

**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): **March 13, 2020**

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 (see General Instruction A.2. below):

- 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 x

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. x

Item 2.02 Results of Operations and Financial Conditions.

On March 13, 2020, Zosano Pharma Corporation issued a press release titled “Zosano Pharma Reports Fourth Quarter and Fiscal Year 2019 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 (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 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 March 13, 2020, titled “Zosano Pharma Reports Fourth Quarter and Fiscal Year 2019 Financial Results”

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: March 13, 2020

By: /s/ Christine Matthews

Name: Christine Matthews

Title: Interim Chief Financial Officer

Zosano Pharma Reports Fourth Quarter and Fiscal Year 2019 Financial Results

FREMONT, Calif.--Mar. 13, 2020-- Zosano Pharma Corporation (NASDAQ:ZSAN), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter and year ended December 31, 2019, as well as recent business highlights.

“2019 was a transformational year for Zosano on multiple fronts,” said Steven Lo, president and chief executive officer of Zosano. “We completed clinical development for Qtrypta™ for the acute treatment of migraine, which supported our submission of a New Drug Application seeking approval of our first product formulated with our microneedle delivery technology. This year will be focused on preparing for potential approval and launch of Qtrypta as a new and differentiated treatment option for patients suffering from acute migraines.”

2019 and Recent Accomplishments

- Submission and subsequent acceptance for filing of the company’s first 505(b)(2) New Drug Application (NDA) for Qtrypta™ with the U.S. Food and Drug Administration for the acute treatment of migraine
- Appointed Steven Lo, an industry veteran with over 25 years of large pharmaceutical and small biotech executive and commercial experience, as president and chief executive officer
- Initiated the C213 Phase 2/3 trial for the acute treatment of cluster headache
- Published Qtrypta™ data in *Headache*, describing its performance in providing pain freedom and freedom from most bothersome symptoms (MBS) at 2 hours
- Presented Migraine-ACT Scores for Qtrypta™ at the American Headache Society (AHS) Annual Scientific Meeting showcasing patient-reported effectiveness of Qtrypta™ in treating their migraines
- Presented keynote address titled, “A Novel Intracutaneous Microneedle Delivery System for the Acute Treatment of Migraine” at the Pharmaceuticals & Advanced Delivery Systems Conference
- Presented positive results from the long-term safety study of Qtrypta™ at the Congress of the International Headache Society
- Appointed Dushyant Pathak, Ph.D., who has a proven track record of executing value-generating strategic alliances, as senior vice president of business development

Expected Upcoming Events

- Zosano to host conference call at 4:30 pm ET on March 26, 2020 to provide a corporate update and share plans for commercialization readiness for Qtrypta™
- FDA decision on the NDA for Qtrypta™ for the acute treatment of migraine

Financial Results for the Fourth Quarter Ended December 31, 2019

Zosano reported a net loss for the fourth quarter of 2019 of \$8.9 million, or \$0.46 per share on a basic and diluted basis, compared with a net loss of \$10.1 million, or \$0.85 per share on a basic and diluted basis, for the same quarter in 2018.

Research and development expenses for the fourth quarter were \$5.6 million, compared with \$7.3 million for the same quarter in 2018. The decrease of \$1.7 million was primarily due to a decrease in clinical trial costs related to our long-term safety study.

General administrative expenses for the fourth quarter of 2019 were \$3.1 million compared with \$2.5 million in 2018. The increase of \$0.6 million was primarily due to an increase in professional service fees and employee expenses.

As of December 31, 2019, cash, cash equivalents and marketable securities were \$6.3 million, compared with \$23.0 million as of December 31, 2018.

Financial Results for the Fiscal Year Ended December 31, 2019

Zosano reported a net loss for the full year 2019 of \$37.6 million, or \$2.29 per share on a basic and diluted basis, compared with a net loss of \$35.4 million, or \$3.74 per share on a basic and diluted basis, for the full year 2018.

