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 29, 2020

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 September 29, 2020, Zosano Pharma Corporation (the "Company") received a discipline review letter ("DRL") from the U.S. Food and Drug Administration ("FDA") in connection with the Qtrypta™ (zolmitriptan transdermal microneedle system) 505(b)(2) New Drug Application ("NDA"). A DRL letter is used by the FDA to convey preliminary thoughts on deficiencies identified during the NDA review with respect to a particular review discipline.

The DRL described two concerns with respect to the clinical pharmacology section of the NDA. First, the FDA raised questions regarding unexpected high plasma concentrations of zolmitriptan observed in five study subjects from two pharmacokinetic studies, and how the data from these subjects affect the overall clinical pharmacology section of the application. Second, the FDA raised questions regarding differences in zolmitriptan exposures observed between subjects receiving different lots of Qtrypta in the Company's clinical trials.

Although a DRL reflects preliminary comments that are subject to change, and does not reflect the FDA's final decision on the NDA, approval of Qtrypta by the Prescription Drug User Fee Act goal date of October 20, 2020 is not expected given the letter.

As of September 29, 2020, the Company had approximately $43.4 million in cash and cash equivalents. This cash and cash equivalents information is preliminary and subject to completion, including the completion of customary financial statement closing and review procedures for the quarter ending September 30, 2020. As a result, the preliminary information set forth above reflects the Company's preliminary estimate with respect to such information, based on information currently available to management, and may vary from the Company's actual cash and cash equivalents as of September 29, 2020.

Forward-Looking Statements

This report contains forward-looking statements. All statements other than statements of historical facts contained herein are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the Company's cash and cash equivalents as of September 29, 2020 and the Company's expectations with respect to approval of Qtrypta by the Prescription Drug User Fee Act goal date. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause the Company's actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the Company's business in general, see the most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. The Company does not plan to publicly update or revise any forward-looking statements contained in this report, whether as a result of any new information, future events, changed circumstances or otherwise, except as required by law.

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: September 30, 2020

ZOSANO PHARMA CORPORATION

By: /s/ Christine Matthews
Christine Matthews
Chief Financial Officer