	(127)	(130)
Proceeds from insurance financing loan	-	1,314
Repayment of insurance financing loan	-	(3,088)
Payments for taxes related to net share settlement of equity awards	(749)	-
Proceeds from public offering, net of issuance costs	62,440	-
Proceeds from purchases of stock under ESPP	219	-
Debt repayment	(50,000)	-
Repurchase of ordinary shares	(8,101)	(2,787)
Net cash provided by (used in) financing activities	3,682	(4,691)
Net change in cash and cash equivalents	18,188	24,856
Effect on cash of change in exchange rate	-	175
Cash and cash equivalents, beginning of period	95,865	70,834
Cash and cash equivalents, end of period	\$ 114,053	\$ 95,865

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

	Year Ended		Three Months Ended	
	December 31,		December 31,	
	2020	2019	2020	2019
Net Loss	\$ (79,589)	\$ (270,901)	\$ (54,874)	\$ (26,641)
Interest expense and amortization of debt discount	14,396	18,211	3,028	4,656
Income tax benefit	(4,697)	(27,121)	(4,718)	(297)
Depreciation and Amortization Expense	21,026	57,015	4,438	6,410
EBITDA	(48,864)	(222,796)	(52,126)	(15,872)
Impairment of intangibles	72,183	283,747	49,026	29,868
Share compensation expense	4,925	4,932	1,308	1,101
Write off of deferred financing fees in connection with prepayment	496	-	-	-
Management Fees	-	(42)	-	-
FX Translation	260	655	72	80
Severance expenses	3,026	1,802	677	164
Legal expenses	4,200	526	1,936	(477)
License related transaction costs	2,546	-	-	-
Milestone payments	750	-	-	-
Other	1,118	-	320	-
Adjusted EBITDA	\$ 40,640	\$ 68,824	\$ 1,213	\$ 14,864



Source: Osmotica Holdings US LLC