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 18, 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 18, 2020, Osmotica Pharmaceuticals plc (the "Company") submitted an amendment to its New Drug Application (the "NDA") for arbaclofen ER tablets for the alleviation of spasticity in multiple sclerosis under consideration by the U.S. Food and Drug Administration (the "FDA"). The amendment was submitted in response to a letter sent by the FDA to the Company on December 4, 2020, as part of FDA's ongoing review of the NDA.

The Company intends to continue its discussions with the FDA to resolve the issues raised in its December 4, 2020 letter. However, at this time it is likely that the FDA will continue to review the NDA past the previously announced user goal date of 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 21, 2020