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 23, 2019

ZOSANO PHARMA CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	001-36570	45-4488360
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

34790 Ardentech Court
Fremont, CA 94555
(Address of principal executive offices) (Zip Code)

(510) 745-1200
(Registrant's telephone number, include area code)

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 Exchange Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value	**ZSAN**	**The Nasdaq Stock 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 23, 2019, Zosano Pharma Corporation (the "Company") announced the submission of a 505(b)(2) New Drug Application ("NDA") for Qtrypta™ to the U.S. Food and Drug Administration ("FDA") for the acute treatment of migraine.

Based on the Company's NDA submission on Friday, December 20, 2019, the company expects to receive notification from the FDA confirming whether the submission was accepted for filing for substantive review in March 2020.

The submission is supported by the results of the ZOTRIP pivotal Phase 2/3 clinical study, in which 41.5% of patients treated with the 3.8 mg dose of Qtrypta achieved pain freedom at 2 hours and 68.3% reported freedom from most bothersome symptom at 2 hours, both of which were co-primary endpoints. Additionally, 80.5% of patients reported pain relief at 2 hours, a secondary endpoint. The results of the study were published in *Cephalalgia* in October 2017.

A post-hoc analysis showing that Qtrypta reduced pain in subjects with difficult to treat migraines was published in *Headache: The Journal of Head and Face Pain* in February 2019.

Additionally, in the Phase 3 safety study, the most frequently reported adverse events were redness and swelling at the application site. Of these, 95% were reported as mild, and more than 80% resolved within 48 hours. Less than 2% of patients reported triptan-like neurological side effects typically found in the class, such as dizziness and paresthesia.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements regarding the expected acceptance for filing by the FDA of the NDA for Qtrypta and the relating timing and other future events and expectations. Readers are urged to consider statements that include the words "may," "will," "would," "could," "should," "might," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal," "unaudited," "approximately" or the negative of those words or other comparable words to be uncertain and forward-looking. These statements are subject to risks and uncertainties that are difficult to predict, and actual outcomes may differ materially. These include risks and uncertainties, without limitation, associated with the NDA submission process, including that the information provided in the NDA will not be sufficient for the FDA to file and substantively review the application, the process of discovering, developing and commercializing products that are safe and effective for use as human therapeutics, risks inherent in the effort to build a business around such products and other risks and uncertainties described under the heading "Risk Factors" in the Company's most recent quarterly report on Form 10-Q. Although the Company believes that the expectations reflected in these forward-looking statements are reasonable, the Company cannot in any way guarantee that the future results, level of activity, performance or events and circumstances reflected in forward-looking statements will be achieved or occur. All forward-looking statements are based on information currently available to the Company and the Company assumes no obligation to update any such forward-looking statements.

SIGNATURE

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.

Date: December 23, 2019

ZOSANO PHARMA CORPORATION

By: /s/ Gregory Kitchener
Gregory Kitchener
Chief Financial Officer