

**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): August 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 August 10, 2021, Zosano Pharma Corporation issued a press release titled “Zosano Pharma Reports Second 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 August 10, 2021, titled “Zosano Pharma Reports Second 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: August 10, 2021

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

Zosano Pharma Reports Second Quarter 2021 Financial Results

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

"We are pleased to have initiated the healthy volunteer pharmacokinetic study that was requested by the FDA for the resubmission of the New Drug Application (NDA) for M207," said Steven Lo, president and chief executive officer of Zosano. "The study is evaluating pharmacokinetics and safety in approximately 48 healthy volunteers. We are diligently working to complete this study in the third quarter. Pending receipt of positive data, we plan to resubmit the NDA for M207 by year-end. Additionally, this quarter we strengthened our patent portfolio with the issuance of a U.S. patent covering method of use of M207."

Select Business Highlights

- Initiated the pharmacokinetic study required to support the resubmission of the M207 (zolmitriptan transdermal microneedle system) 505(b)(2) NDA
- Announced publication of an article titled, "Long Term Safety, Tolerability, and Efficacy of Intracutaneous Zolmitriptan (M207) in the Acute Treatment of Migraine" in *The Journal of Headache and Pain* highlighting the positive safety and efficacy results from this long-term study
- Received notification of a newly issued U.S. patent for method of rapidly achieving therapeutic levels with M207 for the acute treatment of migraine
- Appointed Kathy McGee, an accomplished biopharmaceutical executive currently serving as the chief operating officer of AVITA MEDICAL, to the board of directors

Financial Results for the Second Quarter Ended June 30, 2021

Zosano reported a net loss for the second quarter of 2021 of \$6.1 million, or \$0.06 per share on a basic and diluted basis, compared with a net loss of \$7.9 million, or \$0.14 per share on a basic and diluted basis, for the same quarter in 2020. The net loss for the second quarter of 2021 included a \$1.6 million gain on the forgiveness of our Paycheck Protection Loan.

Research and development expenses for the second quarter of 2021 were \$5.0 million, compared with \$4.9 million for the same quarter in 2020. The increase was primarily due to an increase of \$0.2 million in manufacturing costs related to the scale up and technology transfer to our commercial manufacturing organizations and \$0.2 million in increased spending for clinical trials. These increases were partially offset by a decrease of \$0.3 million in employee and consulting costs.

General and administrative expenses for the second quarter of 2021 were \$3.0 million compared with \$2.8 million for the same quarter in 2020. The increase of \$0.2 million was primarily due to higher employee related costs.

As of June 30, 2021, cash and cash equivalents were \$22.1 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. 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 the company's ongoing pharmacokinetic study and the anticipated timing with respect to the study; the expected timing of the potential resubmission of the NDA for M207, 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.

Zosano Contacts:

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Zosano PR:

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

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
	<u>(unaudited)</u>	
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 22,058	\$ 35,263
Prepaid expenses and other current assets	1,787	453
Total current assets	23,845	35,716
Restricted cash	455	455
Property and equipment, net	32,184	30,909
Operating lease right-of-use assets	4,366	4,928
Other long-term assets	—	3
Total assets	\$ 60,850	\$ 72,011
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities:		
Accounts payable	\$ 1,677	\$ 1,884
Accrued compensation	1,801	2,294
Build-to-suit obligation, current portion, net of debt issuance costs and discount	4,825	4,779
Operating lease liabilities, current portion	1,492	1,378
Paycheck Protection Program loan, current portion	—	809
Other accrued liabilities	1,620	3,367
Total current liabilities	11,415	14,511
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	2,237	4,359
Operating lease liabilities, long-term portion	3,911	4,687
Paycheck Protection Program loan, long-term portion	—	812
Other long-term liabilities	221	127
Total liabilities	17,784	24,496
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; none issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.0001 par value; 250,000,000 shares authorized as of June 30, 2021 and December 31, 2020, respectively; 113,329,291 and 102,066,218 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	11	10
Additional paid-in capital	389,531	379,695
Accumulated deficit	(346,476)	(332,190)
Total stockholders' equity	43,066	47,515
Total liabilities and stockholders' equity	\$ 60,850	\$ 72,011

ZOSANO PHARMA CORPORATION
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Service revenue	\$ 188	\$ —	\$ 446	\$ —
Operating expenses:				
Cost of service revenue	202	—	364	—
Research and development	5,000	4,932	10,330	10,446
General and administrative	2,958	2,766	5,772	5,848
Total operating expenses	8,160	7,698	16,466	16,294
Loss from operations	(7,972)	(7,698)	(16,020)	(16,294)
Other income (expense):				
Interest income	—	5	1	15
Interest expense	(22)	(190)	(119)	(396)
Other income (expense), net	1,850	(12)	1,852	91
Loss before provision for income taxes	(6,144)	(7,895)	(14,286)	(16,584)
Provision for income taxes	—	—	—	—
Net loss and comprehensive loss	\$ (6,144)	\$ (7,895)	\$ (14,286)	\$ (16,584)
Net loss per common share – basic and diluted	\$ (0.06)	\$ (0.14)	\$ (0.13)	\$ (0.36)
Weighted-average common shares used in computing net loss per common share – basic and diluted	108,943	54,927	106,662	45,597