



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

November 10, 2020

Third quarter 2020 total revenue of \$57.2 million

Received U.S Food and Drug Administration ("FDA") approval for Upneeq™ (oxymetazoline hydrochloride ophthalmic solution), 0.1% for acquired blepharoptosis (ptosis or droopy eyelid) in adults

Launched Upneeq from new operating subsidiary, RVL Pharmaceuticals, enabling broad access for providers and patients

Early experience program, Uncovering Ptosis (UP), under way, targeting 650 eyecare practices in the United States

Pooled analysis of data from two Phase 3 clinical trials of Upneeq published in JAMA Ophthalmology

Entered into exclusive license agreement with Santen Pharmaceutical Co. Ltd. for rights to RVL-1201 (Upneeq) in Japan, China and certain other Asian and EMEA countries

BRIDGEWATER, N. J., Nov. 10, 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 September 30, 2020.

"With the commercial introduction of Upneeq, the Company's transformation to a specialty branded pharmaceutical company is well underway. Through nine weeks of a carefully crafted launch, where our sales team focused on a select group of prescribers, we are off to a strong start. Eye care physicians have embraced the product and patients appreciate the result. In short, acceptance to the Upneeq early experience program has exceeded our expectations. With the launch of Upneeq well underway and our December user fee goal date for arbaclofen ER approaching, we have a lot to look forward to," stated Brian Markison, Chief Executive Officer.

Third Quarter 2020 Financial Highlights

- Total revenues were \$57.2 million, compared to \$65.5 million in the third quarter of 2019;
- Net loss was \$8.6 million, compared to a net loss of \$112.7 million in the third quarter of 2019 inclusive of \$19.5 million and \$128.1 million, respectively, of intangible asset impairment charges;
- Adjusted EBITDA¹ was \$26.1 million, compared to Adjusted EBITDA of \$22.9 million in the third quarter of 2019; and
- Cash and cash equivalents were \$126.1 million and debt (net of deferred financing costs) was \$219.3 million as of September 30, 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."

Third Quarter 2020 Financial Results

Total revenues for the three months ended September 30, 2020 were \$57.2 million, compared to \$65.5 million for the three months ended September 30, 2019, primarily due to a decrease in net product sales, partially offset by higher licensing and contract revenue. Net product sales decreased by \$32.8 million to \$31.2 million for the three months ended September 30, 2020, as compared to \$64.0 million for the three months ended September 30, 2019. Approximately \$15.3 million of this decrease is attributable to lower realized net prices, and \$17.5 million was due to lower volumes of products sold. Net sales of methylphenidate ER (including M-72) and Venlafaxine ER Tablets (VERT) decreased 65% and 84%, respectively during the quarter due to price erosion from generic competitors resulting in significantly lower net selling prices and volumes. 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 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 \$1.6 million in the aggregate related to product returns during the three months ended September 30, 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.

Product sales of Divigel increased 22% during the period partly due the launch of a new product strength, while product sales of nitrofurantoin increased due to higher volumes of product sold. Sales of the OBC Complete line of pre-natal vitamins fell by 37% due to lower pricing and volumes, while sales of other products increased 5%.

Licensing and contract revenue increased \$25.5 million during the quarter primarily due to milestone payments received under the license agreement with Santen Pharmaceutical Co. Ltd.

Selling, general and administrative expenses decreased \$1.3 million during the three months ended September 30, 2020 to \$23.5 million as compared to \$24.8 million in the three months ended September 30, 2019. The decrease in our selling, general and administrative expenses reflects salesforce reductions in the first quarter of 2020, offset by higher costs related to the launch of Upneeq and costs associated with the Santen license transaction.

Research and development expenses decreased by \$4.6 million in the three months ended September 30, 2020 to \$3.7 million as compared to \$8.3 million in the three months ended September 30, 2019. The decrease primarily reflects the completion of clinical studies related to arbaclofen ER and the NDA filing fees for Upneeq, which were incurred in the third quarter of 2019.

