UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 15, 2021**

Osmotica Pharmaceuticals plc
(Exact name of registrant as specified in its charter)

Ireland	**001-38709**	**Not Applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

400 Crossing Boulevard **Bridgewater, NJ**	**08807**
(Address of principal executive offices)	(Zip Code)

(Registrant's telephone number, including area code): **(908) 809-1300**

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares	OSMT	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition.

On November 15, 2021, Osmotica Pharmaceuticals plc issued a press release announcing its financial results for the quarter ended September 30, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release issued by Osmotica Pharmaceuticals plc on November 15, 2021.
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

OSMOTICA PHARMACEUTICALS PLC

By: /s/ Brian Markison
Brian Markison
Chief Executive Officer

Date: November 15, 2021

Exhibit 99.1

FOR IMMEDIATE RELEASE

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

Third quarter Upneeq® product sales of $2.2 million, representing 47% growth over second quarter sales

Expansion of Upneeq launch continues with introduction of Direct Dispense program in eyecare and formation of Aesthetics business unit

Sale of legacy business and capital raises streamlined business and strengthened balance sheet

Bridgewater, NJ, November 15, 2021 – Osmotica Pharmaceuticals plc (Nasdaq: OSMT) ("Osmotica" or the "Company"), a specialty pharmaceutical company, today announced business highlights and financial results for the three months ended September 30, 2021.

"With the sale of our legacy business, we have accomplished our strategic goal of transforming the company into one focused on eyecare and medical aesthetics centered around Upneeq, (oxymetazoline hydrochloride ophthalmic solution) 0.1%, the first and only FDA-approved ophthalmic solution for the treatment of acquired blepharoptosis, or low-lying lids, in adults," stated Brian Markison, Chief Executive Officer.

"It is gratifying to see our efforts to build a new market in eyecare begin to flourish. On September 13, 2021, we introduced our Direct Dispense program to eyecare practitioners, and early responses have been encouraging. This program allows us to directly partner with our customers to serve their patients.

"Following our capital raise, we are taking steps to streamline the Company in order to ensure that our resources are driving growth. We are also on schedule with a build out of our medical aesthetics business unit with the hiring and training of key personnel with longstanding aesthetics industry experience. We plan to pilot our approach to the medical aesthetics market this quarter with a full launch expected early in the first quarter of next year.

"Last month we received a response from the FDA to our special protocol assessment submission for a new Phase III trial of arbaclofen extended-release tablets. We are encouraged by the constructive feedback from the agency and look forward to working with the FDA to come to an agreement on a path forward for the development program," Markison concluded.

Third Quarter 2021 Financial Highlights

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

- Upneeq third quarter highlights:
  - Sold over 26,500 thirty-count equivalent Upneeq units, up 62% over 16,400 in the second quarter 2021;
  - Initiated the Direct Dispense program, enrolling over 400 eyecare practices;
  - Over 9,800 cumulative unique prescribers, up 37% from second quarter 2021.
- Total revenues:
  - Third quarter 2021 total revenues were $2.2 million, compared to total revenues of $25.8 million in the third quarter of 2020, the decrease due to a regulatory milestone payment received from Santen Pharmaceutical Co., Ltd. in the prior year period.
- Net loss from continuing operations:
  - Third quarter 2021 net loss from continuing operations was $26.3 million, compared to a net income from continuing operations of $1.7 million in the third quarter of 2020;
  - Third quarter 2021 net income from discontinued operations, net of tax was $8.5 million.
- Adjusted EBITDA:[1]
  - Third quarter 2021 Adjusted EBITDA loss was $20.3 million, compared to Adjusted EBITDA of $9.1 million in the third quarter of 2020.
- Cash and cash equivalents were $8.4 million, and debt (net of deferred financing costs) was $29.9 million as of September 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."

Third Quarter 2021 Financial Results

Total revenues for the three months ended September 30, 2021 were $2.2 million, compared to $25.8 million for the three months ended September 30, 2020, primarily due to a $25.0 million regulatory milestone payment under the Company's license agreement with Santen Pharmaceutical Co., Ltd received in the prior year period.

Net product sales increased $1.6 million to $2.2 million for the three months ended September 30, 2021, compared to $0.6 million for the three months ended September 30, 2020. The increase was primarily attributable to an increase in sales of Upneeq, which was commercially launched in September 2020, partially offset by a decrease in product sales of Osmolex, reflecting the divestiture of the product in January 2021.

Selling, general and administrative expenses increased $3.4 million to $24.8 million in the third quarter of 2021, compared to $21.4 million in the third quarter of 2020. The increase in selling, general and administrative expenses primarily reflects a salesforce expansion during 2021, higher marketing expenses associated with the launch of Upneeq and an increase in share compensation expense triggered by the divestiture of the legacy business.

