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): October 20, 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 October 20, 2020, Zosano Pharma Corporation (the "Company") received a complete response letter ("CRL") 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").

The CRL cited inconsistent zolmitriptan exposure levels observed across clinical pharmacology studies, which had been previously identified in the FDA's discipline review letter received by the Company in September. Specifically, the CRL noted differences in zolmitriptan exposures observed between subjects receiving different lots of Qtrypta in the Company's trials and inadequate pharmacokinetic bridging between the lots that made interpretation of some safety data unclear. The CRL referenced unexpected high plasma concentrations of zolmitriptan observed in five study subjects enrolled in the Company's pharmacokinetic studies. The FDA recommended that the Company conduct a repeat bioequivalence study between three of the lots used during development. The NDA included data on a total of 774 subjects across 5 trials who were administered or dosed with Qtrypta.

The CRL noted that additional product quality validation data, which were planned to be submitted following approval, if received, were required to be submitted with the application. In addition, the CRL mentioned that due to U.S. Government and/or Agency-wide restrictions on travel, inspections of the Company's contract manufacturing facilities were not able to be conducted but would be required before the application may be approved.

The Company plans to request a Type A meeting with the FDA to discuss strategies to address the FDA's comments.

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, the Company's plan to request a Type A meeting with the FDA to discuss strategies to address the FDA's comments in the CRL. 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: October 21, 2020

ZOSANO PHARMA CORPORATION

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