
**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): November 14, 2018

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 November 14, 2018, we issued a press released titled “Zosano Pharma Reports Third Quarter 2018 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 November 14, 2018, titled “Zosano Pharma Reports Third Quarter 2018 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: November 14, 2018

By: /s/ John Walker

Name: John Walker

Title: President and Chief Executive Officer



Zosano Pharma Reports Third Quarter 2018 Financial Results and Operational Update

- Selected a contract manufacturer for commercial launch of M207
- Completed first required data set in long-term safety study of M207
- Appointed Greg Kitchener as Chief Financial Officer

Fremont, Calif., November 14, 2018 – Zosano Pharma Corporation (NASDAQ:ZSAN) (“Zosano” or the “Company”), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2018.

“The Company has continued to execute upon our stated milestones throughout 2018. We recently completed our registration batches; reached an important milestone in our long-term safety study as 150 patients completed 6 months of therapy; secured a capital equipment lease line and contracted with a leading organization to manufacture M207. This manufacturing arrangement provides production capacity for the commercial launch of M207 and frees up our in house manufacturing capacity for research and the production of clinical trial material as we seek to expand our portfolio of proprietary programs,” stated John Walker, chairman and chief executive officer.

“Additionally, Greg Kitchener joined us as Chief Financial Officer in October 2018. He brings to Zosano an enviable track record in capital formation, and solid experience in business and in building strong financial organizations. In concert with Greg and the rest of the team, we will continue to focus our attention on the execution needed to advance M207. By the end of the first quarter of 2019, we anticipate completing the final data set in our long-term safety study, with 50 subjects completing their 12 month visit, and in the third quarter of 2019, we expect to complete stability testing for our GMP manufacturing lots, leading to the filing of the NDA in the fourth quarter of next year.”

Recent Business Highlights and Clinical Update

- In September 2018, Dr. Stewart Tepper presented M207 data, when used for the treatment of difficult to treat migraines at the 17th Biennial Migraine Trust International Symposium (MTIS).
- In September 2018, Zosano presented a phase 3 safety study update for ADAM technology for the delivery of zolmitriptan at the 5th Annual Transdermal and Intradermal Drug Delivery Systems Conference.
- In September 2018, Zosano announced completion and release of registration batches of M207.
- In September 2018, Zosano entered into a financing partnership with Trinity Capital investments that provides a capital equipment leasing line of up to \$14.0 million.
- In October 2018, Zosano entered into a long-term manufacturing and supply agreement with Patheon, a leading global contract development and manufacturing organization.
- In October 2018, Zosano appointed Greg Kitchener as Chief Financial Officer.
- In October 2018, Zosano hosted a key opinion leader meeting on new treatments for Migraine. A replay is accessible via the link [here](#).



- In October 2018, Zosano announced more than 150 evaluable subjects have completed their six month visit in the M207-ADAM study and more than 4,000 migraines treated since study initiation.

Financial Results for the Third Quarter Ended September 30, 2018

- Zosano reported a net loss of \$8.2 million, or \$0.68 per share on a basic and diluted basis, and \$25.2 million, or \$2.93 per share on a basic and diluted basis, for the three and nine months ended September 30, 2018, respectively, compared to a net loss of \$7.9 million, or \$0.20 per share on a basic and diluted basis, and \$21.6 million, or \$0.66 per share on a basic and diluted basis, for the same periods in 2017.
- Research and development expenses were \$5.9 million and \$18.2 million for the three and nine months ended September 30, 2018, respectively, compared to \$5.7 million and \$14.7 million for the same periods in 2017. The increase in research and development expenses was primarily attributable to an increase in clinical trial costs related to the M207-ADAM study and to completion of the registration batches.
- General and administrative (G&A) expenses were \$2.4 million and \$6.9 million for the three and nine months ended September 30, 2018, respectively, compared to \$2.0 million and \$6.3 million for the same periods in 2017. The increase in general and administrative expenses was due to an increase in software implementation costs as well as an increase in payroll and stock compensation costs.
- As of September 30, 2018, Zosano had cash, cash equivalents and marketable securities of \$29.5 million, debt of \$4.6 million and approximately 12 million shares of common stock outstanding.

Conference Call

The Company will host a conference call with the investment community today, November 14th, at 4:30 p.m. 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 3144819. To access the live webcast, please visit the Investor Relations page of the Zosano Pharma website at <http://ir.zosanopharma.com/events.cfm>. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast.

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 and available through December 14, 2018.

About M207

M207 is Zosano's proprietary formulation of zolmitriptan delivered utilizing its proprietary ADAM technology. Zosano's ADAM technology consists of titanium microprojections (microneedles) coated with drug, and in the case of M207, its formulation of zolmitriptan. The drug-coated microneedles penetrate into the epidermis and dermis, where the drug is dissolved and enters into the bloodstream.



In February 2017, the Company announced statistically significant results from the ZOTRIP pivotal study, 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 and expects to file a New Drug Application for M207 in the fourth quarter of 2019.

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 expected timing of a New Drug Application for M207, the expected timing of the final data set in the Company's long-term safety study, and the expected timing of stability testing for GMP manufacturing lots. 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, without limitation, risks and uncertainties associated with the process of discovering, developing and commercializing products that are safe and effective for use as human therapeutics, risks and uncertainties relating to the Company's dependence on third parties for the development and commercialization of M207, risks and uncertainties of the regulatory approval process, risks and uncertainties 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 filed with the Securities and Exchange Commission (the "SEC") on March 12, 2018 and in the Company's most recent quarterly report on Form 10-Q filed with the SEC on November 14, 2018. Although Zosano believes that the expectations reflected in these forward-looking statements are reasonable, it 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. Zosano assumes no obligation to update any forward-looking statements contained in this press release, whether as a result of any new information, future events, changed circumstances, or otherwise.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue:	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development	5,899	5,683	18,238	14,672
General and administrative	2,353	2,036	6,887	6,346
Total operating expenses	8,252	7,719	25,125	21,018
Loss from operations	(8,252)	(7,719)	(25,125)	(21,018)
Other income (expenses):				
Interest income (expense), net	74	(154)	(99)	(608)
Other income, net	9	-	13	10
Net loss	\$ (8,169)	\$ (7,873)	\$ (25,211)	\$ (21,616)
Net loss per common share – basic and diluted	\$ (0.68)	\$ (0.20)	\$ (2.93)	\$ (0.66)
Weighted-average shares used in computing net loss per common share – basic and diluted	11,973	39,228	8,603	32,991

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

	September 30,	December 31,
	2018	2017
	<i>(unaudited)</i>	
Cash, cash equivalents and marketable securities	\$ 29,476	\$ 11,651
Total current assets	30,545	13,393
Total assets	38,855	18,000
Secured promissory note	-	6,687
Equipment line of credit	4,601	-
Total liabilities	10,355	10,952
Stockholders' equity	28,500	7,048