# Osmotica Pharmaceuticals plc Reports Second Quarter 2020 Results and Provides Business Updates

August 11, 2020

*Second quarter 2020 total revenue of $37.5 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*

*Entered into exclusive license agreement with Santen Pharmaceutical Co. Ltd. in Japan, Asia and EMEA for RVL-1201 (Upneeq)*

*User fee goal date of December 29, 2020 set by FDA for arbaclofen extended release ("ER") tablets for spasticity in Multiple Sclerosis patients*

BRIDGEWATER, N.J., Aug. 11, 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 June 30, 2020.

"The past several months have been extremely productive, achieving several critical milestones. In July, we received FDA approval for Upneeq, our first-in-class pharmacologic treatment for acquired ptosis in adults. This is truly an exciting opportunity for patients who have never had a non-surgical solution available to treat what is more commonly known as 'droopy eyelid.' This accomplishment is the culmination of our rigorous clinical program that demonstrated the safety, efficacy and tolerability of this once-a-day eye drop. We are now ready to introduce Upneeq to doctors and their patients and look forward to making the product commercially available after Labor Day," said Brian Markison, Chief Executive Officer of Osmotica Pharmaceuticals.

"We are delighted to have entered into an exclusive license agreement with Santen Pharmaceutical Co., Ltd., a premier global ophthalmology focused company with an extensive international footprint and stellar reputation. This transaction allows us to address the large worldwide unmet need for patients with acquired blepharoptosis, and we are pleased to give eyecare professionals in Japan, Asia and EMEA access to this new therapeutic option," continued Markison.

"As planned, we completed our clinical development program for arbaclofen ER for spasticity in Multiple Sclerosis patients and resubmitted our New Drug Application ("NDA"). The FDA has accepted the application and set a user fee goal date of December 29, 2020. These accomplishments set the stage for an exciting period of growth for our company as we continue to execute our strategic vision," concluded Markison.

**Second Quarter 2020 Financial Highlights**

- Total revenues were $37.5 million, compared to $57.5 million in the second quarter of 2019;
- Net loss was $13.0 million, compared to a net loss of $124.9 million in the second quarter of 2019;
- Adjusted EBITDA[1] was $2.3 million, compared to Adjusted EBITDA of $14.5 million in the second quarter of 2019; and
- Cash and cash equivalents were $140.4 million, and debt (net of deferred financing costs) was $268.5 million as of June 30, 2020.

[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."

**Second Quarter 2020 Financial Results**

Total revenues for the three months ended June 30, 2020 were $37.5 million, compared to $57.5 million for the three months ended June 30, 2019. Net product sales decreased by $20.9 million to $35.3 million for the three months ended June 30, 2020, as compared to $56.2 million for the three months ended June 30, 2019. Net sales of methylphenidate ER (including M-72) decreased 47% during the quarter due to price erosion from generic competitors resulting in significantly lower net selling prices and volumes. Net sales of venlafaxine extended-release tablets (VERT) decreased 76% reflecting additional generic competition resulting in lower volumes and net realized selling prices. The Company expects that additional competition for both methylphenidate ER and VERT from current competitors, as well as additional generic product approvals and launches in the future, if any, will continue to negatively affect sales of these products during the remainder of 2020 and in future years. VERT sales were favorably impacted by $1.3 million in the aggregate related to product returns during the three months ended June 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 for the remainder of 2020 or in future periods.

Selling, general and administrative expenses decreased $8.9 million during the three months ended June 30, 2020 to $16.6 million as compared to $25.5 million in the three months ended June 30, 2019. The decrease in our selling, general and administrative expenses reflects lower expenses associated with a salesforce reduction in the first quarter of 2020, combined with lower spending on marketing and general and administrative expenses during the second quarter of 2020.

Research and development expenses increased by $0.4 million in the three months ended June 30, 2020 to $5.8 million as compared to $5.4 million in the three months ended June 30, 2019. The increase reflects costs associated with the preparation of the filing of the amended NDA for arbaclofen ER and increased costs associated with medical education programs partially offset by the cost of manufacturing development batches of Osmolex in the three month period ended June 30, 2019, which costs were not present in 2020.

