

**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): November 10, 2021

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, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 2.02 Results of Operations and Financial Condition.

On November 10, 2021, Zosano Pharma Corporation issued a press release titled “Zosano Pharma Reports Third Quarter 2021 Financial Results.” The press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 2.02.

The information in Item 2.02 of this Form 8-K (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Press release dated November 10, 2021, titled “Zosano Pharma Reports Third Quarter 2021 Financial 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.

ZOSANO PHARMA CORPORATION

Date: November 10, 2021

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

Zosano Pharma Reports Third Quarter 2021 Financial Results

FREMONT, Calif., November 10, 2021 -- Zosano Pharma Corporation (NASDAQ:ZSAN), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2021, as well as business highlights.

"This quarter we made significant progress towards the resubmission of the NDA for M207 with receipt of top-line data from our pharmacokinetic study," said Steven Lo, president and chief executive officer of Zosano. "We expect to receive written feedback from the FDA through a Type C meeting by mid-December and expect that their feedback will enable us to further refine our regulatory strategy and to provide an update on our resubmission plans for the NDA. We believe there is a significant need for new acute treatment options for migraine as it is estimated that more than 70% of migraine patients experience an inadequate treatment response, and our goal is to help these patients."

Select Business Highlights

- Reported top-line results from a pharmacokinetic study, which evaluated the safety and pharmacokinetics of drug exposure levels of two lots of M207 compared to an intranasal control formulation of two 5 mg doses of zolmitriptan in 48 healthy volunteers
- Granted a Type C (written response only) meeting with the U.S. Food and Drug Administration ("FDA") to obtain feedback on the resubmission strategy for the M207 (zolmitriptan transdermal microneedle system) 505(b)(2) New Drug Application ("NDA")
- Issued U.S. patent for a method of rapidly achieving therapeutic levels with M207 for the acute treatment of migraine
- Dismissal of Securities Class Action and Delaware Derivative Action

Financial Results for the Third Quarter Ended September 30, 2021

Zosano reported a net loss for the third quarter of 2021 of \$8.7 million, or \$0.07 per share on a basic and diluted basis, compared with a net loss of \$8.7 million, or \$0.11 per share on a basic and diluted basis, for the same quarter in 2020.

Research and development expenses for the third quarter of 2021 were \$6.0 million, compared with \$5.8 million for the same quarter in 2020. The increase was primarily due to the conduct of a pharmacokinetic study to support the resubmission of the NDA for M207, partially offset by lower employee and consulting costs.

General and administrative expenses for the third quarter of 2021 were \$2.5 million compared with \$2.7 million for the same quarter in 2020. The decrease of \$0.2 million was primarily due to lower consulting and professional services costs.

As of September 30, 2021, cash and cash equivalents were \$17.1 million, compared with \$35.3 million as of December 31, 2020.

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. 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 expected timing with respect to the written feedback from the FDA, the company's expectation that the FDA's written feedback will enable the company to further refine its regulatory strategy and to provide an update on its resubmission plans for the NDA, the potential benefits and availability of M207 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," "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.

Zosano Contacts:

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510-745-1200

Zosano PR:

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ZOSANO PHARMA CORPORATION
BALANCE SHEETS
(in thousands, except par value and share amounts)

	September 30, 2021	December 31, 2020
	(unaudited)	
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 17,147	\$ 35,263
Prepaid expenses and other current assets	983	453
Total current assets	18,130	35,716
Restricted cash	455	455
Property and equipment, net	32,337	30,909
Operating lease right-of-use assets	4,073	4,928
Other long-term assets	—	3
Total assets	\$ 54,995	\$ 72,011
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities:		
Accounts payable	\$ 1,551	\$ 1,884
Accrued compensation	1,916	2,294
Build-to-suit obligation, current portion, net of debt issuance costs and discount	4,528	4,779
Operating lease liabilities, current portion	1,552	1,378
Paycheck Protection Program loan, current portion	—	809
Other accrued liabilities	2,092	3,367
Total current liabilities	11,639	14,511
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	1,424	4,359
Operating lease liabilities, long-term portion	3,502	4,687
Paycheck Protection Program loan, long-term portion	—	812
Other long-term liabilities	226	127
Total liabilities	16,791	24,496
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; none issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.0001 par value; 250,000,000 shares authorized as of September 30, 2021 and December 31, 2020, respectively; 118,114,793 and 102,066,218 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	12	10
Additional paid-in capital	393,336	379,695
Accumulated deficit	(355,144)	(332,190)
Total stockholders' equity	38,204	47,515
Total liabilities and stockholders' equity	\$ 54,995	\$ 72,011

ZOSANO PHARMA CORPORATION
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Service revenue	\$ 252	\$ —	\$ 698	\$ —
Operating expenses:				
Cost of service revenue	340	—	704	—
Research and development	5,985	5,824	16,315	16,270
General and administrative	2,522	2,704	8,294	8,552
Total operating expenses	8,847	8,528	25,313	24,822
Loss from operations	(8,595)	(8,528)	(24,615)	(24,822)
Other income (expense):				
Interest income	1	2	2	17
Interest expense	(17)	(165)	(136)	(561)
Other income (expense), net	(57)	4	1,795	95
Loss before provision for income taxes	(8,668)	(8,687)	(22,954)	(25,271)
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	\$ (8,668)	\$ (8,687)	\$ (22,954)	\$ (25,271)
Net loss per common share – basic and diluted	\$ (0.07)	\$ (0.11)	\$ (0.21)	\$ (0.45)
Weighted-average common shares used in computing net loss per common share – basic and diluted	115,765	77,883	109,730	56,437