During the three months ended September 30, 2020 we recognized intangible asset impairment charges of \$19.5 million, reflecting write downs of product rights.

Net loss for the third quarter of 2020 was \$8.6 million, compared to a net loss of \$112.7 million in the third quarter of 2019.

Adjusted EBITDA for the third quarter of 2020 was \$26.1 million, compared to Adjusted EBITDA of \$22.9 million for the third 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 September 30, 2020, we had cash and cash equivalents of \$126.1 million and borrowing capacity under our revolving credit facility of \$50.0 million. As of September 30, 2020, we also had \$221.4 million aggregate principal amount borrowed under our term loans following the prepayment of \$50.0 million of term loans during the quarter.

Irish Takeover Rule 2.4 Announcement of Strategic Review, including sale process

The Board of the Company today announces that it is undertaking a comprehensive review of strategic options to maximize shareholder value. The options under consideration include asset disposals, re-financings, commercialization or collaboration agreements. The review will also include the initiation of a process for the sale of the Company, which will commence shortly.

The Board has a strong conviction in the value of the Company's assets especially Upneeq and arbaclofen, its management and its business plan, and is considering all options available to maximize value to shareholders. "We believe we are successfully building the early market for Upneeq and in the future potential of arbaclofen. However, given what we believe is the potential of these assets we are considering all options available to support the growth and success of these and future products," said Markison.

The Board has appointed Barclays Capital Inc. and Jefferies LLC to assist with the strategic review. Ropes & Gray LLP and A&L Goodbody will act as the Company's legal counsel.

Parties with a potential interest in participating in the sale process should contact Barclays or Jefferies (contact details as set out below).

It is currently expected that any party interested in participating in the proposed sale process will, at the appropriate time, enter into a non-disclosure agreement with Osmotica on terms satisfactory to the Board of Osmotica and agree to comply with the terms and conditions of the process. The Company then intends to provide such interested parties with certain information on the business, following which interested parties shall be invited to submit their proposals to Barclays and Jefferies.

The Irish Takeover Panel (the "Panel") has confirmed that as a result of this announcement, the Company is now considered to be in an "offer period", as defined in the Irish Takeover Panel Act 1997, Takeover Rules 2013 (the "Irish Takeover Rules"). The dealing disclosure requirements summarized below will therefore apply.

The Panel has also confirmed that any interested party participating in the process will not be required, solely by reason of the fact that it participates in the process, to be publicly identified as a result of this announcement, but that such parties should nonetheless be mindful of their obligations under the Irish Takeover Rules, including in particular with respect to confidentiality under Rule 2.1 and the circumstances in which an announcement may be required under Rule 2.2. If an interested party has any doubts about its obligations pursuant to the Irish Takeover Rules, it should contact its financial adviser(s) to discuss this and where applicable, it should also consult with the Panel. The Company is not in receipt of any approaches at the time of this announcement.

The Company's review of its strategic alternatives may or may not lead to an offer for the Company or the consummation of any other transaction. Further announcements will be made as and when appropriate.

Dealing Disclosure Requirements under the Irish Takeover Rules

Under the provisions of Rule 8.3 of the Irish Takeover Rules, if any person is, or becomes, "interested" (directly or indirectly) in 1% or more of any class of "relevant securities" of Osmotica, all "dealings" in any "relevant securities" of Osmotica (including by means of an option in respect of, or a derivative referenced to, any such "relevant securities") must be publicly disclosed by not later than 3:30 p.m. (Irish time) on the "business day" following the date of the relevant transaction. This requirement will continue until the date on which the "offer period" ends. If two or more persons co-operate on the basis of any agreement, either express or tacit, either oral or written, to acquire an "interest" in "relevant securities" of Osmotica, they will be deemed to be a single person for the purpose of Rule 8.3 of the Irish Takeover Rules.

