

**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): May 12, 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 May 12, 2021, Zosano Pharma Corporation issued a press release titled “Zosano Pharma Reports First 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 May 12, 2021, titled “Zosano Pharma Reports First 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: May 12, 2021

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

Zosano Pharma Reports First Quarter 2021 Financial Results

FREMONT, Calif., May 12, 2021 -- Zosano Pharma Corporation (NASDAQ:ZSAN), a clinical-stage biopharmaceutical company, today announced financial results for the first quarter ended March 31, 2021, as well as business highlights.

“We have gained clarity from the FDA on the resubmission plan for the Qtrypta™ NDA, and the full weight of our organization is focused on this endeavor,” said Steven Lo, president and chief executive officer of Zosano. “The pharmacokinetic study required for resubmission of our Qtrypta NDA is expected to begin in June with data available in the third quarter. Pending receipt of positive data from this healthy volunteer study, we anticipate resubmitting the NDA for Qtrypta by the end of this year. If approved, we believe that Qtrypta would represent a significant advancement in the acute treatment of migraine, a disease that impacts one in four U.S. households.”

Select Business Highlights

- Received feedback from the U.S. Food and Drug Administration on the protocol for the pharmacokinetic (“PK”) study required to support the resubmission of the Qtrypta™ (zolmitriptan transdermal microneedle system) 505(b)(2) New Drug Application (“NDA”)
- Established an agreement with Worldwide Clinical Trials to conduct the Qtrypta PK study, which is expected to involve 48 healthy volunteers to generate comparative pharmacokinetic and safety data
- Presented a post-hoc retrospective analysis of data from the ZOTRIP trial at the January 2021 Annual Headache Cooperative of the Pacific Winter Conference that suggested that Qtrypta conferred therapeutic benefit at 30 minutes consistent with recently published criteria for early onset of action, and that those patients who were pain free at 30 minutes were still pain free at 2 hours

Financial Results for the First Quarter Ended March 31, 2021

The company reported a net loss for the first quarter of 2021 of \$8.1 million, or \$0.08 per share on a basic and diluted basis, compared with a net loss of \$8.7 million, or \$0.24 per share on a basic and diluted basis, for the same quarter in 2020.

In the first quarter of 2021, we recognized service revenue and cost of service revenue on agreements with three pharmaceutical companies in which we provide research and development services to determine the feasibility of using our transdermal microneedle system technology in connection with their pharmaceutical agents.

Research and development expenses for the first quarter of 2021 were \$5.3 million, compared with \$5.5 million for the same quarter in 2020. The decrease of \$0.2 million was primarily due to lower employee and temporary employee expenses and lower clinical trial costs partially offset by higher production and manufacturing costs due to the scale up and technology transfer to our commercial manufacturing organizations and additional depreciation expense.

General and administrative expenses for the first quarter of 2021 were \$2.8 million, compared with \$3.1 million for the same quarter in 2020. The decrease of \$0.3 million was primarily due to lower professional service fees.

As of March 31, 2021, cash and cash equivalents were \$26.9 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 Qtrypta™ (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 company's plans for and the anticipated timing with respect to the commencement of the PK study and the availability of data from the study, the expected timing of the resubmission of the company's Qtrypta NDA to the FDA, the potential benefits and availability of Qtrypta 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," "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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ZOSANO PHARMA CORPORATION
BALANCE SHEETS
(in thousands, except par value and share amounts)

	March 31, 2021	December 31, 2020
	<u>(unaudited)</u>	
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 26,882	\$ 35,263
Prepaid expenses and other current assets	1,591	453
Total current assets	<u>28,473</u>	<u>35,716</u>
Restricted cash	455	455
Property and equipment, net	32,128	30,909
Operating lease right-of-use assets	4,651	4,928
Other long-term assets	3	3
Total assets	<u>\$ 65,710</u>	<u>\$ 72,011</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities:		
Accounts payable	\$ 2,661	\$ 1,884
Accrued compensation	2,703	2,294
Build-to-suit obligation, current portion, net of debt issuance costs and discount	4,697	4,779
Operating lease liabilities, current portion	1,434	1,378
Paycheck Protection Program loan, current portion	1,422	809
Other accrued liabilities	1,491	3,367
Total current liabilities	<u>14,408</u>	<u>14,511</u>
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	3,426	4,359
Operating lease liabilities, long-term portion	4,304	4,687
Paycheck Protection Program loan, long-term portion	204	812
Other long-term liabilities	217	127
Total liabilities	<u>22,559</u>	<u>24,496</u>
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; none issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.0001 par value; 250,000,000 shares authorized as of March 31, 2021 and December 31, 2020, respectively; 106,372,820 and 102,066,218 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	11	10
Additional paid-in capital	383,472	379,695
Accumulated deficit	(340,332)	(332,190)
Total stockholders' equity	<u>43,151</u>	<u>47,515</u>
Total liabilities and stockholders' equity	<u>\$ 65,710</u>	<u>\$ 72,011</u>

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

	Three Months Ended March 31,	
	2021	2020
Service revenue	\$ 258	\$ —
Operating expenses:		
Cost of service revenue	162	—
Research and development	5,330	5,514
General and administrative	2,814	3,082
Total operating expenses	8,306	8,596
Loss from operations	(8,048)	(8,596)
Other income (expense):		
Interest income	1	10
Interest expense	(97)	(206)
Other income (expense), net	2	103
Loss before provision for income taxes	(8,142)	(8,689)
Provision for income taxes	—	—
Net loss and comprehensive loss	\$ (8,142)	\$ (8,689)
Net loss per common share – basic and diluted	\$ (0.08)	\$ (0.24)
Weighted-average common shares used in computing net loss per common share – basic and diluted	104,356	36,266