

---

---

**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): **May 9, 2019**

**Osmotica Pharmaceuticals plc**

(Exact name of registrant as specified in its charter)

**Ireland**  
(State or other jurisdiction of  
incorporation)

**001-38709**  
(Commission File Number)

**Not Applicable**  
(IRS Employer  
Identification No.)

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

**08807**  
(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))

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.

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

---

---

**Item 2.02 Results of Operations and Financial Condition.**

On May 9, 2019, Osmotica Pharmaceuticals plc issued a press release announcing its financial results for the quarter ended March 31, 2019. 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**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press Release issued by Osmotica Pharmaceuticals plc on May 9, 2019.</a>

**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/ Andrew Einhorn  
Andrew Einhorn  
Chief Financial Officer

Date: May 9, 2019



**Osmotica Pharmaceuticals plc Reports First Quarter 2019 Financial Results and Highlights Pipeline and Business Progress**

*First quarter 2019 total revenue of \$57.1 million; net loss of \$6.2 million*

*Positive topline results from second Phase III clinical trials of RVL-1201 for ptosis or droopy eyelid*

**Bridgewater, NJ, May 9, 2019** — Osmotica Pharmaceuticals plc (“Osmotica” or the “Company”) (Nasdaq: OSMT), a fully integrated biopharmaceutical company, today announced business highlights and financial results for the three months ended March 31, 2019.

“During the first quarter, and more recently, we made significant progress in our transition to a specialty branded business. We have made advances in our pipeline and experienced month-over-month prescription growth in our newly launched products, M-72 and Osmolex ER. Our non-promoted portfolio continued to generate meaningful cash despite the unfavorable competitive dynamics in generic markets,” said Brian Markison, Chief Executive Officer.

“As disclosed earlier in the week, we also completed two Phase III clinical trials for one of our late-stage pipeline products, RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%), which is in development for the treatment of acquired blepharoptosis (or droopy eyelid). We are very excited about the positive topline data from our recently completed clinical trials that provides additional evidence of the safety and efficacy of RVL-1201. We are preparing our submission to the FDA later this year, and, if approved, we could have a product on the market as soon as the second half of 2020,” added Markison.

**First Quarter 2019 Financial Results**

- Total revenues were \$57.1 million, compared to \$59.8 million in the first quarter of 2018;
- Net loss was \$6.2 million, compared to a net loss of \$4.6 million in the first quarter of 2018;
- Adjusted EBITDA(1) was \$16.4 million, compared to Adjusted EBITDA of \$20.5 million in the first quarter of 2018; and
- Cash and cash equivalents were \$63.1 million and debt (net of deferred financing costs) was \$267.9 million as of March 31, 2019.

---

(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.”

---

## First Quarter 2019 Financial Results

Total revenues were \$57.1 million for the three months ended March 31, 2019, compared to \$59.8 million for the three months ended March 31, 2018, primarily due to a decline in net product sales.

Net product sales were \$56.4 million for three months ended March 31, 2019, compared to \$58.8 million for the three months ended March 31, 2018, a decrease of \$2.4 million. This decrease was driven by lower net sales of methylphenidate ER, (first quarter 2019 includes M-72 which was launched in the second quarter of 2018), which decreased by 26% during the quarter compared to the prior year period due to increased market competition that resulted in lower net selling prices, partially offset by higher volumes. Net sales of VERT increased 46%, reflecting lower than estimated product returns and government rebates, partially offset by lower volumes.

Selling, general and administrative expenses increased to \$21.7 million in the three months ended March 31, 2019, compared to \$17.2 million in the three months ended March 31, 2018. The increase reflects additions to our field force headcount and marketing costs associated with the launch of Osmolex ER, which began in the fourth quarter of 2018, together with share-compensation expense and higher costs associated with being a public company.

