

ZOSANO PHARMA CORP

FORM 8-K (Current report filing)

Filed 08/10/17 for the Period Ending 08/10/17

Address	34790 Ardentech Court Fremont, CA 94555
Telephone	(510) 745-1200
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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): August 10, 2017

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 August 10, 2017, Zosano Pharma Corporation (the “Company”) issued a press release titled “Zosano Pharma Reports Second Quarter 2017 Financial Results and Operational Update.” The press release is furnished herewith as Exhibit 99.1

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Press release dated August 10, 2017, titled “Zosano Pharma Reports Second Quarter 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: August 10, 2017

By: /s/ Georgia Erbez

Name: Georgia Erbez

Title: Chief Business Officer and

Chief Financial Officer

EXHIBIT INDEX

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Zosano Pharma Reports Second Quarter 2017 Financial Results and Operational Update

- *John Walker appointed permanent CEO at Zosano*

FREMONT, CA, August 10, 2017—Zosano Pharma Corporation (NASDAQ:ZSAN) a clinical stage biopharmaceutical company focused on providing systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray (ADAM) technology, today announced financial results for the second quarter ended June 30, 2017. In addition, the Company's Board of Directors has appointed John Walker, Zosano's current Chairman and Interim CEO as the permanent CEO, effective immediately. Mr. Walker will also remain Chairman of the Board.

"It is with great pleasure that I accept the role of permanent CEO. I believe the company has a great deal of promise, and our lead asset, M207, has demonstrated that it can be a significant addition to the treatment options available to migraine sufferers, if approved by the FDA," commented John P. Walker, Chairman and Chief Executive Officer. "Zosano continues to execute on its operating plan, and is progressing towards initiating our long-term safety study as previously announced. In the second quarter, we received from the U.S. Food and Drug Administration (FDA) confirmation of our previously announced study design and requirements to advance M207 towards an NDA filing. In addition, we participated in the American Headache Society meeting in Boston as a late-breaking oral presentation. We continue to prioritize increased awareness of M207 in the physician community, and plan additional conference presentations and publications in the second half of 2017."

Recent Business Highlights and Clinical Update

- In June 2017, Zosano held its end of Phase 2 meetings with the FDA, where the FDA confirmed the previously announced design of the Long-term Safety Study as sufficient to support an NDA filing for M207, that the recently completed single, positive efficacy study is sufficient for NDA filing for M207, and the FDA concurred that the development strategy, which conforms to relevant regulatory guidelines, appears adequate for registration of M207.
- June 2017, Zosano presented additional data from its pivotal Phase 2/3 ZOTRIP study evaluating M207 as an acute treatment for migraine during the 59th Annual Scientific Meeting of the American Headache Society in Boston, Massachusetts. The 3.8mg dose achieved significance in the secondary endpoints of pain freedom at 45 minutes and 1 hour and showed durability of effect on sustained pain freedom at 24 and 48 hours.
- In July, Zosano announced the publication of positive phase 1 data of zolmitriptan delivery in Future Medicine's *Pain Management Journal*
- Additionally, in July we strengthened our focus on manufacturing leadership by promoting Hayley Lewis to Senior Vice President of Operations. In addition to Quality, Regulatory and FDA communications, her role has expanded to include the additional responsibility of overseeing commercial scale process development and manufacturing.

Financial Results for the Second Quarter Ended June 30, 2017

- Zosano reported a net loss for the second quarter of 2017 of \$6.7 million, or \$0.17 per share on a basic and diluted basis, compared with a net loss of \$6.6 million, or \$0.54 per share on a basic and diluted basis, for the same quarter in 2016.
- Research and development (R&D) expenses for the second quarter of 2017 were \$4.4 million, compared with \$4.3 million for the same quarter in 2016. Increased costs in the second quarter of 2017 for labor, medical affairs, and the M207 long-term safety study were largely offset by decreased costs for the M207 efficacy study upon completion of the pivotal efficacy trial.
- General and administrative (G&A) expenses for the second quarter of 2017 were \$2.2 million, compared with \$2.0 million for the same quarter in 2016. G&A expenses for the second quarter of 2017 were up slightly, due primarily to severance costs paid to former executives.
- As of June 30, 2017, we had cash and cash equivalents of \$21.2 million, short-term investments in marketable securities of \$7.1 million, and debt of \$9.6 million. As of June 30, 2017, we had approximately 39.2 million common shares outstanding. In March, Zosano announced the completion of a public offering of common stock that generated aggregate gross proceeds of approximately \$29.3 million. The financing provides funding for the continued advancement of M207 towards an NDA submission.

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 Adhesive Dermally-Applied Microarray, or 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.

About Zosano Pharma

Zosano Pharma Corporation is a clinical stage biopharmaceutical company focused on providing systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray, or ADAM technology. The Company recently 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. 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.

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ZOSANO PHARMA CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited; in thousands, except per share amounts)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	4,363	4,298	8,989	9,920
General and administrative	2,188	1,951	4,310	4,127
Total operating expenses	<u>6,551</u>	<u>6,249</u>	<u>13,299</u>	<u>14,047</u>
Loss from operations	(6,551)	(6,249)	(13,299)	(14,047)
Other income (expense):				
Interest expense, net	(207)	(321)	(454)	(637)
Other income, net	12	50	10	49
Net loss	<u>\$ (6,746)</u>	<u>\$ (6,520)</u>	<u>\$ (13,743)</u>	<u>\$ (14,635)</u>
Net loss per common share – basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.54)</u>	<u>\$ (0.46)</u>	<u>\$ (1.22)</u>
Weighted-average shares used in computing net loss per common share – basic and diluted	<u>39,200</u>	<u>12,012</u>	<u>29,820</u>	<u>11,989</u>

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

	<u>June 30,</u> <u>2017</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2016</u>
Cash, cash equivalents and marketable securities	\$ 28,225	\$ 15,003
Total current assets	29,391	15,276
Total assets	34,644	20,906
Secured promissory note	9,634	12,542
Total liabilities	12,687	16,421
Stockholders' equity	21,957	4,485

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