Zosano Pharma Corp
Form 10-Q
August 09, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2018

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 001-36570

ZOSANO PHARMA CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**45-4488360**
(State or other jurisdiction of incorporation or organization)	**(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)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of large accelerated filer, accelerated filer, smaller reporting company, and emerging growth company in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 2, 2018, the registrant had a total of 11,973,039 shares of its common stock, $0.0001 par value per share, outstanding.

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ZOSANO PHARMA CORPORATION

CONDENSED BALANCE SHEETS

(in thousands, except par value and share amounts)

	June 30, 2018 *(unaudited)*	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,197	$ 11,651
Short-term investments in marketable securities at fair value	21,441	
Prepaid expenses and other current assets	869	1,742
Total current assets	38,507	13,393
Restricted cash	35	35
Property and equipment, net	6,132	4,152
Other long-term assets	552	420
Total assets	$ 45,226	$ 18,000
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,391	$ 1,511
Accrued compensation	1,434	1,571
Deferred revenue	62	
Secured promissory note (including accrued interest), net of issuance costs	3,600	6,687
Other accrued liabilities	741	688
Total current liabilities	8,228	10,457
Deferred rent	918	495
Total liabilities	9,146	10,952
Commitments and contingencies (note 6)		
Stockholders equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized as of June 30, 2018 and December 31, 2017; none issued and outstanding as of June 30, 2018 and December 31, 2017		
Common stock, $0.0001 par value; 250,000,000 and 100,000,000 shares authorized as of June 30, 2018 and December 31, 2017, respectively; 11,973,039 and 1,973,039 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	1	
Additional paid-in capital	278,995	232,922
Accumulated deficit	(242,916)	(225,874)

Stockholders equity	36,080	7,048
Total liabilities and stockholders equity	$ 45,226	$ 18,000

The accompanying notes are an integral part of these condensed financial statements.

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ZOSANO PHARMA CORPORATION

CONDENSED STATEMENTS OF OPERATIONS

(unaudited; in thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue	$	$	$	$
Operating expenses:				
Research and development	6,533	4,363	12,339	8,989
General and administrative	2,272	2,188	4,532	4,310
Total operating expenses	8,805	6,551	16,871	13,299
Loss from operations	(8,805)	(6,551)	(16,871)	(13,299)
Other income (expense):				
Interest expense, net	(33)	(207)	(174)	(454)
Other income, net	2	12	3	10
Net loss	$ (8,836)	$ (6,746)	$ (17,042)	$ (13,743)
Net loss per common share basic and diluted	$ (0.75)	$ (3.44)	$ (2.47)	$ (9.22)
Weighted-average shares used in computing net loss per common share basic and diluted	11,753	1,960	6,890	1,491

The accompanying notes are an integral part of these condensed financial statements.

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ZOSANO PHARMA CORPORATION

CONDENSED STATEMENTS OF CASH FLOWS

(unaudited; in thousands)

	Six Months Ended June 30,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (17,042)	$ (13,743)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	391	1,261
Stock-based compensation	469	416
Gain on sale of equipment		(13)
Gross unrealized losses of marketable securities	14	
Amortization of debt discount/accretion of premium	(5)	(11)
Accretion of interest	36	48
Deferred rent	515	75
Change in operating assets and liabilities:		
Interest receivable	56	
Prepaid expenses and other assets	579	(1,156)
Accounts payable	615	(236)
Accrued compensation and other accrued liabilities	(83)	(766)
Deferred revenue	62	
Net cash used in operating activities	(14,393)	(14,125)
Cash flows from investing activities:		
Purchase of property and equipment	(2,106)	(625)
Proceeds from sales of property and equipment		22
Purchase of marketable securities	(37,475)	(7,071)
Proceeds from maturities of marketable securities	16,000	
Net cash used in investing activities	(23,581)	(7,674)
Cash flows from financing activities:		
Proceeds from public offering of securities, net of underwriting commissions, discounts and other offering costs	45,603	26,623
Proceeds from exercise of warrants and issuance of common stock		4,041
Payment of loan principal	(3,083)	(2,846)
Proceeds from exercise of stock options and issuance of common stock		137
Net cash provided by financing activities	42,520	27,955
Net increase in cash and cash equivalents	4,546	6,156
Cash and cash equivalents at beginning of period	11,686	15,038

Cash and cash equivalents at end of period	$	16,232	$	21,194
Supplemental cash flow information:				
Interest paid	$	203	$	540
Acquisition of property and equipment under accounts payable	$	264	$	7
Offering costs accrued but not yet paid	$	98	$	

The accompanying notes are an integral part of these condensed financial statements.