Research and development expenses decreased $0.4 million to $1.4 million in the third quarter of 2021, compared to $1.8 million in the third quarter of 2020, primarily reflecting lower spending on arbaclofen and lower R&D headcount costs, partially offset by higher spending on a new formulation of Upneeq and the acceleration of share compensation expense.

Net loss from continuing operation for the third quarter of 2021 was $26.3 million, compared to net income from continuing operations of $1.7 million in the third quarter of 2020.

Adjusted EBITDA loss for the third quarter of 2021 was $20.3 million, compared to Adjusted EBITDA of $9.1 million for the third 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 September 30, 2021, the Company had cash and cash equivalents of $8.4 million and debt of $29.9 million (net of deferred financing costs).

On October 1, 2021, the Company entered into a Note Purchase Agreement with several parties, which allows for the issuance of senior secured notes in an aggregate principal amount of up to $100 million payable in three separate tranches. The first tranche of $55 million was issued on October 12, 2021. At any time prior to October 12, 2022, upon the satisfaction of certain conditions, the Company may issue a second tranche of up to $20 million, with the issuance of a third tranche of up to $25 million any time prior to October 12, 2023 at the option of both the lender and the Company.

On October 12, 2021 the Company completed a follow-on offering of 14 million ordinary shares and warrants to purchase up to 14 million shares, at a public offering price of $2.50 per share and accompanying warrant. The warrants have an exercise price of $3.10 per share, are immediately exercisable, and will expire three and one-half years from the date of issuance. The Company granted the underwriter a 30-day option to purchase up to an additional 2.1 million shares and/or warrants to purchase additional 2.1 ordinary shares at the public offering price. On October 11, 2021 the underwriter exercised its option to purchase an additional 2.1 million warrants. The aggregate net proceeds from the follow-on offering were approximately $32.5 million after deducting underwriting commissions and offering expenses.

The Company's cash balance was approximately $53 million as of November 12, 2021.

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, share compensation expense, 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 results of operations, financial condition, liquidity, prospects, financial guidance, growth plan, strategies, trends and other events, particularly relating to sales of our product 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 dependence on Upneeq; our ability to successfully launch Upneeq into the medical aesthetics market; our ability to raise additional capital to continue our operations; our ability to successfully market and sell Upneeq; 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; the impact of competition from both other manufacturers or compounding pharmacies; any interruption at our pharmacy or at facilities operated by third parties that we rely on for our product; our ability to develop and maintain our sales capabilities; the impact of any litigation related to allegations of infringement of intellectual property; 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 Current Report on Form 8-K filed on September 8, 2021 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 2021 conference call as follows:

Date	Monday, November 15, 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, “Investor & News”
Conference call ID	6917339

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 betablockers, 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 specialty pharmaceutical company focused on the development and commercialization 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

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-Financial tables follow-

Osmotica Pharmaceuticals plc
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 8,352	$ 114,053
Accounts receivable, net	4,190	3,149
Inventories, net	824	1,831
Prepaid expenses and other current assets	10,019	12,592
Assets held for sale	-	41,529
Total current assets	23,385	173,154
Property, plant and equipment, net	851	2,391
Operating lease assets	1,651	1,953
Intangibles, net	27,210	35,090
Goodwill	55,847	55,847
Other non-current assets	603	373
Assets held for sale	-	102,141
Total assets	$ 109,547	$ 370,949
Liabilities and Shareholders' Equity		
Current liabilities:		
Trade accounts payable	$ 4,449	$ 3,128
Accrued liabilities	18,521	16,951
Current portion of debt, net of deferred financing costs	29,925	-
Current portion of obligation under finance leases	6	20
Current portion of lease liability	1,029	1,199
Income taxes payable - current portion	—	2
Liabilities held for sale	—	34,484
Total current liabilities	53,930	55,784
Long-term debt, net of non-current deferred financing costs	—	219,525
Long-term portion of lease liability	701	871
Income taxes payable-long term portion	1	—
Deferred taxes	165	345
Liabilities held for sale	—	568
Total liabilities	54,797	277,093
Commitments and contingencies		
Shareholders' equity		
Ordinary shares	631	625
Additional paid in capital	554,156	548,070
Accumulated deficit	(497,808)	(452,610)
Accumulated other comprehensive loss	(2,229)	(2,229)
Total shareholders' equity	54,750	93,856
Total liabilities and shareholders' equity	$ 109,547	$ 370,949