Net loss for the second quarter of 2020 was $13.0 million, compared to a net loss of $124.9 million in the second quarter of 2019.

During the second quarter of 2020, we recognized an intangible asset impairment charge of $3.6 million, reflecting the write-off of a developed technology asset, as compared with intangible asset impairment charges of $125.8 million in the second quarter of 2019.

Adjusted EBITDA for the second quarter of 2020 was $2.3 million, compared to Adjusted EBITDA of $14.5 million for the second 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 June 30, 2020, we had cash and cash equivalents of $140.4 million and borrowing capacity under our revolving credit facility of $50.0 million. In July 2020, we completed an equity offering generating net proceeds of $30.4 million. Additionally, on July 28, 2020, we announced a licensing transaction with Santen Pharmaceutical Co., Ltd. pursuant to which we received an upfront cash payment of $25 million. As of June 30, 2020, we also had $271.3 million aggregate principal amount borrowed under our term loans. The Company is prepaying $25 million of term loans as part of its strategy to reduce financial leverage.

**Presentation of Non-GAAP Measures**

In addition to the results provided in accordance with GAAP throughout this press release, the Company has presented Adjusted EBITDA, which is a non-GAAP measure. Adjusted EBITDA represents earnings before interest, taxes, depreciation and amortization ("EBITDA") adjusted for (i) non-operating income or expense, and (ii) the impact of certain non-cash, nonrecurring or other items that are included in net loss and EBITDA that we do not consider indicative of our ongoing operating performance. In particular, Adjusted EBITDA excludes the following from EBITDA, as applicable: impairment of intangible assets and fixed assets, impairment of goodwill, share compensation expense, loss on debt extinguishment, management fees, public offering expenses, foreign currency translation, severance expenses and legal and contractual settlements and litigation reserves. We use Adjusted EBITDA for business planning purposes, in assessing our performance and determining the compensation of substantially all of our employees, including our executive officers, and in measuring our performance relative to that of our competitors. We also believe that Adjusted EBITDA provides investors with useful information to understand our operating results and analyze financial and business trends on a period-to-period basis. Adjusted EBITDA has important limitations as an analytical tool, however, and you should not consider it in isolation or as a substitute for analysis of our results as reported under GAAP. Adjusted EBITDA is not intended to replace, and should not be considered superior to, the presentation of our financial results in accordance with GAAP. Our definition of Adjusted EBITDA may differ from similar measures reported by other companies and may not be comparable to other similarly titled measures. Adjusted EBITDA is reconciled from the net loss as determined under GAAP in the attached table "Osmotica Pharmaceuticals plc GAAP to Non-GAAP Reconciliations."

**Forward Looking Statements**

This press release includes statements that express the Company's opinions, expectations, beliefs, plans, objectives, assumptions or projections regarding future events or future results and therefore are, or may be deemed to be, "forward-looking statements." The Company's actual results may vary significantly from the results anticipated in these forward-looking statements, which can generally be identified by the use of forward-looking terminology, including the terms "believes," "expects," "may," "will," "should," "seeks," "projects," "approximately," "intends," "plans," "estimates" or "anticipates," or, in each case, their negatives or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They include statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, our results of operations, financial condition, liquidity, prospects, financial guidance, growth plan, strategies, trends and other events, particularly relating to sales of current products and the development, approval and introduction of new products, FDA and other regulatory applications, approvals and actions, the continuation of historical trends, and the sufficiency of our cash balances and cash generated from operating and financing activities for future liquidity and capital resource needs. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place significant reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Important factors that could cause actual results and events to differ materially from those indicated in the forward-looking statements include the following: our business may be adversely affected by the ongoing coronavirus outbreak; our ability to successfully develop or commercialize new products, or do so on a timely or cost effective basis; our dependence on a limited number of products; failures of or delays in clinical trials or other delays in obtaining regulatory approval or commencing product sales for new products; the impact of legal proceedings; our ability to service our substantial debt; our ability to raise additional capital; the impact of competition from both brand and generic companies; any interruption at our manufacturing facility, our warehouses or at facilities operated by third parties that we rely on for our products; our dependence on our major customers; our ability to develop and maintain our sales capabilities; the impact of any litigation related to allegations of infringement of intellectual property; any changes to the coverage and reimbursement levels for our products by governmental authorities and other third-party payors as a result of healthcare reform or otherwise; the impact of any changes in the extensive governmental regulation that we face; manufacturing or quality control issues that we may face; and other risks and uncertainties more fully described in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2019 and other filings that the Company makes with the Securities and Exchange Commission. These forward-looking statements speak only as of the time of this release and we do not undertake to publicly update or revise them, whether as a result of new information, future events or otherwise, except as required by law.