Research and development expenses for the full year 2019 were \$25.4 million, compared with \$25.5 million in 2018. The decrease of \$0.1 million was primarily due to a decrease in pre-clinical and clinical trial costs, related to the completion of the Qtrypta™ long-term safety study, offset by an increase in costs associated with the scale up and technology transfer to our commercial manufacturing organizations and increased employee expenses.

General administrative expenses for the full year 2019 were \$11.8 million, compared with \$9.4 million in 2018. The increase of \$2.4 million was primarily due to costs spent on strategic development and pre-commercialization activities and an increase in employee expenses and professional service fees.

Conference Call on March 26, 2020

The Company will host a conference call with the investment community Thursday, March 26, 2020 at 1:30 Pacific Time / 4:30 Eastern Time. The dial-in numbers for the conference call are (844) 379-5311 (U.S.) or (209) 905-5963 (international). The conference ID number is

4536336. To access the live webcast, please visit the Investor Relations page of the Zosano Pharma website at <http://ir.zosanopharma.com/events.cfm>.

For interested individuals unable to join the live call, an archived webcast will be available on the Company's website at <http://ir.zosanopharma.com/events.cfm> approximately three hours after the call.

About Zosano

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 intracutaneous 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 delivered via its intracutaneous microneedle system technology, as an acute treatment for migraine. The company anticipates that many of its current and future development programs may enable the company to utilize a regulatory pathway that would streamline clinical development and accelerate the path towards commercialization.

Forward-Looking Statements

This press release contains forward-looking statements regarding the preparation for potential approval and launch of Qtrypta, the expected FDA decision on the NDA for Qtrypta and other future events and expectations described under "Expected Upcoming Milestones" and elsewhere 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," "unaudited," "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 for the remainder of 2020, 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, we 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
STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2019 (unaudited)	2018 (unaudited)	2019	2018
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	5,643	7,270	25,385	25,508
General and administrative	3,103	2,470	11,812	9,357
Impairment loss	—	511	—	511
Total operating expenses	8,746	10,251	37,197	35,376
Loss from operations	(8,746)	(10,251)	(37,197)	(35,376)
Other income (expense):				
Interest income	4	134	207	381
Interest expense	(166)	(33)	(523)	(379)
Other income (expense), net	(32)	3	(76)	16
Net loss	\$ (8,940)	\$ (10,147)	\$ (37,589)	\$ (35,358)
Net loss per common share – basic and diluted	\$ (0.46)	\$ (0.85)	\$ (2.29)	\$ (3.74)
Weighted-average common shares used in computing net loss per common share – basic and diluted	19,408,544	11,973,039	16,383,730	9,452,491

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

	December 31, 2019	December 31, 2018
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 6,316	\$ 9,140
Marketable securities at fair value	—	13,862
Prepaid expenses and other current assets	497	358
Total current assets	6,813	23,360
Restricted cash	455	455
Property and equipment, net	24,636	11,916
Operating lease right-of-use assets	5,763	—
Other long-term assets	3	49
Total assets	\$ 37,670	\$ 35,780
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities:		
Accounts payable	\$ 4,356	\$ 4,450
Accrued compensation	2,015	2,092
Build-to-suit obligation, current portion	4,554	2,326
Operating lease liabilities, current portion	1,140	—
Other accrued liabilities	4,154	2,414
Finance lease obligation, current portion	18	5
Total current liabilities	16,237	11,287
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	6,095	4,478
Operating lease liabilities	5,931	—
Finance lease obligation, long-term portion	15	18
Deferred rent	—	1,287
Total liabilities	28,278	17,070
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 5,000,000 shares authorized; none issued and outstanding as of December 31, 2019 and 2018	—	—
Common stock, \$0.0001 par value; 250,000,000 shares authorized as of December 31, 2019 and 2018, respectively; 23,503,214 and 11,973,039 shares issued and outstanding as of December 31, 2019 and 2018, respectively	2	1
Additional paid-in capital	308,211	279,946
Accumulated deficit	(298,821)	(261,232)
Accumulated other comprehensive loss	—	(5)
Total stockholders' equity	9,392	18,710
Total liabilities and stockholders' equity	\$ 37,670	\$ 35,780