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 28, 2021

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, 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 1.01. Entry into a Material Definitive Agreement.

On September 28, 2021, Zosano Pharma Corporation (the "Company") entered into an Amendment No. 1, effective as of September 29, 2021 (the "Amendment"), to the Master Services Agreement with Eversana Life Science Services, LLC, dated August 6, 2020 (the "MSA"), which provides that either party may terminate the MSA if New Drug Application ("NDA") approval is not received by December 31, 2021, with written notice within sixty days of such date. In addition, the Amendment provides that if the NDA is approved, the deferral mechanism, payment terms and loan terms in the MSA will be adjusted as mutually agreed by both parties.

The foregoing description of the Amendment is not complete and is qualified in its entirety by reference to the full text of such Amendment, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 8.01. Other Events.

On October 4, 2021, the Company announced that it has been granted a Type C written response only meeting with the U.S. Food and Drug Administration regarding the resubmission of the M207 (zolmitriptan transdermal microneedle system) 505(b)(2) NDA following receipt of preliminary top-line results from the pharmacokinetic study. 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
10.1	Amendment No. 1, effective as of September 29, 2021, to Master Services Agreement by and between the Company and Eversana Life Science Services, LLC
99.1	Press Release dated October 4, 2021 titled "Zosano Pharma Granted Type C Meeting with FDA Regarding NDA Resubmission for M207 Following Preliminary Top-Line Pharmacokinetic Study Results"
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: October 4, 2021

ZOSANO PHARMA CORPORATION

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

Exhibit 10.1

AMENDMENT NO. 1 TO MASTER SERVICES AGREEMENT

THIS AMENDEMENT NO. 1 TO MASTER SERVICES AGREEMENT (this "Amendment") is entered into as of September 29, 2021 (the "Amendment Effective Date"), by and between **ZOSANO PHARMA CORPORATION**, with its principal offices located at 34790 Ardentech Court, Fremont, California 94555 ("**Zosano**") and **EVERSANA LIFE SCIENCES SERVICES, LLC**, a Wisconsin limited liability company, with its principal offices located at 190 North Milwaukee Street, Milwaukee,
Wisconsin 53202 ("**Eversana**").

BACKGROUND

WHEREAS, Zosano and Eversana entered into a Master Services Agreement, effective August 6, 2020 (the "Agreement");

WHEREAS, Zosano and Eversana desire to revise the Agreement in accordance with the terms and conditions contained herein;

WHEREAS, the Agreement as amended is in full force and effect; and

WHEREAS, except as may be expressly provided otherwise in this Amendment, capitalized terms in this Amendment have the meaning set forth in the Agreement.

NOW, THEREFORE, in consideration of the mutual promises hereinafter set forth, and intending to be legally bound hereby, Zosano and Eversana agree as follows:

1. Section 14.2(b) of the Agreement is deleted in its entirety and replace with the following:

"**Termination for Late Approval**. Either Party shall have the right to terminate this Agreement if NDA Approval does not occur by December 31, 2021 effectively upon providing written notice to the other Party within sixty (60) days after such date (such notice to be effective upon receipt thereof by the other Party).

2. The Parties agree and acknowledge that, upon FDA approval, the deferral mechanism, payment terms, and loan terms in the Agreement, including without limitation, Section 5 and Exhibit F of the Agreement shall be adjusted as mutually agreed by both Parties.

3. Entire Amendment. This Amendment sets forth the entire agreement of the Parties with respect to the subject matter set forth herein and may not be modified other than by an agreement in writing signed by the Parties hereto or their respective successors in interest.

4. Acknowledgment. The Parties hereto each acknowledge that except as expressly modified by this Amendment, all the terms and conditions of the Agreement remain unchanged and are in full force and effect and enforceable in accordance with their terms. In the event of a conflict between the Agreement and this Amendment, the terms and provisions of this Amendment control.