A disclosure table, giving details of the companies in whose "relevant securities" "dealings" should be disclosed can be found on the Panel's website at www.irishtakeoverpanel.ie.

"Interests in securities" arise, in summary, when a person has long economic exposure, whether conditional or absolute, to changes in the price of securities. In particular, a person will be treated as having an "interest" by virtue of the ownership or control of securities, or by virtue of any option in respect of, or derivative referenced to, securities.

Terms in quotation marks are defined in the Irish Takeover Rules, which can also be found on the Panel's website. If you are in any doubt as to whether or not you are required to disclose a dealing under Rule 8, please consult the Panel's website at www.irishtakeoverpanel.ie or contact the Panel on telephone number +353 1 678 9020 or fax number +353 1 678 9289.

For the purposes of Rule 2.10 of the Irish Takeover Rules, the Company confirms that, as of November 9, 2020, it has in issue 62,585,832 ordinary shares of US\$0.01 each. The ISIN for the shares is IE00BF2HDL56.

THIS IS AN ANNOUNCEMENT UNDER RULE 2.4 OF THE IRISH TAKEOVER RULES AND IS NOT AN ANNOUNCEMENT OF A FIRM INTENTION TO MAKE AN OFFER UNDER RULE 2.5 OF THE IRISH TAKEOVER RULES. THERE CAN BE NO CERTAINTY THAT AN OFFER WILL BE MADE, NOR AS TO THE TERMS ON WHICH ANY OFFER MIGHT BE MADE.

Responsibility Statement Required by the Irish Takeover Rules

The directors of the Company accept responsibility for the information contained in this release. 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 release is in accordance with the facts and does not omit anything likely to affect the import of such information.

A copy of this release 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 release. The content of the Company's website is not incorporated into, and does not form part of, this release.

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 review of strategic alternatives and efforts to maximize shareholder value, 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, our Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2020 and June 30, 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 third quarter 2020 conference call as follows:

Date	Tuesday, November 10, 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	4356477

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 Condensed Consolidated Balance Sheets (in thousands)

	September 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 126,093	\$ 95,865
Trade accounts receivable, net	21,569	43,914
Inventories, net	21,703	21,305
Prepaid expenses and other current assets	6,805	11,546
Total current assets	176,170	172,630
Property, plant and equipment, net	28,664	30,238
Operating lease assets	3,233	4,983
Intangibles, net	117,904	153,986
Goodwill	100,855	100,855
Other non-current assets	420	563
Total assets	\$ 427,246	\$ 463,255
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	\$ 7,909	\$ 8,495
Accrued liabilities	45,376	65,253
Current portion of obligation under finance leases	65	127
Current portion of lease liability	1,596	2,062
Total current liabilities	54,946	75,937
Long-term debt, net of non-current deferred financing costs	219,290	267,950
Long-term portion of obligation under finance leases	8	44
Long-term portion of lease liability	1,790	3,116
Deferred taxes	526	1,500
Total liabilities	276,560	348,547
Commitments and contingencies		
Shareholders' equity		
Ordinary shares	631	518
Additional paid in capital	550,020	489,440
Accumulated deficit	(397,736)	(373,021)
Accumulated other comprehensive loss	(2,229)	(2,229)
Total shareholders' equity	150,686	114,708
Total liabilities and shareholders' equity	\$ 427,246	\$ 463,255

