

**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 14, 2019

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 communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 Conditions.

On March 14, 2019, we issued a press released titled “Zosano Pharma Reports Fourth Quarter and Fiscal Year 2018 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 14, 2019, titled “Zosano Pharma Reports Fourth Quarter and Fiscal Year 2018 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

Dated: March 14, 2019

By: /s/ Gregory Kitchener
Name: Gregory Kitchener
Title: Chief Financial Officer



Zosano Pharma Reports Fourth Quarter and Fiscal Year 2018 Financial Results

FREMONT, Calif., March 14, 2019 -- Zosano Pharma Corporation (NASDAQ:ZSAN), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter and year ended December 31, 2018, as well as recent business highlights.

“Following the completion of our Phase 3 clinical program for Qtrypta™ (M207), we see a clear path to the filing of our NDA in the fourth quarter of this year,” commented John Walker, Chairman and CEO. “We are very proud of the manner in which our entire team pulled together to conclude our long-term safety study, and to facilitate the scaling up of our manufacturing capability, completing our registration batches and successfully transferring our proprietary manufacturing processes to our contract manufacturer.” Mr. Walker further added, “as we look to 2019, we plan to build on these accomplishments with the initiation of partnering discussions for the marketing and distribution of Qtrypta, the expansion of our pipeline and the further development of our unique intracutaneous microneedle system for the delivery of biologic agents, where we can offer an alternative to intravenous (IV), intramuscular (IM), and subcutaneous (SC) injections.”

Recent Business Highlights

- Achieved the final milestone in the Phase 3 long-term safety study of Qtrypta, with a cohort of patients completing 12 months on study drug
- Received patent covering the use of Qtrypta as an acute treatment for migraine and cluster headache, providing protection through 2037
- Welcomed both Steve Elms, Managing Partner of Aisling Capital and Linda Grais, MD, JD, an experienced founder, investor and CEO of biotechnology companies to our Board of Directors
- Appointed Greg Kitchener, a seasoned financial executive, as our Chief Financial Officer
- Announced the treatment of nearly 6,000 migraines in our long-term safety study
- Published clinical data in *Headache: The Journal of Head and Face Pain* demonstrating the potential of Qtrypta as an acute treatment for patients that present with difficult to treat migraines, defined as morning migraine, delayed treatment, severe pain and those accompanied by nausea
- Completed contracts for the outsourcing of manufacturing to established and FDA experienced contract manufacturers
- Published data from the pivotal efficacy study of Qtrypta on Most Bothersome Symptom Relief in *Headache: The Journal of Head and Face Pain*
- Completed the registration batches of Qtrypta under GMP guidelines as part of the preparation for the filing of the NDA

Expected Upcoming Milestones

- File NDA for Qtrypta in acute migraine in the fourth quarter of 2019
 - In concert with our anticipated NDA filing, put in place a partnership for the marketing and distribution of Qtrypta
 - Initiate the clinical development program for Qtrypta in patients with cluster headaches with the filing of an IND in the second quarter of 2019 and initiating a Phase 2 clinical study in the third quarter of 2019
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- Initiate the clinical development program of a 5-HT₃ antagonist in the anti-emetics market with the filing of an IND or equivalent in the third quarter of 2019 and completing a Phase 1 clinical study in the fourth quarter of 2019
- Initiate a pre-clinical development program in biologics in the second half of 2019

Financial Results for the Fourth Quarter Ended December 31, 2018

Zosano reported a net loss for the fourth quarter of 2018 of \$10.1 million, or \$0.85 per share on a basic and diluted basis, compared with a net loss of \$7.5 million, or \$3.80 per share on a basic and diluted basis, for the same quarter in 2017.

Research and development expenses for the fourth quarter of 2018 were \$7.3 million, compared with \$5.4 million for the same quarter in 2017. The increase of \$1.9 million was primarily due to the scale up and transfer of technology to our contract manufacturers, along with costs associated with our long-term safety study.

General and administrative (G&A) expenses for the fourth quarter of 2018 were \$2.5 million, compared with \$1.8 million in 2017. The increase of \$0.7 million was primarily due to higher stock compensation and personnel expense, and taxes.

As of December 31, 2018, cash, cash equivalents and marketable securities were \$23.0 million, compared with \$11.7 million as of December 31, 2017.

