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): January 29, 2021

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 February 1, 2021, Zosano Pharma Corporation issued a press release announcing that a Type A meeting with the U.S. Food and Drug Administration ("FDA") was held on January 29, 2021, during which the Company and the FDA discussed the requirements for resubmission of the Qtrypta™ (zolmitriptan transdermal microneedle system) 505(b)(2) New Drug Application following the complete response letter received on October 20, 2020. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

	Description
99.1	Press Release dated February 1, 2021 titled "Zosano Pharma Announces NDA Resubmission Plans Following Type A Meeting with FDA"
104.1	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 1, 2021

ZOSANO PHARMA CORPORATION

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

Zosano Pharma Announces NDA Resubmission Plans Following Type A Meeting with FDA

FREMONT, Calif., February 1, 2021 (GLOBE NEWSWIRE) — Zosano Pharma Corporation (NASDAQ:ZSAN), a clinical-stage biopharmaceutical company, today announced that the company completed its Type A meeting with the U.S. Food and Drug Administration ("FDA") Division of Neurology II (the "Division") regarding the requirements for resubmission of the Qtrypta™ (zolmitriptan transdermal microneedle system) 505(b)(2) New Drug Application ("NDA") following the Complete Response Letter received on October 20, 2020.

Based on feedback from the Type A meeting held with the Division, the company plans to conduct an additional pharmacokinetic ("PK") study for inclusion in an NDA resubmission package. During the meeting, the Division did not request that the company conduct any further clinical efficacy studies to support the resubmission. Prior to initiating the PK study, the company plans to submit the study protocol to the Division for additional comment and review. The Division indicated willingness to review the study protocol and provide comments prior to the initiation of the study. The company's plans for resubmitting the NDA are based on the discussions between the company and the Division during the Type A meeting and may be subject to change upon receipt of the FDA's official meeting minutes from the Type A meeting.

"We appreciate the FDA's willingness to discuss our application, and the Division providing confirmation that an additional PK study will be necessary to resubmit the NDA for Qtrypta," said Steven Lo, President and CEO of Zosano. "We are working to have a protocol for the PK study finalized this quarter. We look forward to initiating and completing the study, and ultimately resubmitting our NDA application. Qtrypta leverages our proprietary microneedle technology that has been supported by data from five trials in 774 subjects, and we are encouraged by its potential to treat patients with debilitating migraines."

About Zosano Pharma

Zosano Pharma Corporation is a clinical-stage biopharmaceutical company focused on developing products where rapid administration of approved molecules with established safety and efficacy profiles may provide substantial benefit to patients, in markets where patients remain underserved by existing therapies. The company's transdermal microneedle system technology consists of titanium microneedles coated with drug that are designed to enable rapid systemic administration of therapeutics to patients. Zosano's lead product candidate is Qtrypta™ (M207), which is a proprietary formulation of zolmitriptan designed to be delivered via its transdermal microneedle system technology, as an acute treatment for migraine. Learn more at www.zosanopharma.com.

Forward-Looking Statements

This press release 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 plans to conduct an additional PK study, the outcomes of the Type A Meeting as will be reflected in the FDA's forthcoming official meeting minutes, including the feedback from the FDA suggesting that an additional PK study will be necessary to resubmit the NDA for Qtrypta and the lack of any request for additional clinical efficacy studies, timing of protocol finalization, initiation, and completion of the PK study, plans for resubmission of the company's Qtrypta NDA to the FDA, the potential benefits of Qtrypta for patients and other future

events and expectations described in this press release. 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,” “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 related to any differences between the company’s understanding of the FDA’s feedback during the Type A meeting and the official meeting minutes from the meeting and other risks and uncertainties, without limitation, associated with the company’s ability to obtain additional cash resources to continue operations, 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 annual report on Form 10-K and quarterly reports on Form 10-Q. Although Zosano believes that the expectations reflected in these forward-looking statements are reasonable, Zosano 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 Zosano and Zosano assumes no obligation to update any such forward-looking statements.

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