5. Counterparts; Electronic Signatures**.** The Parties acknowledge and agree that this Amendment may be signed (a) in any number of counterparts, which may be transmitted by facsimile or PDF, all of which taken together constitutes one and the same instrument; and (b) electronically using an e-signature program or service; and (c) for all purposes, including but not limited to admissibility, enforceability and validity, treat the counterpart facsimiles or PDFs and electronic signatures as if those documents were signed by hand and the electronic signatures were hand-written signatures.

IN WITNESS WHEREOF, the undersigned, intending to be legally bound, has duly executed this Agreement as of the date first above written.

ZOSANO PHARMA CORPORATION

By: /s/ Steven Lo
Name: Steven Lo
Title: President & Chief Executive Officer

EVERSANA LIFE SCIENCES SERVICES, LLC

By: /s/ Gregory Skalicky
Name: Gregory Skalicky
Title: Chief Revenue Officer

(Signature Page to Amendment No. 1 to MSA)

Zosano Pharma Granted Type C Meeting with FDA Regarding NDA Resubmission for M207 Following Preliminary Top-Line Pharmacokinetic Study Results

FREMONT, Calif., October 4, 2021 — Zosano Pharma Corporation (NASDAQ:ZSAN), a clinical-stage biopharmaceutical company, today announced the company has been granted a Type C written response only meeting with the U.S. Food and Drug Administration ("FDA") regarding the resubmission of the M207 (zolmitriptan transdermal microneedle system) 505(b)(2) New Drug Application ("NDA") following receipt of preliminary top-line results from the pharmacokinetic ("PK") study.

The PK study included 48 healthy volunteers and evaluated approximately 2,500 samples utilizing lots of M207 produced with two different pieces of manufacturing equipment ("equipment A" and "equipment B"). The study was designed to evaluate safety and the pharmacokinetics of drug exposure levels compared to an intranasal control formulation of two 5 mg doses of zolmitriptan. The safety assessment showed that M207 was generally well tolerated, consistent with previous studies. The preliminary data from the PK analysis showed that there were no outliers with unexpected high plasma concentrations of zolmitriptan, which was a focus of the FDA, as identified in the Complete Response Letter for the original M207 NDA. Drug plasma concentration levels from M207 produced with equipment A were within range and comparable to the intranasal control. Drug plasma concentration levels of M207 produced with equipment B were lower compared to control and to M207 produced by equipment A, but within ranges consistent with approved therapeutic dose levels of zolmitriptan. The FDA had also raised questions regarding differences in zolmitriptan exposures observed between subjects receiving different lots of M207 in the company's clinical trials.

"We are pleased that the preliminary top-line PK study results did not identify any outliers with unexpected high plasma concentrations of zolmitriptan," said Steven Lo, president and chief executive officer of Zosano. "We requested a meeting with the FDA to review the data, including the preliminary bioequivalence data from the lots produced with the different manufacturing equipment, and, following written feedback from the FDA from the Type C meeting, we plan to refine our strategy for the resubmission of an NDA. We look forward to providing an update on our resubmission plans after we receive written feedback from the FDA, which is expected to occur by mid-December. There are thousands of people experiencing migraine attacks in the U.S. that are not adequately served by existing therapies, and we believe in the potential of M207 to provide much-needed relief from this disease."

Unless and until the company resubmits an NDA and potentially receives FDA approval, the company is unable to estimate a timeframe for product launch or revenues for 2022, if any, or beyond.

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 M207, which is a proprietary formulation of zolmitriptan designed to be delivered via its transdermal microneedle system technology, as an acute treatment for migraine. Previously, M207 was known as Qtrypta, which the company no longer intends to use as the proprietary name of M207. The company is currently in the process of identifying an alternative proprietary name for M207. 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 preliminary results from the company's pharmacokinetic study, the timing of written feedback from the Type C meeting with the FDA, plans to refine the company's strategy for the resubmission of an NDA and the timing of an update on resubmission plans, the potential benefits and availability of M207 for patients, the expectations for identifying a proprietary name for M207 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," "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.

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