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 18, 2022

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:

☐ 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 ☐

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 January 18, 2022, Zosano Pharma Corporation ("Zosano" or the "Company") resubmitted its M207 (zolmitriptan transdermal microneedle system) 505(b)(2) New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") following the Complete Response Letter received on October 20, 2020.

In line with the Company's previously disclosed resubmission strategy, the NDA has been resubmitted under Section 505(b)(2) of the Food, Drug, and Cosmetic Act and relies on the FDA's findings of safety and efficacy of ZOMIG® nasal spray (NDA 21-450) ("Listed Drug"). The resubmitted NDA relies primarily on data from the recently completed Phase 1 pharmacokinetic ("PK") study (CP 2021-001), along with previous PK studies evaluating M207 (CP-2018-002 and CP-2019-002), to establish a PK bridge to the Listed Drug, with the goal of establishing comparative bioavailability to the Listed Drug. Prior to the resubmission, the FDA provided Zosano with written feedback which, among other things, noted concerns regarding the Company's approach for establishing a PK bridge to the Listed Drug through comparisons across multiple PK studies of M207, particularly Study CP-2019-002, which included PK outliers.

Zosano believes that the data provided in its resubmitted NDA demonstrates an adequate bridge to the Listed Drug. With this resubmission that includes additional PK data from our CP 2021-001 study, the FDA can evaluate and determine the adequacy of the data package to potentially support M207 approval.

Forward Looking Statements

This current report on Form 8-K 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 resubmission strategy of the M207 NDA and other future events and expectations described in this report. 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," "scheduled," "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, without limitation, associated with the Company's ability to obtain additional cash resources to continue operations, the possibility that FDA will require additional studies in support of the M207 NDA resubmission, 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.

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: January 24, 2022

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