Osmotica Pharmaceuticals plc Reports Second Quarter 2021 Results and Provides Business Update

August 16, 2021

Sale of legacy business to Alora Pharmaceuticals, LLC expected to close in third quarter 2021

Second quarter 2021 total Upneeq revenue of $11.5 million including a $10.0 million milestone payment from Santen Pharmaceutical Co., Ltd

Upneeq prescriptions nearly doubled in the second quarter compared to first quarter

BRIDGEWATER, N.J., Aug. 16, 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 ended June 30, 2021.

"With the announcement of the sale of our legacy assets to Alora, we took an important step in the transformation of our company. We will now be able to focus on maximizing the value of Upneeq, the first and only FDA-approved ophthalmic solution for the treatment of acquired blepharoptosis in adults. The response to Upneeq from eye care providers and patients alike, has been encouraging, and we are delighted that the initial enthusiasm for the brand has meaningfully converted into increased prescriptions and sales. Prescriptions in the second quarter nearly doubled from first-quarter levels, and we are seeing new prescribers come on stream every week," stated Brian Markison, Chief Executive Officer.

"Looking ahead, we are expanding our reach and depth in eyecare and finalizing our plans to launch into the ocular aesthetics market. We are also building upon the early success of our pharmacy and adding direct purchase options for our eyecare partners. This unique capability continues to provide exemplary customer service and meaningfully differentiate our business model. Our recently completed third-party consumer market research supports our belief in the large opportunity for Upneeq.

"We recently submitted an amended protocol for an arbaclofen Phase III study to the FDA. We look forward to working with the agency on the developmental plans for this product and the potentially meaningful benefits it can deliver to patients," concluded Markison.

Second Quarter 2021 Financial Highlights

Financial results for the Company's legacy assets are reported as discontinued operations in the Company's financial statements.

- Net loss:
  - Second quarter 2021 net loss from continuing operations was $22.0 million, compared to a net loss from continuing operations of $17.5 million in the second quarter of 2020;
  - Net income from discontinued operations, net of tax was $4.2 million.
- Total revenues:
  - Second quarter 2021 total revenues were $11.5 million and include a $10.0 million regulatory milestone payment under the Company's license agreement with Santen Pharmaceutical Co., Ltd, compared to revenues of $0.2 million in the second quarter of 2020.
- Upneeq second quarter highlights:
  - Over 7,000 unique prescribers, up 75% from first quarter 2021;
  - Paid prescriptions increased 85% to nearly 9,000 compared to the first quarter 2021.
- Adjusted EBITDA[1]:
  - Second quarter 2021 Adjusted EBITDA loss was $8.4 million, compared to Adjusted EBITDA loss of $15.3 million in the second quarter of 2020.
- Cash and cash equivalents were $99.8 million, and debt (net of deferred financing costs) was $214.7 million as of June 30, 2021.

[1]Adjusted EBITDA is a non-GAAP measure. Adjusted EBITDA is more fully described and reconciled from net loss from continuing operations 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 2021 Financial Results

Total revenues for the three months ended June 30, 2021 were $11.5 million, as compared to $0.2 million for the three months ended June 30, 2020 primarily due to a $10 million increase in license revenue.

Net product sales of Upneeq were $1.5 million for the three months ended June 30, 2021. As Upneeq was commercially launched in the third quarter of 2020, there were no net product sales in the three months ended June 30, 2020.

Licensing revenue was$10.0 million during the three months ended June 30, 2021 due to the achievement of a regulatory milestone under the license agreement with Santen Pharmaceutical Co. Ltd. We entered into our license agreement with Santen in the third quarter of 2020 and therefore did not have any licensing revenue in the prior year period.

Selling, general and administrative expenses increased to $21.0 million in the second quarter of 2021, compared to $14.3 million in the second quarter of 2020. The increase in selling, general and administrative expenses primarily reflects a salesforce expansion during the second quarter of 2021, higher marketing expenses associated with Upneeq, severance and other expenses related to the cessation of operations in the Company's subsidiary in Argentina and higher legal expenses in the three months ended June 30, 2020.

Research and development expenses decreased to $2.1 million in the second quarter of 2021, compared to $3.0 million in the second quarter of 2020, primarily reflecting lower spending on arbaclofen ER and Upneeq, partially offset by severance costs related to the cessation of operations in the Company's Argentine subsidiary during the quarter.

Other non-operating expenses increased to $1.7 million in the second quarter of 2021, compared to $1.4 million in the second quarter of 2020. The increase primarily reflected a disposal of fixed assets of our Argentine subsidiary during the quarter.

Net loss from continuing operation for the second quarter of 2021 was $22.0 million, compared to a net loss from continuing operations of $17.5 million in the second quarter of 2020.

Adjusted EBITDA loss for the second quarter of 2021 was $8.4 million, compared to Adjusted EBITDA loss of $15.3 million for the second quarter of 2020.