Financial Results for the Fiscal Year Ended December 31, 2018

Zosano reported a net loss for the full year 2018 of \$35.4 million, or \$3.74 per share on a basic and diluted basis, compared with a net loss of \$29.1 million, or \$16.82 per share on a basic and diluted basis, for the full year 2017.

Research and development expenses for the full year 2018 were \$25.5 million, compared with \$20.1 million in 2017. The increase was primarily due to costs associated with our long-term safety study, the scale up and transfer of technology to our contract manufacturers, personnel and stock compensation expense.

General and administrative expenses for the full year 2018 were \$9.4 million, compared with \$8.2 million in 2017. The increase was primarily due to higher taxes, professional services related to our ERP implementation, personnel and stock compensation expense.

About Zosano Pharma

Zosano Pharma Corporation is a clinical stage biopharmaceutical company focused on providing administration of therapeutics to patients using its intracutaneous delivery system, which consists of titanium microneedles coated with drug that can enable rapid systemic administration to patients. The company's lead product candidate is Qtrypta™ (M207), which is Zosano's proprietary formulation of zolmitriptan delivered via its intracutaneous delivery technology for the treatment of migraine disease. In February 2017, the company announced statistically significant results from the ZOTRIP pivotal study and in February 2019, Zosano announced the completion of the final milestone in its long-term safety study and its expectations to file an NDA for Qtrypta in the fourth quarter of 2019. Learn more at www.zosanopharma.com.

Forward-Looking Statements



This press release contains forward-looking statements regarding the expected timing of a New Drug Application (NDA) for Qtrypta (M207), partnering discussions, expansion of our pipeline, development of our intracutaneous delivery system 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 2019, 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,	
	2018	2017	2018	2017
	(unaudited)	(unaudited)	(unaudited)	
Revenue:	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	7,270	5,446	25,508	20,118
General and administrative	2,470	1,836	9,357	8,182
Impairment loss	511	70	511	70
Total operating expenses	<u>10,251</u>	<u>7,352</u>	<u>35,376</u>	<u>28,370</u>
Loss from operations	(10,251)	(7,352)	(35,376)	(28,370)
Other income (expenses):				
Interest income	134	19	381	75
Interest expense	(33)	(153)	(379)	(817)
Other income (expense), net	<u>3</u>	<u>(3)</u>	<u>16</u>	<u>7</u>
Net loss	<u>\$ (10,147)</u>	<u>\$ (7,489)</u>	<u>\$ (35,358)</u>	<u>\$ (29,105)</u>
Net loss per common share – basic and diluted	<u>\$ (0.85)</u>	<u>\$ (3.80)</u>	<u>\$ (3.74)</u>	<u>\$ (16.82)</u>
Weighted-average shares used in computing net loss per common share – basic and diluted	<u>11,973,039</u>	<u>1,970,326</u>	<u>9,452,491</u>	<u>1,730,388</u>



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

	December 31, 2018 (unaudited)	December 31, 2017
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 9,140	\$ 11,651
Marketable securities at fair value	13,862	—
Prepaid expenses and other current assets	358	1,742
Total current assets	23,360	13,393
Restricted cash	455	455
Property and equipment, net	11,916	4,152
Other long-term assets	49	—
Total assets	\$ 35,780	\$ 18,000
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
Current liabilities:		
Accounts payable	\$ 4,450	\$ 1,511
Accrued compensation	2,092	1,571
Capital lease obligation, current portion	5	—
Build-to-suit obligation, current portion	2,326	—
Secured promissory note (including accrued interest), net of issuance costs	—	6,687
Other accrued liabilities	2,414	688
Total current liabilities	11,287	10,457
Capital lease obligation, long-term portion	18	—
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	4,478	—
Deferred rent	1,287	495
Total liabilities	17,070	10,952
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 5,000,000 shares authorized; none issued and outstanding as of December 31, 2018 and 2017	—	—
Common stock, \$0.0001 par value; 250,000,000 and 100,000,000 shares authorized as of December 31, 2018 and 2017, respectively; 11,973,039 and 1,973,039 shares issued and outstanding as of December 31, 2018 and 2017, respectively	1	—
Additional paid-in capital	279,946	232,922
Accumulated deficit	(261,232)	(225,874)
Accumulated other comprehensive loss	(5)	—
Stockholders' equity	18,710	7,048
Total liabilities and stockholders' equity	\$ 35,780	\$ 18,000