

Zosano Pharma Corp  
Form 10-Q  
August 09, 2018  
Table of Contents

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

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.



**Table of Contents**

**Zosano Pharma Corporation**  
**Quarterly Report on Form 10-Q**

**INDEX**

	<b>Page</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	<b>3</b>
Item 1. <u>Financial Statements</u>	3
<u>Condensed Balance Sheets</u>	3
<u>Condensed Statements of Operations</u>	4
<u>Condensed Statements of Cash Flows</u>	5
<u>Notes to Condensed Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	22
<b><u>PART II. OTHER INFORMATION</u></b>	<b>22</b>
Item 1. <u>Legal Proceedings</u>	22
Item 1A <u>Risk Factors</u>	22
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	23
Item 3. <u>Defaults Upon Senior Securities</u>	23
Item 4. <u>Mine Safety Disclosures</u>	23
Item 5. <u>Other Information</u>	23
Item 6. <u>Exhibits</u>	23
<b><u>SIGNATURES</u></b>	<b>24</b>

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

	<b>June 30, 2018</b>	<b>December 31, 2017</b>
	<i>(unaudited)</i>	
<b><u>ASSETS</u></b>		
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
<b><u>LIABILITIES AND STOCKHOLDERS EQUITY</u></b>		
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)

Edgar Filing: Zosano Pharma Corp - Form 10-Q

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.

**Table of Contents**

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

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
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.

**Table of Contents**

**ZOSANO PHARMA CORPORATION**  
**CONDENSED STATEMENTS OF CASH FLOWS**

(unaudited; in thousands)

	<b>Six Months Ended June 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>Cash flows from operating activities:</b>		
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)
<b>Cash flows from investing activities:</b>		
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)
<b>Cash flows from financing activities:</b>		
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.

---

**Table of Contents**

**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 Form 10-Q.

**Table of Contents**

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:

	<b>June 30,</b>	
	<b>2018</b>	<b>2017</b>
Cash and cash equivalents	\$ 16,197	\$ 21,159
Restricted cash	35	35
	<b>\$ 16,232</b>	<b>\$ 21,194</b>

***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.

## **Table of Contents**

### ***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:

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

---

**Table of Contents****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 – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This new guidance is intended to present credit losses on available for sale debt securities as an allowance rather than as a write-down. ASU 2016-13 is effective for annual reporting periods, including interim periods within those annual periods, beginning after December 15, 2019, with early adoption permitted for those fiscal years beginning after December 15, 2018. Adoption of ASU 2016-13 is not expected to have a significant impact in the Company's financial statements and disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases*. Under the new guidance, lessees will be required to recognize substantially all leases on the balance sheet as a right-of-use asset and recognize a corresponding lease liability. The accounting applied by a lessor is largely unchanged from that applied under previous U.S. GAAP. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We are currently evaluating the impact of this accounting standard on our financial position, results of operation or cash flows.

**3. Cash, Cash Equivalents and Investments in Marketable Securities**

As June 30, 2018 and December 31, 2017, cash, cash equivalent, and investments in marketable securities, comprised of funds in depository, money market accounts, U.S. treasury securities, commercial paper, and corporate bonds. The Company classifies all highly liquid investments with maturities of three months or less at the date of purchase as cash equivalents. The following table presents cash equivalents and investments carried at fair value in accordance with the fair value hierarchy defined in Note 2.



	<b>Fair Value Measurements</b>		
	<b>Quoted prices in active market Level I</b>	<b>Significant other observable inputs Level II</b>	<b>Significant unobservable inputs Level III</b>
	<i>(unaudited; in thousands)</i>		
<b>As of June 30, 2018:</b>			
Cash and restricted cash, included in cash equivalents <sup>(1)</sup>	\$ 1,893		
	<b>Total</b>		
Money market funds, included in cash equivalents	5,109	5,109	
Commercial paper, included in cash equivalents	5,733		5,733
U.S. treasuries, included in cash equivalents	1,000	1,000	
U.S. government agencies, included in cash equivalents	2,497		2,497
Commercial paper	5,205		5,205
Corporate notes and bonds	6,482		6,482
U.S. treasuries	9,754	9,754	
Total	\$ 35,780	\$ 15,863	\$ 19,917
<b>As of December 31, 2017:</b>			
Cash and restricted cash, included in cash equivalents <sup>(1)</sup>	\$ 4,587		
	<b>Total</b>		
Money market funds, included in cash equivalents	6,414	6,414	
U.S. government agencies, included in cash equivalents	650		650
Total	\$ 7,064	\$ 6,414	\$ 650

