

**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 12, 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

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 Condition.

On November 13, 2020, Zosano Pharma Corporation (the "Company") issued a press release titled "Zosano Pharma Reports Third Quarter 2020 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, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On November 12, 2020, the Company received written notice from The Nasdaq Stock Market, LLC ("Nasdaq") indicating that the Company is not in compliance with the \$1.00 minimum bid price requirement for continued listing on The Nasdaq Capital Market, as set forth in Listing Rule 5550(a)(2). In accordance with Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days, or until May 11, 2021, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of the Company's common stock must meet or exceed \$1.00 per share for a minimum of ten consecutive business days during this 180-day period.

If the Company is not in compliance by May 11, 2021, the Company may be eligible for additional time to regain compliance. To qualify, the Company would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the minimum bid price requirement. In addition, the Company would be required to notify Nasdaq of its intent to cure the minimum bid price deficiency.

If the Company does not regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that the Company's common stock will be subject to delisting. The Company would then be entitled to appeal Nasdaq's determination, but there can be no assurance that Nasdaq would grant the Company's request for continued listing.

The Company intends to monitor the closing bid price of its common stock and consider options to resolve the noncompliance with the minimum bid price requirement. There can be no assurance that the Company will be able to regain compliance with the minimum bid price requirement or will otherwise be in compliance with other Nasdaq listing criteria.

Item 9.01 Financial Statements and Exhibits.(d) Exhibits.

| Exhibit | Description |
|---------|--|
| 99.1 | Press release dated November 13, 2020, titled "Zosano Pharma Reports Third Quarter 2020 Financial Results" |
| 104.1 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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: November 13, 2020

By: /s/ Christine Matthews
Name: Christine Matthews
Title: Chief Financial Officer

Zosano Pharma Reports Third Quarter 2020 Financial Results

FREMONT, Calif., Nov. 13, 2020 (GLOBE NEWSWIRE) -- Zosano Pharma Corporation (NASDAQ:ZSAN), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2020, as well as recent business updates.

“Our priority focus is obtaining resolution regarding the NDA for Qtrypta™,” said Steven Lo, President and CEO of Zosano. “We plan on having a Type A meeting with the FDA as soon as possible and look forward to clarification on next steps and the possibility of resubmitting our NDA. We continue to believe in the promise that Qtrypta holds as an attractive alternative for patients suffering from migraine. Separately during the quarter, we executed a feasibility study agreement with Mitsubishi Tanabe Pharma Corporation that reinforces the potential of our transdermal microneedle system technology.”

Recent Business Updates

- Entered into a feasibility study agreement with Mitsubishi Tanabe Pharma Corporation. Under the agreement, Zosano plans to evaluate the feasibility of formulating a pharmaceutical agent being developed by Mitsubishi Tanabe Pharma Corporation for administration with its proprietary transdermal microneedle system technology
- Partnered with EVERSANA, a leading provider of commercial services to the life science industry, to commercialize and distribute Qtrypta™, if approved, in the United States
- Received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA) in connection with the Qtrypta™ (zolmitriptan transdermal microneedle system) 505(b)(2) New Drug Application (NDA)
- To conserve resources, decided to end enrollment of new subjects into the placebo-controlled Phase 2/3 clinical trial evaluating the potential of C213 as an acute treatment for cluster headache as of December 31, 2020; subjects enrolled prior to that time will continue to be evaluated

Financial Results for the Third Quarter Ended September 30, 2020

Zosano reported a net loss for the third quarter of 2020 of \$8.7 million, or \$0.11 per share on a basic and diluted basis, compared with a net loss of \$9.9 million, or \$0.55 per share on a basic and diluted basis, for the same quarter in 2019.

Research and development expenses for the third quarter of 2020 were \$5.8 million, compared with \$6.5 million for the same quarter in 2019. The decrease of \$0.7 million was primarily attributable to lower clinical trial costs of \$0.8 million due to the completion of Zosano’s long-term safety study in 2019, a decrease of \$0.2 million in compensation costs due to reduced headcount and a \$0.3 million decrease in travel and general business expenses due to COVID-19. These decreases were partially offset by an increase of \$0.3 million associated with the scale up and technology transfer to Zosano’s contract manufacturers and an increase in depreciation expense of \$0.3 million related to assets placed into service at its contract manufacturers.

General and administrative expenses for the third quarter of 2020 were \$2.7 million, compared with \$3.1 million in 2019. The decrease of \$0.4 million was primarily attributable to a \$0.4 million decrease in professional services costs related to strategic and pre-commercial activities and a \$0.2 million decrease in compensation costs related to lower headcount. These decreases were partially offset by a \$0.2 million increase in legal and professional services costs related to corporate and intellectual property matters and audit fees.

As of September 30, 2020, cash and cash equivalents were \$43.6 million as compared with \$6.3 million as of December 31, 2019.