Osmotica Pharmaceuticals plc
Condensed Consolidated Statements of Operations
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net product sales	\$ 31,175	\$ 64,041	\$ 113,783	\$ 176,657
Royalty revenue	432	1,325	2,875	2,826
Licensing and contract revenue	25,564	95	26,694	637
Total revenues	57,171	65,461	143,352	180,120
Cost of goods sold (inclusive of amortization of intangibles)	16,717	27,312	57,301	89,160
Gross profit	40,454	38,149	86,051	90,960
Selling, general and administrative expenses	23,543	24,751	61,276	71,919
Research and development expenses	3,726	8,285	15,185	23,410
Impairment of intangibles	19,539	128,113	23,157	253,879
Total operating expenses	46,808	161,149	99,618	349,208
Operating loss	(6,354)	(123,000)	(13,567)	(258,248)
Interest expense and amortization of debt discount	3,564	4,504	11,368	13,555
Other non-operating gain	(153)	(177)	(241)	(719)
Total other non-operating expense	3,411	4,327	11,127	12,836
Loss before income taxes	(9,765)	(127,327)	(24,694)	(271,084)
Income tax benefit (expense)	1,132	14,623	(21)	26,824
Net and other comprehensive loss	\$ (8,633)	\$ (112,704)	\$ (24,715)	\$ (244,260)
Loss per share attributable to shareholders				
Basic and Diluted	\$ (0.14)	\$ (2.15)	\$ (0.41)	\$ (4.65)
Weighted average shares basic and diluted				
Basic and Diluted	62,785,866	52,476,540	59,979,834	52,504,518

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

(in thousands)

	Nine Months Ended September 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (24,715)	\$ (244,260)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	16,589	50,605
Share compensation	3,836	3,831
Loss on sale of fixed and leased assets	281	75
Impairment of intangibles	23,157	253,879
Deferred income tax benefit	(974)	(28,493)
Bad debt provision	6	(160)
Amortization of deferred financing and loan origination fees	985	1,000
Write off of deferred financing fees in connection with prepayment	496	-
Change in operating assets and liabilities:		
Trade accounts receivable, net	22,339	22,722
Inventories, net	(398)	(2,857)
Prepaid expenses and other current assets	4,741	12,536
Trade accounts payable	(586)	(14,964)
Accrued and other current liabilities	(19,915)	(21,022)
Net cash provided by (used in) operating activities	25,842	32,892
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed and leased assets	50	12
Payments on disposal of leased assets	(209)	(34)
Purchase of property, plant and equipment	(2,213)	(3,042)

Net cash used in investing activities	(2,372)	(3,064)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Payments on finance lease obligations	(98)	(97)
Proceeds from public offering, net of issuance costs	62,440		-	
Repurchases of ordinary shares	(4,835)	(1,338)
Payments for taxes related to net share settlement of equity awards	(749)	-	
Proceeds from insurance financing loan	-		1,314	
Repayment of insurance financing loan	-		(2,691)
Repayment of debt	(50,000)	-	
Net cash provided by (used in) financing activities	6,758		(2,812)
Net change in cash and cash equivalents	30,228		27,016	
Effect on cash of changes in exchange rate	-		164	
Cash and cash equivalents, beginning of period	95,865		70,834	
Cash and cash equivalents, end of period	\$ 126,093		\$ 98,014	

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

	Three Months Ended		Nine Months Ended	
	September 30, 2020	2019	September 30, 2020	2019
Net loss	\$ (8,633)	\$ (112,704)	\$ (24,715)	\$ (244,260)
Interest expense and amortization of debt discount	3,564	4,504	11,368	13,555
Income tax expense (benefit)	(1,132)	(14,623)	21	(26,824)
Depreciation and amortization expense	5,440	14,614	16,589	50,605
EBITDA	(761)	(108,209)	3,263	(206,924)
Impairment of intangibles	19,539	128,113	23,157	253,879
Management fees	-	-	-	(43)
Severance expenses	271	1,275	2,349	1,638
FX translation	66	363	188	575
Legal expenses	1,737	-	2,265	1,002
Public offering expenses	(18)	-	-	-
Share compensation expense	1,379	1,335	3,618	3,831
Write off of deferred financing fees in connection with prepayment	496	-	496	-
License related transaction costs	2,546	-	2,546	-
Other	810	-	1,543	-
Adjusted EBITDA	\$ 26,065	\$ 22,877	\$ 39,425	\$ 53,958



Source: Osmotica Holdings US LLC