For a reconciliation of Adjusted EBITDA to net loss from continuing operations, 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, 2021, the Company had cash and cash equivalents of $99.8 million and borrowing availability under our revolving credit facility of $25.0 million. The Company also had debt of $214.7 million (net of deferred financing costs).

Presentation of Non-GAAP Measures

In addition to the results provided in accordance with GAAP throughout this press release, the Company has presented Adjusted EBITDA, which is a non-GAAP measurement. Adjusted EBITDA represents earnings before interest, taxes, depreciation and amortization ("EBITDA") adjusted for (i) non-operating income or expense, and (ii) the impact of certain non-cash, nonrecurring or other items that are included in net loss from continuing operations 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, disposals of fixed assets, 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 net loss from continuing operations 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 pending divestiture of our legacy assets, including the time we expect to close the transaction, 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 inability to compete our pending divestiture of our legacy assets, or at all; our ability to obtain additional funding to continue our operations; 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 second quarter 2021 conference call as follows:

Date	Monday, August 16, 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	1278168

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

IMPORTANT SAFETY INFORMATION

INDICATION

UPNEEQ® (oxymetazoline hydrochloride ophthalmic solution), 0.1% is indicated for the treatment of acquired blepharoptosis in adults.

WARNINGS AND PRECAUTIONS

- Ptosis may be associated with neurologic or orbital diseases such as stroke and/or cerebral aneurysm, Horner syndrome, myasthenia gravis, external ophthalmoplegia, orbital infection and orbital masses. Consideration should be given to these conditions in the presence of ptosis with decreased levator muscle function and/or other neurologic signs.
- Alpha-adrenergic agonists as a class may impact blood pressure. Advise UPNEEQ patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension or hypotension to seek medical care if their condition worsens.
- Use UPNEEQ with caution in patients with cerebral or coronary insufficiency or Sjögren’s syndrome. Advise patients to seek medical care if signs and symptoms of potentiation of vascular insufficiency develop.
- UPNEEQ may increase the risk of angle closure glaucoma in patients with untreated narrow-angle glaucoma. Advise patients to seek immediate medical care if signs and symptoms of acute narrow-angle glaucoma develop.
- Patients should not touch the tip of the single patient-use container to their eye or to any surface, in order to avoid eye injury or contamination of the solution.

ADVERSE REACTIONS

Adverse reactions that occurred in 1-5% of subjects treated with UPNEEQ were punctate keratitis, conjunctival hyperemia, dry eye, blurred vision, instillation site pain, eye irritation and headache.

DRUG INTERACTIONS

- Alpha-adrenergic agonists, as a class, may impact blood pressure. Caution in using drugs such as beta-blockers, anti-hypertensives, and/or cardiac glycosides is advised. Caution should also be exercised in patients receiving alpha adrenergic receptor antagonists such as in the treatment of cardiovascular disease, or benign prostatic hypertrophy.
- Caution is advised in patients taking monoamine oxidase inhibitors which can affect the metabolism and uptake of circulating amines.

About Osmotica Pharmaceuticals plc
Osmotica Pharmaceuticals plc (Nasdaq: OSMT) is a fully integrated specialty pharmaceutical company focused on the commercialization and development of products that target markets with underserved patient populations. RVL Pharmaceuticals, Inc. is the Company’s ophthalmic subsidiary supporting UPNEEQ®.

Osmotica has operations in the United States and Hungary.

Investor and Media Relations for Osmotica Pharmaceuticals plc

Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

-Financial tables follow-

Osmotica Pharmaceuticals plc
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		

Current assets:		
Cash and cash equivalents	$ 99,777	$ 114,053
Trade accounts receivable, net	645	1,583
Inventories, net	1,020	1,831
Prepaid expenses and other current assets	13,908	12,592
Assets held for sale	134,133	43,095
Total current assets	249,483	173,154
Property, plant and equipment, net	848	2,391
Operating lease assets	1,344	1,953
Intangibles, net	27,210	35,090
Goodwill	55,847	55,847
Other non-current assets	279	373
Assets held for sale	-	102,141
Total assets	$ 335,011	$ 370,949
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	$ 1,549	$ 3,129
Accrued liabilities	13,420	15,437
Current portion of debt, net of deferred financing costs	214,720	-
Current portion of obligation under finance leases	7	20
Current portion of lease liability	1,003	1,199
Income taxes payable - current portion	138	2
Liabilities held for sale	34,674	35,998
Total current liabilities	265,511	55,785
Long-term debt, net of non-current deferred financing costs	—	219,525
Long-term portion of lease liability	434	871
Income taxes payable-long term portion	1	—
Deferred taxes	611	345
Liabilities held for sale	—	567
Total liabilities	266,557	277,093
Commitments and contingencies		
Shareholders' equity		
Ordinary shares	628	625
Additional paid in capital	550,004	548,070
Accumulated deficit	(479,949)	(452,610)
Accumulated other comprehensive loss	(2,229)	(2,229)
Total shareholders' equity	68,454	93,856
Total liabilities and shareholders' equity	$ 335,011	$ 370,949

