ZOSANO PHARMA CORP

FORM 8-K
(Current report filing)

Filed 03/12/18 for the Period Ending 03/12/18

Address	34790 Ardentech Court
	Fremont, CA, 94555
Telephone	(510) 745-1200
CIK	0001587221
Symbol	ZSAN
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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 12, 2018

ZOSANO PHARMA CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**001-36570**	**45-4488360**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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))

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 12, 2018, we issued a press released titled "Zosano Pharma Reports Fourth Quarter and Fiscal 2017 Financial Results and Operational Update." 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 12, 2018, titled "Zosano Pharma Reports Fourth Quarter and Fiscal Year 2017 Financial Results and Operational Update"

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 12, 2018

By: /s/ Georgia Erbez
Name: Georgia Erbez
Title: Chief Business Officer and Chief Financial Officer

Exhibit 99.1

Zosano Pharma Reports Fourth Quarter and Fiscal Year 2017 Financial Results and Operational Update

- *First patient enrolled in long term safety study in November 2017*
- *Pivotal efficacy data for M207 published in October 2017*
- *Allowed patent application to be issued in March 2018 extends proprietary position for M207 to 2037*

FREMONT, Calif., March 12, 2018 (BUSINESS WIRE)—Zosano Pharma Corporation (NASDAQ:ZSAN) ("Zosano" or the "Company") a clinical-stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using its proprietary Adhesive Dermally-Applied Microarray ("ADAM™"), today announced financial results for the fourth quarter ended December 31, 2017.

"The fourth quarter continued to see strong execution in bringing M207 to market. We are pleased with the enrollment in our open label, Long-Term Safety Study, and note that we now have 28 sites up and running. We remain confident that we will hit our targets of having 100 subjects on study drug by the end of the first quarter and 250 by the end of the second quarter," commented John Walker, Chairman and Chief Executive Officer.

"Our efforts to highlight our efficacy data to the clinical community continues, most notably by the publication of our pivotal data in Cephalalgia in October," Mr. Walker continued. "The issuance of our new patent on the use of M207 to treat migraine and cluster headaches is also significant as it provides intellectual property protection through 2037."

Recent Business Highlights and Clinical Update

- In October 2017, Zosano announced that Cephalalgia had published the results from our ZOTRIP Phase 2/3 efficacy trial.
- In October 2017, Zosano announced the appointment of Kenneth R. Greathouse to the Board of Directors. Mr. Greathouse is a seasoned pharmaceutical executive with over 40 years of experience in sales, marketing, business development and commercial operations.
- In October 2017, Zosano entered into a purchase agreement and a registration rights agreement with Lincoln Park Capital Fund, LLC providing for the purchase of up to $35 million worth of our common stock over a 30-month period, subject to certain limitations.

- In November 2017, Zosano announced initiation of our long-term safety study evaluating M207.
- In November 2017, Zosano presented at the 29 th Annual Piper Jaffray Health Conference.
- In December 2017, Zosano received Notice of Allowance from the United States Patent and Trademark Office for our patent application directed to M207. This newly allowed application will issue on March 20, 2018 as U.S. Pat. No. 9,918,932 and will expire in 2037.
- In January 2018, Zosano effected a 1-for-20 reverse stock split of our outstanding shares of common stock and regained compliance with Nasdaq Listing Rule 5550(a)(2) as of the close of trading on February 8, 2018.

Financial Results for the Fourth Quarter Ended December 31, 2017

- Zosano reported a net loss for the fourth quarter of 2017 of $7.5 million, or $3.80 per share on a basic and diluted basis, compared with a net loss of $7.7 million, or $9.23 per share on a basic and diluted basis, for the same quarter in 2016.
- Research and development expenses for the fourth quarter of 2017 were $5.5 million, compared with $5.4 million for the same quarter in 2016. R&D expenses for the fourth quarter of 2017 and 2016 were essentially unchanged.
- General and administrative (G&A) expenses for the fourth quarter of 2017 was $1.8 million, compared with $2.0 million in 2016. The decrease of $0.2 million was due to the reduction in general corporate expenses.
- As of December 31, 2017, we had cash, cash equivalents and marketable securities of $11.7 million, debt of $6.7 million and 2.0 million common shares outstanding.
- All share and per share information in this press release has been retroactively adjusted to give effect to the reverse stock split.