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,	
	2021	**2020**	**2021**	**2020**
Net product sales	$ 2,196	$ 586	$ 4,451	$ 998
Royalty revenue	—	165	190	629
Licensing revenue	—	25,000	10,000	25,000
Total revenues	2,196	25,751	14,641	26,627
Cost of goods sold	1,147	1,185	2,535	1,794
Gross profit	1,049	24,566	12,106	24,833
Selling, general and administrative expenses	24,841	21,360	63,769	54,028
Research and development expenses	1,376	1,779	5,789	9,264
Impairment of intangibles	-	-	7,880	-
Total operating expenses	26,217	23,139	77,438	63,292
Gain on sales of product rights, net	-	-	5,636	-
Operating income (loss)	(25,168)	1,427	(59,696)	(38,459)
Interest expense and amortization of debt discount	735	1,071	1,750	3,560
Other non-operating (gain) loss	120	(51)	1,312	246
Total other non-operating expense	855	1,020	3,062	3,806
Income (loss) before income taxes	(26,023)	407	(62,758)	(42,265)
Income tax expense (benefit)	324	(1,308)	415	(5,042)
Income (loss) from continuing operations	(26,347)	1,715	(63,173)	(37,223)
Gain on sales of discontinued operations, net	4,373	-	4,373	-
Income (loss) from discontinued operations before income tax expense	3,983	(10,171)	14,219	17,571
Income tax expense (benefit) - discontinued operations	(132)	177	617	5,063
Income (loss) from discontinued operations, net of tax	8,488	(10,348)	17,975	12,508
Net and other comprehensive loss	$ (17,859)	$ (8,633)	$ (45,198)	$ (24,715)
(Loss) income per share attributable to shareholders:				
Basic and Diluted - loss from continuing operations	$ (0.42)	$ 0.03	$ (1.01)	$ (0.62)
Basic and Diluted - income from discontinued operations	$ 0.13	$ (0.16)	$ 0.29	$ 0.21
Basic and Diluted loss per share	$ (0.28)	$ (0.14)	$ (0.72)	$ (0.41)
Weighted average shares basic and diluted:				
Basic	62,945,898	62,785,866	62,798,123	59,979,834
Diluted	62,945,898	63,285,258	62,798,123	59,979,834

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

	Nine Months Ended September 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss from continuing operations	$ (63,173)	$ (37,223)
Net income from discontinued operations	17,975	12,508
Net loss	(45,198)	(24,715)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	8,068	16,589
Share compensation	6,592	3,836
Loss on sale of fixed and leased assets	1,229	281
Impairment of intangibles	7,880	23,157
Deferred income tax benefit	(180)	(974)
Gain on sales of product rights, net	(5,636)	-
Gain on sales of discontinued operations, net	(4,373)	-
Bad debt provision	—	6
Amortization of deferred financing and loan origination fees	746	985
Write off of deferred financing and loan origination fees in connection with prepayment	1,387	496
Change in operating assets and liabilities:		
Accounts receivable, net	4,643	22,339
Inventories, net	2,256	(398)
Prepaid expenses and other current assets	(3,316)	4,741
Other non-current assets	(603)	-
Trade accounts payable	515	(586)
Accrued and other current liabilities	(4,347)	(19,915)
Net cash provided by (used in) operating activities	(30,337)	25,842
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of fixed and leased assets	40	50
Payments on disposal of leased assets	-	(209)
Proceeds from product rights disposal	7,300	-
Proceeds from discontinued operations	110,845	-
Purchase of property, plant and equipment	(1,657)	(2,213)
Net cash provided by (used in) investing activities	116,528	(2,372)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payments on finance lease obligations	(35)	(98)
Proceeds from public offering, net of issuance costs	36	62,440
Repurchases of ordinary shares	-	(4,835)
Payments for taxes related to net share settlement of equity awards	(767)	(749)
Proceeds from purchases of stock under ESPP	234	-
Debt repayment	(191,360)	(50,000)
Net cash provided by (used in) financing activities	(191,892)	6,758
Net change in cash and cash equivalents	(105,701)	30,228
Cash and cash equivalents, beginning of period	114,053	95,865
Cash and cash equivalents, end of period	$ 8,352	$ 126,093

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Net income (loss) from continuing operations	$ (26,347)	$ 1,715	$ (63,173)	$ (37,223)
Interest expense and amortization of debt discount	735	1,071	1,750	3,560
Income tax expense (benefit)	324	(1,308)	415	(5,042)
Depreciation and amortization expense	154	848	1,485	2,664
EBITDA	(25,134)	2,326	(59,523)	(36,041)
Impairment of intangibles	-	-	7,880	-
Severance expenses	769	271	4,656	2,349
FX translation	(28)	66	(819)	188
Legal expenses	221	1,719	612	2,265
Gain on sale of product rights, net	-	-	(5,636)	-
Share compensation expense	3,711	1,233	5,879	3,251
Asset disposal charge	-	-	1,245	-
License related milestone and transaction costs	-	3,296	-	3,296
Other	138	161	196	230
Adjusted EBITDA	$ (20,323)	$ 9,072	$ (45,510)	$ (24,462)