**Conference Call**

As previously announced, Osmotica management will host its second quarter 2020 conference call and provide a business update as follows:

| | |
|---|---|
| Date | Tuesday, August 11, 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 | 5287688 |

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. RVL Pharmaceuticals, Inc. is the Company's ophthalmic subsidiary supporting Upneeq.

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)

| | June 30, 2020 (Unaudited) | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 140,376 | $ 95,865 |
| Trade accounts receivable, net | 17,024 | 43,914 |
| Inventories, net | 20,301 | 21,305 |
| Prepaid expenses and other current assets | 9,091 | 11,546 |
| Total current assets | 186,792 | 172,630 |
| Property, plant and equipment, net | 29,281 | 30,238 |
| Operating lease assets | 3,658 | 4,983 |
| Intangibles, net | 141,643 | 153,986 |
| Goodwill | 100,855 | 100,855 |
| Other non-current assets | 468 | 563 |
| Total assets | $ 462,697 | $ 463,255 |
| | | |
| Liabilities and Shareholders' Equity | | |
| Current liabilities: | | |
| Trade accounts payable | $ 8,798 | $ 8,495 |
| Accrued liabilities | 48,353 | 65,253 |
| Current portion of obligation under finance leases | 89 | 127 |
| Current portion of lease liability | 1,650 | 2,062 |
| Total current liabilities | 58,890 | 75,937 |
| Long-term debt, net of non-current deferred financing costs | 268,522 | 267,950 |
| Long-term portion of obligation under finance leases | 17 | 44 |
| Long-term portion of lease liability | 2,175 | 3,116 |
| Deferred taxes | 2,182 | 1,500 |
| Total liabilities | 331,786 | 348,547 |
| Commitments and contingencies | | |
| Shareholders' equity | | |
| Ordinary shares | 588 | 518 |
| Additional paid in capital | 521,655 | 489,440 |
| Accumulated deficit | (389,103) | (373,021) |
| Accumulated other comprehensive loss | (2,229) | (2,229) |
| Total shareholders' equity | 130,911 | 114,708 |
| Total liabilities and shareholders' equity | $ 462,697 | $ 463,255 |

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

(in thousands, except share and per share data)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| Net product sales | $ 35,300 | $ 56,215 | $ 82,608 | $ 112,615 |
| Royalty revenue | 1,574 | 780 | 2,443 | 1,501 |
| Licensing and contract revenue | 658 | 537 | 1,130 | 543 |
| Total revenues | 37,532 | 57,532 | 86,181 | 114,659 |
| Cost of goods sold (inclusive of amortization of intangibles) | 19,995 | 32,644 | 40,585 | 61,847 |
| Gross profit | 17,537 | 24,888 | 45,596 | 52,812 |
| Selling, general and administrative expenses | 16,555 | 25,511 | 37,731 | 47,168 |
| Research and development expenses | 5,771 | 5,360 | 11,459 | 15,125 |
| Impairment of intangibles | 3,618 | 125,766 | 3,618 | 125,766 |
| Total operating expenses | 25,944 | 156,637 | 52,808 | 188,059 |
| Operating loss | (8,407) | (131,749) | (7,212) | (135,247) |
| Interest expense and amortization of debt discount | 3,740 | 4,552 | 7,804 | 9,052 |
| Other non-operating (gain) loss | 659 | 15 | (87) | (542) |
| Total other non-operating expense | 4,399 | 4,567 | 7,717 | 8,510 |
| Loss before income taxes | (12,806) | (136,316) | (14,929) | (143,757) |
| Income tax benefit (expense) | (193) | 11,447 | (1,152) | 12,201 |
| Net and other comprehensive loss | $ (12,999) | $ (124,869) | $ (16,081) | $ (131,556) |
| Loss per share attributable to shareholders | | | | |
| Basic and Diluted | $ (0.22) | $ (2.38) | $ (0.27) | $ (2.50) |
| Weighted average shares basic and diluted | | | | |
| Basic and Diluted | 58,863,508 | 52,518,924 | 58,560,842 | 52,518,924 |

