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): **December 29, 2020**

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 8.01 Other Events.

On December 29, 2020, Osmotica Pharmaceuticals plc (the "Company") issued a press release announcing that it received a Complete Response Letter from the U.S. Food and Drug Administration regarding the Company's New Drug Application for arbaclofen ER tablets for the alleviation of spasticity in multiple sclerosis.

The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Osmotica Pharmaceuticals plc on December 29, 2020

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: December 29, 2020

FOR IMMEDIATE RELEASE

Osmotica Pharmaceuticals plc Receives Complete Response Letter from U.S. Food and Drug Administration for Arbaclofen Extended Release Tablets

Bridgewater, NJ, December 29, 2020 – Osmotica Pharmaceuticals plc (Nasdaq: OSMT) ("Osmotica" or the "Company") today announced that the U.S. Food and Drug Administration ("FDA") has issued a Complete Response Letter ("CRL") regarding the Company's New Drug Application ("NDA") seeking approval for the investigational agent arbaclofen extended release (ER) tablets to treat spasticity resulting from multiple sclerosis.

The CRL stated that the Company did not provide adequate justification (including in its most recent NDA amendment) for the statistical analysis of the change from baseline to Day 84 in TNmAS-MAL scores comparing arbaclofen 40 mg to placebo, one of the co-primary endpoints. The FDA made a number of recommendations in its CRL, including that the Company conduct a new study in order to provide substantial evidence of efficacy of arbaclofen.

"We believe we have provided data supporting the efficacy and safety for both the 40 mg/day and 80 mg/day doses of arbaclofen. There is a tremendous unmet need for better treatments to help MS patients cope with spasticity, and we believe our safety and efficacy database for both strengths of arbaclofen provides a meaningful body of evidence that should support approval," said Brian Markison, CEO of Osmotica.

The Company intends to review the CRL with its advisors and to request a meeting with the FDA to discuss their recommendations.

About Arbaclofen ER

Osmotica Pharmaceutical plc is developing arbaclofen (the active R-enantiomer of baclofen) ER tablets for the treatment of spasticity in patients with MS. This program aims to demonstrate the clinical efficacy and safety of arbaclofen ER tablets in patients with spasticity due to MS.

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. 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.

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; 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, June 30, 2020 and September 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.

Investor and Media Relations for Osmotica Pharmaceuticals plc

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