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Zosano Pharma Corporation

Notes to Condensed Financial Statements

June 30, 2018

(unaudited)

1. Organization and Basis of Presentation

The Company

Zosano Pharma Corporation (the Company) is a clinical stage biopharmaceutical company focused on providing rapid systemic administration of therapeutics to patients using our proprietary Adhesive Dermally-Applied Microarray, or ADAM , technology. In February 2017, the Company announced positive results from its ZOTRIP pivotal efficacy trial, or ZOTRIP trial, that evaluated M207, which is its proprietary formulation of zolmitriptan delivered via the Company s ADAM technology, as an acute treatment for migraine. The Company 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 our 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.

Basis of Presentation

The condensed financial statements have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP) for interim financial information, the instructions to Form 10-Q and Regulation S-X. They do not include all the information and notes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018, or any other subsequent period. These financial statements should be read in conjunction with the Company s audited financial statements for the year ended December 31, 2017, included in the Company s annual report on Form 10-K and filed with the United States Securities and Exchange Commission (SEC) filed March 12, 2018.

On January 23, 2018, the Company s stockholders approved an increase to the number of authorized shares of the Company s common stock from 100,000,000 to 250,000,000 shares. On January 23, 2018, the board of directors approved a 1-for-20 reverse stock split of our outstanding common stock, which was effected on January 25, 2018. At the effective time, every twenty shares of common stock issued and outstanding were automatically combined into one share of issued and outstanding common stock. The par value of the Company s stock remained unchanged at $0.0001 per share. No fractional shares of our common stock were issued in the reverse stock split, but in lieu thereof, each holder of common stock who would otherwise have been entitled to a fraction of a share in the reverse stock split received a cash payment. In addition, by reducing the number of the Company s outstanding shares, its loss per share in all prior periods increased by a factor of twenty. A proportionate adjustment was also made to the per share exercise price and the number of shares issuable upon the exercise of its outstanding equity awards, options and warrants to purchase shares of its common stock and to the number of shares reserved for issuance pursuant to its equity incentive compensation plans. The reverse stock split affected all stockholders uniformly. As a result of the reverse stock split, the number of the Company s outstanding shares of common stock as of January 25, 2018 decreased from 39,460,931

(pre-split) shares to 1,973,039 (post-split) shares. Unless otherwise noted, all share and per share information included in the financial statements have been retroactively adjusted to give effect to the reverse stock split.

Liquidity

As of June 30, 2018, the Company has an accumulated deficit of $242.9 million, as well as recurring operating losses and negative cash flows from operating activities. Cash and cash equivalents at June 30, 2018 were approximately $16.2 million and short-term investments of $21.4 million. On April 3, 2018, the Company closed a public offering of 10,000,000 shares of common stock at a public offering price of $5.00 per share. The Company received gross proceeds of $50.0 million and approximately $45.6 million of net proceeds from the offering and plans to use the net proceeds from the offering to complete the long-term safety study of M207, and for working capital and general corporate purposes. The Company believes the completion of the public offering will allow it to continue executing on the timely filing of its NDA for M207, which it expects will occur in the fourth quarter of 2019. We expect cash and cash equivalents and investments will be sufficient to enable us to fund our anticipated level of operations based on our current operating plans beyond twelve months following the date of issuance of this Quarterly Report on From 10-Q.

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The Company has financed its operations through the sale of equity securities and debt financing. To date, none of the Company s product candidates have been approved by the United States Food and Drug Administration for sale. The Company will continue to require additional financing to develop its product candidate, develop additional product candidates and fund operating losses. Management intends to seek capital to support the Company s initiatives through financing activities such as public or private offerings of its common stock, and/or preferred stock offerings, issuances of debt and convertible debt instruments and collaborative or other arrangements with corporate partners. However, if such financing is not available at adequate levels or on acceptable terms, the Company could be required to significantly reduce its operating expenses and delay, reduce the scope of or eliminate some of its development programs, out-license intellectual property rights, or a combination of the above, which may have a material adverse effect on the Company s business, results of operations, financial condition and/or its ability to meet its scheduled obligations on a timely basis, if at all.