About Zosano Pharma

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 transdermal 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 designed to be delivered via its transdermal microneedle system technology, as an acute treatment for migraine. Learn more at www.zosanopharma.com or connect through LinkedIn at <https://www.linkedin.com/company/zosano-pharma>, Twitter at <https://twitter.com/ZosanoPharma> and Instagram at <https://www.instagram.com/zosanopharma/>.

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, the company's plan to have a Type A meeting with the FDA and the company's expectations with respect to the meeting with the FDA, the company's plan to evaluate the feasibility of formulating a pharmaceutical agent being developed by Mitsubishi Tanabe Pharma Corporation for administration, with the company's proprietary transdermal microneedle system technology and the company's plan with respect to the placebo-controlled Phase 2/3 clinical trial evaluating the potential of C213 as an acute treatment for cluster headache. Such forward-looking statements involve known and unknown risks, uncertainties, and other important factors that may cause the company's actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the company's business in general, see the most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. The company does not plan to publicly update or revise any forward-looking statements contained in this press release, whether as a result of any new information, future events, changed circumstances or otherwise, except as required by law.

Zosano Contacts:

Christine Matthews
Chief Financial Officer
510-745-1200

Zosano PR:

Sylvia Wheeler or Alexandra Santos - swheeler@wheelhousesa.com or asantos@wheelhousesa.com

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

| | September 30, 2020 | December 31, 2019 |
|--|-----------------------|----------------------|
| | <i>(unaudited)</i> | |
| <u>ASSETS</u> | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 43,554 | \$ 6,316 |
| Prepaid expenses and other current assets | 615 | 497 |
| Total current assets | 44,169 | 6,813 |
| Restricted cash | 455 | 455 |
| Property and equipment, net | 30,621 | 24,636 |
| Operating lease right-of-use assets | 5,204 | 5,763 |
| Other long-term assets | 3 | 3 |
| Total assets | <u>\$ 80,452</u> | <u>\$ 37,670</u> |
| <u>LIABILITIES AND STOCKHOLDERS' EQUITY</u> | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,972 | \$ 4,356 |
| Accrued compensation | 1,982 | 2,015 |
| Build-to-suit obligation, current portion | 4,293 | 4,554 |
| Operating lease liabilities, current portion | 1,332 | 1,140 |
| Paycheck Protection Program loan, current portion | 201 | — |
| Other accrued liabilities | 3,394 | 4,172 |
| Total current liabilities | 13,174 | 16,237 |
| Build-to-suit obligation, long-term portion, net of debt issuance costs and discount | 5,447 | 6,095 |
| Operating lease liabilities, long-term portion | 5,058 | 5,931 |
| Paycheck Protection Program loan, long-term portion | 1,416 | — |
| Other liabilities | 113 | 15 |
| Total liabilities | 25,208 | 28,278 |
| Stockholders' equity: | | |
| Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; none issued and outstanding as of September 30, 2020 and December 31, 2019 | — | — |
| Common stock, \$0.0001 par value; 250,000,000 shares authorized; 102,066,218 and 23,503,214 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively | 10 | 2 |
| Additional paid-in capital | 379,326 | 308,211 |
| Accumulated deficit | (324,092) | (298,821) |
| Total stockholders' equity | 55,244 | 9,392 |
| Total liabilities and stockholders' equity | <u>\$ 80,452</u> | <u>\$ 37,670</u> |

ZOSANO PHARMA CORPORATION
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)
(unaudited)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|----------------------------------|------------|---------------------------------|-------------|
| | 2020 | 2019 | 2020 | 2019 |
| Revenue | \$ — | \$ — | \$ — | \$ — |
| Operating expenses: | | | | |
| Research and development | 5,824 | 6,486 | 16,270 | 19,742 |
| General and administrative | 2,704 | 3,071 | 8,552 | 8,709 |
| Total operating expenses | 8,528 | 9,557 | 24,822 | 28,451 |
| Loss from operations | (8,528) | (9,557) | (24,822) | (28,451) |
| Other income (expense): | | | | |
| Interest income | 2 | 41 | 17 | 203 |
| Interest expense | (165) | (281) | (561) | (357) |
| Other income (expense), net | 4 | (66) | 95 | (44) |
| Loss before provision for income taxes | (8,687) | (9,863) | (25,271) | (28,649) |
| Provision for income taxes | — | — | — | — |
| Net loss | \$ (8,687) | \$ (9,863) | \$ (25,271) | \$ (28,649) |
| Unrealized gain on marketable securities, net of tax | — | — | — | 5 |
| Comprehensive loss | \$ (8,687) | \$ (9,863) | \$ (25,271) | \$ (28,644) |
| Net loss per common share – basic and diluted | \$ (0.11) | \$ (0.55) | \$ (0.45) | \$ (1.84) |
| Weighted-average shares used in computing net loss per common share – basic and diluted | 77,883,158 | 17,832,092 | 56,437,417 | 15,579,387 |