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

| | Six Months Ended June 30, | |
|---|---|---|
| | 2020 | 2019 |
| **CASH FLOWS FROM OPERATING ACTIVITIES** | | |
| Net loss | $ (16,081) | $ (131,556) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | |
| Depreciation and amortization | 11,150 | 35,991 |
| Share compensation | 2,328 | 2,496 |
| Loss on sale of fixed and leased assets | 212 | 53 |
| Impairment of intangibles | 3,618 | 125,766 |
| Deferred income tax benefit | 682 | (11,460) |
| Bad debt provision | 10 | (157) |
| Amortization of deferred financing and loan origination fees | 667 | 656 |
| Change in operating assets and liabilities: | | |
| Trade accounts receivable, net | 26,880 | (11,561) |
| Inventories, net | 1,004 | (3,492) |
| Prepaid expenses and other current assets | 2,454 | 6,816 |
| Trade accounts payable | 304 | (5,953) |
| Accrued and other current liabilities | (16,927) | (11,758) |
| Net cash provided by (used in) operating activities | 16,301 | (4,159) |
| **CASH FLOWS FROM INVESTING ACTIVITIES:** | | |
| Proceeds from sale of fixed and leased assets | 49 | - |
| Payments on disposal of leased assets | (138) | - |
| Purchase of property, plant and equipment | (1,591) | (2,091) |
| Net cash used in investing activities | (1,680) | (2,091) |
| **CASH FLOWS FROM FINANCING ACTIVITIES:** | | |
| Payments on finance lease obligations | (66) | (64) |
| Proceeds from public offering, net of issuance costs | 31,791 | - |
| Repurchases of ordinary shares | (1,086) | - |

| | | |
|---|---|---|
| Payments for taxes related to net share settlement of equity awards | (749) | - |
| Proceeds from insurance financing loan | - | 1,314 |
| Repayment of insurance financing loan | - | (2,097) |
| Net cash provided by (used in) financing activities | 29,890 | (847) |
| Net change in cash and cash equivalents | 44,511 | (7,097) |
| Cash and cash equivalents, beginning of period | 95,865 | 70,834 |
| Cash and cash equivalents, end of period | $ 140,376 | $ 63,737 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| Net loss | $ (12,999) | $ (124,869) | $ (16,081) | $ (131,556) |
| Interest expense and amortization of debt discount | 3,740 | 4,552 | 7,804 | 9,052 |
| Income tax benefit | 193 | (11,447) | 1,152 | (12,201) |
| Depreciation and amortization expense | 5,587 | 17,999 | 11,150 | 35,991 |
| EBITDA | (3,479) | (113,765) | 4,025 | (98,714) |
| Impairment of intangibles | 3,618 | 125,766 | 3,618 | 125,766 |
| Management fees | - | - | - | (43) |
| Severance expenses | 114 | 181 | 2,079 | 363 |
| FX translation | 63 | (11) | 122 | 211 |
| Legal expenses | - | 1,003 | - | 1,003 |
| Public offering expenses | 18 | - | 546 | - |
| Share compensation expense | 1,222 | 1,327 | 2,238 | 2,496 |
| Other | 733 | - | 733 | - |
| Adjusted EBITDA | $ 2,289 | $ 14,501 | $ 13,361 | $ 31,082 |

Source: Osmotica Holdings US LLC