# 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): March 4, 2020**

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

| **Delaware** | **001-36570** | **45-4488360** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(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, 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 Exchange Act:

| **Title of each class** | **Trading Symbol(s)** | **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 x

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. x

**Item 8.01. Other Events.**

On March 4, 2020, Zosano Pharma Corporation (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") accepted the Company's New Drug Application (the "NDA") for Qtrypta™ for filing and substantive review.

The Prescription Drug User Fee Act goal date for the completion of the FDA's review of Qtrypta™ is set for October 20, 2020. This date reflects a standard 10-month review period and is consistent with the review timeline for a 505(b)(2) NDA submission.

The NDA is supported by the clinical results of the ZOTRIP pivotal Phase 2/3 clinical study, which evaluated the efficacy, safety and tolerability of Qtrypta™ compared to placebo. A total of 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 also 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 migraine attacks was published in *Headache: The Journal of Head and Face Pain* in February 2019.

Additionally, in the Phase 3 long term safety study, the most frequently reported adverse event was redness at the application site. Of these adverse events, 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 NDA for Qtrypta™ and other future events and expectations. 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, 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.

**ZOSANO PHARMA CORPORATION**

Date: March 4, 2020

By: /s/ Christine Matthews

Name: Christine Matthews

Title: Interim Chief Financial Officer