

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 6, 2020**

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**ZOSANO PHARMA CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

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**001-36570**  
(Commission  
File Number)

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**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.)

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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.

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## Zosano Pharma Reports Second Quarter 2020 Financial Results and Provides Corporate Update

**FREMONT, Calif., August 6, 2020** -- Zosano Pharma Corporation (NASDAQ:ZSAN), a clinical-stage biopharmaceutical company, today announced financial results for the second quarter ended June 30, 2020, as well as recent business highlights.

“Zosano is on the cusp of potentially accomplishing what few biotech companies have the privilege of doing, namely becoming a commercial organization with an approved product designed to help address a significant treatment gap,” said Steven Lo, president and CEO of Zosano. “If approved, we believe Qtrypta’s novel drug delivery approach for the acute treatment of migraine has the potential to address patients’ needs for an effective, fast and durable therapy. Additionally, if approved, Qtrypta’s simple administration as a patch may be preferred by patients whose migraine is associated with nausea, which makes it challenging for them to take oral medications. We are now focused on executing on pre-commercial activities in preparation for Qtrypta’s possible approval later this year and potential subsequent launch in 2021.”

### Business Highlights

- Received U.S. Food and Drug Administration (FDA) acceptance of the 505(b)(2) NDA filing for Qtrypta™ for the acute treatment of migraine
- Presented new post-hoc analyses of Qtrypta’s clinical trial data comparing key efficacy results from the pivotal ZOTRIP study and the open-label long-term safety study at the American Headache Society’s Virtual Annual Scientific Meeting
  - Analyses suggest that Qtrypta’s efficacy results and favorable tolerability results across approximately 6,000 migraine episodes treated in the long-term safety study were consistent with the statistically significant results and tolerability results noted in the pivotal study
- Completed a blinded market research study conducted with high-volume physicians and payors, including 100 physician specialists and five national payors representing over 100 million covered lives, which found that:
  - 79% of the physicians strongly agree there remains an unmet need in the treatment of migraine in the acute setting, even in patients that respond to preventive therapy
  - 70% of the physicians would offer their patients a non-oral triptan that has fast and complete pain relief that is sustained and well-tolerated

### Financial Results for the Second Quarter Ended June 30, 2020

Zosano reported a net loss for the second quarter of 2020 of \$7.9 million, or \$0.14 per share on a basic and diluted basis, compared with a net loss of \$9.4 million, or \$0.55 per share on a basic and diluted basis, for the same quarter in 2019.

Research and development expenses for the second quarter of 2020 were \$4.9 million, compared with \$6.6 million for the same quarter in 2019. The decrease was mainly due to lower clinical trial costs resulting from the completion of the Qtrypta long-term safety study in 2019.

General and administrative expenses for each of the second quarters of 2020 and 2019 were \$2.8 million.

As of June 30, 2020, cash and cash equivalents were \$10.5 million as compared with \$6.3 million as of December 31, 2019.

### About Qtrypta™ (M207)

Qtrypta is Zosano’s proprietary investigational formulation of zolmitriptan delivered utilizing its proprietary transdermal microneedle system (the “System”) in development for the acute treatment of migraine. The System consists of titanium microneedles coated with drug, and in the case of Qtrypta™, the formulation is zolmitriptan. The drug-coated microneedles are designed to penetrate the stratum corneum, where the investigational drug dissolves and easily enters into the bloodstream. In February 2017, the Company announced statistically significant results from the ZOTRIP pivotal study, in which the 3.8 mg dose of Qtrypta™ met both co-primary endpoints, achieving pain freedom and most bothersome symptom freedom at 2 hours.

### About Migraine

Migraine is a highly prevalent neurological disease impacting 12% of the US population and 1 in 4 households. Patients impacted by migraine experience significant disability, with 90% unable to function normally. Migraine attacks are estimated to lead to lost productivity costs as high as \$36 billion annually in the United States, including both direct and indirect costs. Zosano believes that there is a significant need for new acute treatment options since 74% of migraine patients experience inadequate treatment response.

### 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 delivered via its transdermal microneedle system technology, as an acute treatment for migraine. The company anticipates that many of its current and future development programs may enable the company to utilize a regulatory pathway that has the potential to streamline clinical development and accelerate the path towards commercialization. Learn more at [www.zosanopharma.com](http://www.zosanopharma.com).

### **Forward-Looking Statements**

This press release contains forward-looking statements regarding the preparation for potential approval and launch of Qtrypta and other future events and expectations events and expectations described 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 2020, 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, Zosano 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:**

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### **PR Contacts:**

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

	June 30, 2020 <i>(unaudited)</i>	December 31, 2019
<b><u>ASSETS</u></b>		
Current assets:		
Cash and cash equivalents	\$ 10,547	\$ 6,316
Prepaid expenses and other current assets	699	497
Total current assets	11,246	6,813
Restricted cash	455	455
Property and equipment, net	30,712	24,636
Operating lease right-of-use assets	5,296	5,763
Other long-term assets	3	3
Total assets	\$ 47,712	\$ 37,670
<b><u>LIABILITIES AND STOCKHOLDERS' EQUITY</u></b>		
Current liabilities:		
Accounts payable	\$ 4,809	\$ 4,356
Accrued compensation	2,754	2,015
Build-to-suit obligation, current portion	3,085	4,554
Operating lease liabilities, current portion	1,228	1,140
Paycheck Protection Program loan, current portion	725	—
Other accrued liabilities	3,945	4,172
Total current liabilities	16,546	16,237
Build-to-suit obligation, long-term portion, net of debt issuance costs and discount	6,509	6,095
Operating lease liabilities, long-term portion	5,297	5,931
Paycheck Protection Program loan, long-term portion	888	—
Other liabilities	8	15
Total liabilities	29,248	28,278
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; none issued and outstanding as of June 30, 2020 and December 31, 2019	—	—
Common stock, \$0.0001 par value; 250,000,000 shares authorized; 57,245,251 and 23,503,214 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	6	2
Additional paid-in capital	333,863	308,211
Accumulated deficit	(315,405)	(298,821)
Total stockholders' equity	18,464	9,392
Total liabilities and stockholders' equity	\$ 47,712	\$ 37,670

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	4,932	6,640	10,446	13,256
General and administrative	2,766	2,767	5,848	5,638
Total operating expenses	7,698	9,407	16,294	18,894
Loss from operations	(7,698)	(9,407)	(16,294)	(18,894)
Other income (expense):				
Interest income	5	82	15	162
Interest expense	(190)	(35)	(396)	(76)
Other income (expense), net	(12)	—	91	22
Loss before provision for income taxes	(7,895)	(9,360)	(16,584)	(18,786)
Provision for income taxes	—	—	—	—
Net loss	\$ (7,895)	\$ (9,360)	\$ (16,584)	\$ (18,786)
Unrealized gain (loss) on marketable securities, net of tax	—	(1)	—	5
Comprehensive loss	\$ (7,895)	\$ (9,361)	\$ (16,584)	\$ (18,781)
Net loss per common share – basic and diluted	\$ (0.14)	\$ (0.55)	\$ (0.36)	\$ (1.30)
Weighted-average shares used in computing net loss per common share – basic and diluted	54,927,408	16,868,643	45,596,713	14,434,365