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,	
	2021	2020	2020	2019
Net product sales	$ 1,482	$ —	$ 2,255	$ -
Royalty revenue	28	234	190	464
Licensing revenue	10,000	—	10,000	-
Total revenues	11,510	234	12,445	464
Cost of goods sold	709	261	1,388	495
Gross profit	10,801	(27)	11,057	(31)
Selling, general and administrative expenses	21,047	14,337	38,002	32,384
Research and development expenses	2,052	2,953	4,256	7,375
Impairment of intangibles	7,880	-	7,880	-
Total operating expenses	30,979	17,290	50,138	39,759

Gain on sales of product rights, net	-	-	5,636	-
Operating loss	(20,178)	(17,317)	(33,445)	(39,790)
Interest expense and amortization of debt discount	494	1,239	1,015	2,489
Other non-operating (gain) loss	1,202	130	1,193	(87)
Total other non-operating expense	1,696	1,369	2,208	2,402
Loss before income taxes	(21,874)	(18,686)	(35,653)	(42,192)
Income tax expense (benefit)	94	(1,150)	90	(3,714)
Loss from continuing operations	(21,968)	(17,536)	(35,743)	(38,478)
Income from discontinued operations before income tax expense	4,454	5,880	9,153	27,262
Income tax expense - discontinued operations	213	1,343	752	4,866
Income from discontinued operations, net of tax	4,241	4,537	8,401	22,396
Net and other comprehensive loss	$ (17,727)	$ (12,999)	$ (27,342)	$ (16,082)
(Loss) income per share attributable to shareholders:				
Basic and Diluted - continuing operations	$ (0.35)	$ (0.30)	$ (0.57)	$ (0.66)
Basic and Diluted - discontinued operations	$ 0.07	$ 0.08	$ 0.13	$ 0.38
Basic and Diluted loss per share	$ (0.28)	$ (0.22)	$ (0.44)	$ (0.27)
Weighted average shares basic and diluted:				
Basic and Diluted	62,767,400	58,863,508	62,723,011	58,560,842

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

	Six Months Ended June 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss from continuing operations	$ (35,743)	$ (38,478)
Net income from discontinued operations	8,401	22,396
Net loss	(27,342)	(16,082)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	577	406
Share compensation	1,744	1,763
Loss on sale of fixed and leased assets	1,244	212
Impairment of intangibles	7,880	-
Deferred income tax benefit	267	682
Gain on sales of product rights, net	(5,636)	-
Amortization of deferred financing and loan origination fees	163	275
Write off of deferred financing fees in connection with prepayment	5	-
Change in operating assets and liabilities:		
Trade accounts receivable, net	939	(370)
Inventories, net	482	393
Prepaid expenses and other current assets	(2,074)	1,547
Trade accounts payable	(1,577)	(523)
Accrued and other current liabilities	(2,484)	(5,482)
Net cash used in operating activities - continuing operations	(25,812)	(17,179)
Net cash provided by operating activities-discontinued operations	11,404	33,480
Net cash provided by (used in) operating activities	(14,408)	16,301
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed and leased assets	25	49
Payments on disposal of leased assets	-	(138)
Proceeds from product rights disposal	7,300	-
Purchase of property, plant and equipment	(1,398)	(1,591)
Net cash provided by (used in) investing activities - continuing operations	5,927	(1,680)
Net cash provided by (used in) financing activities - discontinued operations	-	-
Net cash provided by (used in) investing activities	5,927	(1,680)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on finance lease obligations	(13)	(66)
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	(607)	(749)
Proceeds from purchases of stock under ESPP	139	-
Debt repayment	(5,300)	-
Net cash provided by (used in) financing activities - continuing operations	(5,781)	29,890
Net cash used in financing activities - discontinued operations	(14)	-
Net cash provided by (used in) financing activities	(5,795)	29,890
Net change in cash and cash equivalents - continuing operations	(25,666)	11,031
Net change in cash and cash equivalents - discontinued operations	11,390	33,480
Cash and cash equivalents, beginning of period	114,053	95,865
Cash and cash equivalents, end of period	$ 99,777	$ 140,376

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Net loss from continuing operations	$ (21,968)	$ (17,536)	$ (35,743)	$ (38,478)
Interest expense and amortization of debt discount	494	1,239	1,015	2,489
Income tax expense	94	(1,150)	90	(3,714)
Depreciation and amortization expense	285	211	577	406
EBITDA	(21,095)	(17,236)	(34,061)	(39,297)
Impairment of intangibles	7,880	-	7,880	-
Severance expenses	3,192	114	3,868	2,079
FX translation	(857)	63	(791)	122
Legal expenses	373	-	392	-
Gain on sale of product rights	-	-	(5,636)	-
Public offering expenses	-	18	-	546
Share compensation expense	901	1,018	1,744	1,763
Asset disposal charge	1,245	-	1,245	-
Other	11	714	21	714
Adjusted EBITDA	$ (8,350)	$ (15,309)	$ (25,338)	$ (34,073)