Financial Results for the Fiscal Year Ended December 31, 2017

- Zosano reported a net loss for the year 2017 of $29.1 million, or $16.82 per share on a basic and diluted basis, compared with a net loss of $29.8 million, or $43.36 per share on a basic and diluted basis, for the year 2016.
- Research and development expenses for the year 2017 were $20.2 million, compared with $20.5 million in 2016. In 2017, our research and development efforts and resources focused primarily on advancing the development of M207. Expenses in 2016 primarily consisted of M207 ZOTRIP trial, Phase 1 clinical trial and related preclinical toxicology studies.
- General and administrative (G&A) expenses for the year 2017 were $8.2 million, essentially unchanged from the same year ended 2016.

About Migraine

Migraine is the leading cause of disability among neurological disorders in the United States according to the American Migraine Foundation. Migraine symptoms can include moderate to severe headache pain combined with nausea and vomiting, or abnormal sensitivity to light and sound. According to the Migraine Research Foundation, migraine affects 30 million men, women and children in the United States. Most migraines last between four and 24 hours, but some last as long as three days. According to published studies, 63% of migraine patients experience between one and four migraines per month. According to Decision Resources, prescription drug sales for migraine in the top seven countries were estimated to be $3.3 billion in 2015, and are expected to grow to $4.4 billion in 2020. Triptans, a family of tryptamine-based drugs first sold in the 1990s, account for almost 75% of anti-migraine therapies prescribed at office visits.

About M207

M207 is our proprietary formulation of zolmitriptan delivered utilizing Zosano's proprietary ADAM technology. Zosano's ADAM technology consists of titanium microprojections coated with drug, and in the case of M207, our formulation of zolmitriptan. Our ADAM technology delivers drug by abrading the stratum corneum and allowing drug to be absorbed into the microcapillary system of the skin. In February 2017, the Company announced statistically significant results from the ZOTRIP trial, which demonstrated that the 3.8mg dose of M207 met both co-primary endpoints, achieving pain freedom and most bothersome symptom freedom at 2 hours. In November 2017, the Company announced the initiation of its long term safety study evaluating M207.

About Zosano Pharma

Zosano Pharma Corporation is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary ADAM technology. The Company previously announced positive results from our ZOTRIP study that evaluated M207, which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine, and has initiated a long term safety study of M207. Zosano is focused on developing products where rapid administration of established molecules with known safety and efficacy profiles provides an increased benefit to patients, for markets where patients remain underserved by existing therapies. 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. Learn more at www.zosanopharma.com.

Forward-Looking Statements

This press release contains forward-looking statements regarding the timing of expected clinical development milestones, sufficiency of our capital resources and need for future funding and other future events and expectations. 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 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. Although we believe 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.

Zosano Contact:
Georgia Erbez
Chief Business Officer and
Chief Financial Officer
510-745-1200

ZOSANO PHARMA CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Revenue:	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	5,516	5,413	20,188	20,457
General and administrative	1,836	2,039	8,182	8,176
Total operating expenses	7,352	7,452	28,370	28,633
Loss from operations	(7,352)	(7,452)	(28,370)	(28,633)
Other income (expenses):				
Interest expense, net	(134)	(241)	(742)	(1,192)
Other income (expense), net	(3)	(56)	7	(7)
Net loss	$(7,489)	$(7,749)	$(29,105)	$(29,832)
Net loss per common share–basic and diluted	$ (3.80)	$ (9.23)	$ (16.82)	$ (43.36)
Weighted-average shares used in computing net loss per common share–basic and diluted	1,970	840	1,730	688

ZOSANO PHARMA CORPORATION
SELECTED CONDENSED CONSOLIDATED BALANCE SHEETS DATA
(in thousands)

	December 31, 2017	December 31, 2016
Cash, cash equivalents and marketable securities	$ 11,651	$ 15,003
Total current assets	13,393	15,276
Total assets	18,000	20,906
Secured promissory note	6,687	12,542
Total liabilities	10,952	16,421
Stockholders' equity	7,048	4,485