The Company will continue to evaluate its timelines, strategic needs, and balance sheet requirements. There can be no assurance that if the Company attempts to raise additional capital, it will be successful in doing so on terms acceptable to the Company, or at all. Further there can be no assurance that it will be able to gain access and/or be able to execute on securing new sources of funding, new development opportunities, successfully obtain regulatory approvals for and commercialize new products, achieve significant product revenues from its products, or achieve or sustain profitability in the future.

2. Summary of Significant Accounting Policies

Significant Accounting Policies

There have been no material changes to the Company s significant accounting policies during the six months ended June 30, 2018, as compared to the significant accounting policies described in Note 2 of the Notes to Financial Statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2017.

Use of Estimates

The preparation of the accompanying condensed financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the condensed financial statements, and the reported amounts of revenue and expenses during the periods reported. Actual results could differ from those estimates.

Cash and Cash Equivalents and Restricted Cash

The following table provides a reconciliation of cash, cash equivalents and restricted cash to amounts shown in the statement of cash flows in thousand:

	June 30,	
	2018	**2017**
Cash and cash equivalents	$ 16,197	$ 21,159
Restricted cash	35	35
	$ 16,232	$ 21,194

Restricted Cash

The Company s restricted cash consists of funds set aside by a contractual pledge and security agreement with a bank whereby $35,000 is held as a security for corporate purchasing cards.

Marketable Securities

The Company classifies its investments in marketable securities as available-for sale. Investments with original maturities between three and twelve (12) months are considered short-term investments. Investments with original maturities greater than 12 months are considered long-term investments. The Company s investments that are classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses are recorded in earnings. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold.

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Fair Value Instruments

The Company records its financial assets and liabilities at fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1: Inputs which include quoted prices in active markets for identical assets and liabilities.

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying values of certain assets and liabilities of the Company, such as cash and cash equivalents, accounts receivable, and accounts payable, approximate fair value due to their relatively short maturities. The carrying value of the Company s short-term notes payable approximates their fair value as the terms of the borrowing are consistent with current market rates and the duration to maturity is short.

Revenue

Effective January 1, 2018, the Company adopted Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers. In accordance with ASC Topic 606, the Company recognizes revenue when the customer obtains control of promised goods or services, in an amount that reflects the consideration which it expects to receive in exchange for those goods and services. To determine revenue recognition for arrangements that the Company deems are within the scope of ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) calculate transfer price; (iv) allocate the transaction price to the performance obligation in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Deferred Revenue

Deferred revenue consists of amounts related to fees resulting from feasibility research projects received prior to satisfying the revenue recognition criteria (see, Revenue) and are recognized as deferred revenue in our balance sheet. Amounts are recognized as revenue upon satisfaction of the performance obligation as prescribed under ASC Topic 606.

Research and Development Expenses

Research and development costs are charged to expense as incurred and consist of costs related to (i) furthering the Company s research and development efforts, and (ii) designing and manufacturing products that incorporate the Company s ADAM technology for the Company s clinical and nonclinical studies.

Net Loss Per Common Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive common stock equivalents. Diluted earnings per common share is computed by giving effect to all potentially dilutive common stock equivalents outstanding for the period. For purposes of this calculation, warrants and options to purchase common stock are considered potentially dilutive common stock equivalents. For the six months ended June 30, 2018 and 2017, diluted net loss per common share was the same as basic net loss per common share since the effect of inclusion of potentially dilutive common stock equivalents would have an antidilutive effect due to the loss reported. The following outstanding common stock equivalents were excluded from the computations of diluted net loss per common share for the periods presented as the effect of including such securities would be antidilutive:

	June 30,	
	2018	**2017**
Warrants to purchase common stock	199,524	347,311
Options to purchase common stock	1,186,318	109,173
	1,385,842	456,484

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Recent Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, *Compensation Stock Compensation (Topic 718); Improvements to Nonemployee Share-Based Payment Accounting* which aligned certain aspects of share-based payments accounting between employees and non-employees. Specifically nonemployee share-based payment awards within the scope of Topic 718 are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied and an entity considers the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions. ASU No. 2018-07 is effective for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity s adoption date of Topic 606. The Company is currently evaluating ASU 2018-07 to determine the impact to its condensed financial statements and related disclosures.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815), (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*, which allows for the exclusion of a down round feature, when evaluating whether or not an instrument or embedded feature requires derivative classification. ASU No. 2017-11 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating ASU 2017-11 to determine the impact to its condensed financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments &#1*