Research and development expenses were \$9.8 million in the three months ended March 31, 2019, compared to \$10.2 million in the three months ended March 31, 2018. The decrease reflects the completion of the Phase III clinical trial of arbaclofen ER during the quarter, partially offset by the higher clinical trial expenses related to RVL-1201, additional developmental batch expenses and share-compensation expense.

Net loss for the first quarter of 2019 was \$6.2 million, compared to net loss of \$4.6 million in the first quarter of 2018.

Adjusted EBITDA for the first quarter of 2019 was \$16.4 million, compared to Adjusted EBITDA of \$20.5 million in the first quarter of 2018.

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 March 31, 2019, Osmotica had cash and cash equivalents of \$63.1 million and \$267.9 million in debt (net of deferred financing costs). The Company had \$50.0 million of unused borrowing capacity available under its revolving credit facility as of March 31, 2019.

---

## **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 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. Adjusted EBITDA excludes, share-based compensation expense, management fees, IPO expenses, severance expenses. 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, our ability to operate our business under our new capital and operating structure, and the sufficiency of our cash balances and cash generated from operating and financing activities for future liquidity and capital resource needs. By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place significant reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Important factors that could cause actual results and events to differ materially from those indicated in the forward-looking statements include the following: our ability to successfully develop or commercialize

---

new products, or do so on a timely or cost effective basis; our dependence on a limited number of products; failures of or delays in clinical trials or other delays in obtaining regulatory approval or commencing product sales for new products; the impact of legal proceedings; our ability to service our substantial debt; our ability to raise additional capital; the impact of competition from both brand and generic companies; any interruption at our manufacturing facility, our warehouses or at facilities operated by third parties that we rely on for our products; our dependence on our major customers; our ability to develop and maintain our sales capabilities; the impact of any litigation related to allegations of infringement of intellectual property; any changes to the coverage and reimbursement levels for our products by governmental authorities and other third-party payors as a result of healthcare reform or otherwise; the impact of any changes in the extensive governmental regulation that we face; manufacturing or quality control issues that we may face; and other risks and uncertainties more fully described in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2018 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 first quarter 2019 conference call as follows:

Date	Thursday, May 9, 2019
Time	4:30 p.m. EDT
Toll free (U.S.)	(866) 672-5029
International	(409) 217-8312
Webcast (live and replay)	<a href="http://www.osmotica.com">www.osmotica.com</a> , under the “Investor & News” section
Conference call ID	2984053

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. Our diversified product portfolio in the specialty neurology and women’s health therapeutic areas, together with our non-promoted complex formulations of generic drugs, form the foundation of our unwavering commitment to improve patients’ lives.

---

Osmotica has a late-stage development pipeline highlighted by two NDA candidates in Phase III clinical trials: arbaclofen extended-release tablets for spasticity in multiple sclerosis patients and RVL-1201 (oxymetazoline hydrochloride ophthalmic solution, 0.1%) for the treatment of blepharoptosis, or droopy eyelid.

Osmotica has operations in the United States, Argentina, 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](mailto:lwilson@insitecony.com)

-Financial tables follow-

---

**Osmotica Pharmaceuticals plc**  
**Condensed Consolidated Balance Sheets**  
(in thousands)

	March 31, 2019 (Unaudited)	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 63,062	\$ 70,834
Trade accounts receivable, net	56,887	56,424
Inventories, net	27,815	24,383
Prepaid expenses and other current assets	16,198	20,744
Total current assets	163,962	172,385
Property, plant and equipment, net	30,738	31,263
Operating lease assets	6,365	—
Intangibles, net	473,522	490,390
Goodwill	100,855	100,855
Other non-current assets	705	752
Total assets	\$ 776,147	\$ 795,645
<b>Liabilities and Shareholders Equity</b>		
Current liabilities:		
Trade accounts payable	\$ 20,591	\$ 24,870
Accrued liabilities	72,477	87,236
Current portion of long-term debt, net of deferred financing costs	795	1,774
Current portion of lease liability	2,007	—
Current portion of obligation under finance leases	125	119
Income taxes payable - current portion	496	394
Total current liabilities	96,491	114,393
Long-term debt, net of non-current deferred financing costs	267,080	266,803
Long-term portion of obligation under finance leases	120	138
Long-term portion of lease liability	4,577	—
Income taxes payable	1,804	1,804
Deferred taxes	24,837	26,238
Total liabilities	394,909	409,376
Commitments and contingencies		
Shareholders' equity		
Ordinary shares	525	525
Additional paid in capital	491,119	489,950
Accumulated deficit	(108,560)	(102,360)
Accumulated other comprehensive loss	(1,846)	(1,846)
Total shareholders' equity	381,238	386,269
Total liabilities and shareholders' equity	\$ 776,147	\$ 795,645

