

**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): February 17, 2022

ZOSANO PHARMA CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36570
(Commission
File Number)

45-4488360
(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 17, 2022, Zosano Pharma Corporation (“Zosano” or the “Company”) received a response letter from the U.S. Food and Drug Administration (“FDA”) with regard to the Company’s January 18, 2022 resubmission of the 505(b)(2) New Drug Application for M207 (zolmitriptan microneedle system) (“M207 NDA”). The response letter stated that the FDA did not consider the resubmitted M207 NDA to be a complete response to the deficiencies identified in the FDA’s October 19, 2020 Complete Response Letter, and that the FDA will not begin substantive review of the application until a complete response is received.

Among other things, the FDA’s response letter stated that the Company’s strategy for establishing a pharmacokinetic (“PK”) bridge to Zomig Nasal Spray 5 mg (“Zomig NS”) by relying primarily on data from the Company’s recently completed Phase 1 PK study (“Study CP-2021-001”) was not acceptable, due in part to differences between the design of Study CP-2021-001, which compared the PK of M207 to two sequential doses of 5 mg Zomig NS, and the criteria for re-dosing set forth in the labeling instructions for 5 mg Zomig NS.

The FDA’s response letter described alternative methods through which the Company may establish a PK bridge to 5mg Zomig NS, including: (i) by demonstrating bioequivalence to Zomig NS using standard criteria for all PK exposure metrics, including through a combination of relevant PK data and modeling or simulation procedures; or (ii) by conducting a relative bioavailability study in healthy volunteer subjects.

The Company is evaluating next steps in relation to the FDA’s response letter as part of its financial and strategic planning; however, there can be no assurances that the Company’s resources will enable the Company to continue to pursue FDA approval of M207. As previously disclosed, the Company has retained SierraConstellation Partners, LLC as an independent financial advisor to assist in exploring financial and strategic alternatives to maximize value, which may include, but not be limited to, asset or equity sales, joint venture and partnership opportunities, and restructuring, amendment or refinancing of existing liabilities, and is evaluating various alternatives to improve its liquidity. However, there can be no assurances that the Company will achieve any of these objectives.

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 evaluation of next steps in relation to the FDA’s response letter, capital requirements, exploration of financial and strategic alternatives to maximize value 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 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.

Date: February 18, 2022

ZOSANO PHARMA CORPORATION

By: /s/ Christine Matthews

Christine Matthews

Chief Financial Officer