

**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): September 9, 2019

ZOSANO PHARMA CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36570
(Commission
File Number)

45-4488360
(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, including 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 (see General Instruction A.2. below):

- 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 September 9, 2019, Zosano Pharma Corporation (the “Company”) announced an oral presentation and two poster presentations of positive data from a one-year long-term safety study of Qtrypta™ (M207) for the acute treatment of migraine were presented at the 19th Congress of the International Headache Society (“IHC”) in Dublin, Ireland. The Qtrypta long-term safety study was an open-label trial evaluating the safety of a 3.8 mg dose of intracutaneous zolmitriptan in adults with migraine who had historically experienced at least 2 migraine attacks per month.

An oral presentation by Stephanie Nahas, M.D., M.S.Ed., of Thomas Jefferson University reviewed an analysis of the approximately 6,000 attacks treated over one year with Qtrypta for the acute treatment of migraine. Following treatment with Qtrypta, 44% of patients reported pain freedom from the attacks and 62% of patients reported freedom from the most bothersome symptoms at two hours, which is consistent with the positive clinical results seen in the Phase 2/3 pivotal study.

Data from safety assessments showed that Qtrypta was well-tolerated throughout the 12 months of repeated use. The most common adverse events were redness and swelling at the application site of which more than 95% were classified as mild. 80% of these site reactions were gone within 48 hours. Patients treated with Qtrypta reported less triptan-like neurological side effects than are typically found with the class, with less than 2% of patients reporting effects such as dizziness and paresthesia.

Two late-breaking posters were also presented at the IHC congress. The first analyzed data from six patients enrolled in the long-term safety study who received prophylactic anti-CGRP antibodies and subsequently took Qtrypta for the acute treatment of their migraine attacks. 76% of the patients reported pain freedom and 88% reported freedom from the most bothersome symptoms at two hours. These preliminary data suggest that Qtrypta has the potential to be effective for the acute treatment of breakthrough migraine attacks in patients receiving prophylactic treatment with anti-CGRP antibody therapy.

The second poster presentation reviewed safety data from the 22 study participants who were on serotonergic drugs while taking Qtrypta for the acute treatment of migraine, and there were no reports of serotonin syndrome.

The Company expects to file a New Drug Application for Qtrypta in the fourth quarter of 2019.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements regarding the potential effects and safety of Qtrypta (M207), the expected timing of a New Drug Application for Qtrypta (M207) 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 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, we 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.

ZOSANO PHARMA CORPORATION

Dated: September 9, 2019

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