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

(in thousands, except share and per share data)

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Net product sales	\$ 56,400	\$ 58,834
Royalty revenue	721	963
Licensing and contract revenue	5	4
Total revenues	<u>57,126</u>	<u>59,801</u>
Cost of good sold (inclusive of amortization of intangibles)	<u>29,203</u>	<u>33,562</u>
Gross profit	<u>27,923</u>	<u>26,239</u>
Selling, general and administrative expenses	21,656	17,162
Research and development expenses	9,764	10,174
Total operating expenses	<u>31,420</u>	<u>27,336</u>
Operating loss	(3,497)	(1,097)
Interest expense and amortization of debt discount	4,501	4,843
Other non-operating income, net	(557)	(137)
Total other non-operating expense, net	<u>3,944</u>	<u>4,706</u>
Loss before income taxes	(7,441)	(5,803)
Income tax benefit	1,240	1,195
Net loss	<u>\$ (6,200)</u>	<u>\$ (4,607)</u>
Loss per share attributable to shareholders		
Basic and diluted	\$ (0.12)	(0.11)
Weighted average shares basic and diluted		
Basic and diluted	52,519	42,856

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

	<b>Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (6,200)	\$ (4,607)
Adjustments to reconcile net loss to cash (used in) provided by operating activities		
Depreciation and amortization	17,993	20,414
Share compensation	1,169	—
Loss on sale of fixed assets	53	—
Deferred income tax benefit	(1,401)	(3,296)
Bad debt provision	(84)	(100)
Amortization of deferred financing and loan origination fees	323	415
Change in operating assets and liabilities		
Trade accounts receivable, net	(378)	(23,251)
Inventories, net	(3,432)	(6,604)
Prepaid expenses and other current assets	4,545	3,100
Other non-current assets	—	(272)
Trade accounts payable	(4,279)	32,183
Accrued and other current liabilities	(14,436)	(10,880)
Net cash (used in) provided by operating activities	<u>(6,128)</u>	<u>7,102</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property, plant and equipment	(635)	(1,437)
Net cash used in investing activities	<u>(635)</u>	<u>(1,437)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Payments to affiliates	—	(2)
Payments on finance lease obligations	(31)	(27)
Repayment of insurance financing loan	(979)	—
Debt repayment	—	(2,047)
Net cash used in financing activities	<u>(1,010)</u>	<u>(2,076)</u>
Net change in cash and cash equivalents	(7,773)	3,589
Effect on cash of change in exchange rate	—	(138)
Cash and cash equivalents, beginning of period	70,834	34,743
Cash and cash equivalents, end of period	<u>\$ 63,062</u>	<u>\$ 38,194</u>

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

	Three Months Ended	
	March 31,	
	2019	2018
Net Loss	\$ (6,200)	\$ (4,607)
Interest expense and amortization of debt discount	4,501	4,843
Income tax benefit	(1,240)	(1,195)
Depreciation and Amortization Expense	17,993	20,414
EBITDA	15,053	19,455
Management Fees	(43)	250
IPO expenses		396
Severance expenses	182	445
Share compensation expense	1,169	—
Adjusted EBITDA	\$ 16,361	\$ 20,545