(1) *Not subject to leveling*

**Table of Contents**

As of June 30, 2018 and December 31, 2017 available-for-sale investments are detailed as follows:

	<b>Cost</b>	<b>June 30, 2018</b>		<b>Fair Value</b>
		<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	
		<i>(unaudited; in thousands)</i>		
Commercial paper	\$ 10,943		(5)	\$ 10,938
Corporate notes and bonds	6,489		(7)	6,482
U.S. Treasuries	10,756		(2)	10,754
U.S. Government agencies	2,497			2,497
	<b>\$ 30,685</b>	<b>\$</b>	<b>\$ (14)</b>	<b>\$ 30,671</b>

	<b>Cost</b>	<b>December 31, 2017</b>		<b>Fair Value</b>
		<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	
		<i>(in thousands)</i>		
U.S. government agency bonds	\$ 650			\$ 650
	<b>\$ 650</b>	<b>\$</b>	<b>\$</b>	<b>\$ 650</b>

**4. Property and Equipment**

The following summarizes the Company's property and equipment for each of the periods presented:

	<b>June 30, 2018</b>		<b>December 31, 2017</b>	
	<i>(unaudited; in thousands)</i>			
Laboratory and office equipment	\$	1,343	\$	1,159
Manufacturing equipment		10,423		10,387
Computer equipment and software		223		209
Leasehold improvements		16,460		15,660
Construction in progress		3,637		2,351
		32,086		29,766
Less: accumulated depreciation		(25,954)		(25,614)
	<b>\$</b>	<b>6,132</b>	<b>\$</b>	<b>4,152</b>



**Table of Contents**

Depreciation and amortization expense was approximately \$0.2 million and \$0.6 million for the three months ended June 30, 2018 and 2017, respectively. Depreciation and amortization expense was \$0.4 million and \$1.3 million for the six months ended June 30, 2018 and 2017, respectively.

**5. Debt Financing*****Senior Secured Term Loan with Hercules***

The Company entered into a loan and security agreement with Hercules Capital Inc, ( Hercules ). Hercules provided the Company a \$15 million loan ( Hercules Term Loan ) of which equal installment payments of principal and interest are due monthly, with all outstanding amounts due and payable on December 1, 2018. The Hercules Term Loan bears interest at a variable rate equal to the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. The interest rate on the Hercules Term Loan was 7.95% as of June 30, 2018 and December 31, 2017. On June 1, 2017, the Company paid a \$100,000 legacy end of term charge and is required to pay a \$351,135 end of term charge on the earlier of loan maturity or at the date the Company prepays the Hercules Term Loan. The Company may prepay all, but not less than all, of the Hercules Term Loan with no prepayment charge. The Hercules Term Loan is secured by a first priority security interest and lien in and to all of the Company's tangible and intangible properties and assets, including intellectual properties.

The following is a summary of the Company's debt, net of unamortized debt discount and issuance costs for the periods presented:

	<b>June 30, 2018</b>	<b>December 31, 2017</b>
	<i>(unaudited; in thousands)</i>	
Principal amount	\$ 3,233	\$ 6,316
Less: unamortized debt issuance costs	(2)	(10)
unamortized fair value of free standing warrant	(4)	(18)
Plus: unamortized fair value debt premium	8	35
accrued terminal interest	344	320
accrued interest	21	44
Secured promissory note, net of unamortized debt issuance cost and premium, current	\$ 3,600	\$ 6,687

For the three and six months ended June 30, 2018, the Company recorded total interest expense of \$0.1 million and \$0.3 million, respectively. For the three and six months ended June 30, 2017, the Company recorded interest expense of \$0.2 million and \$0.5 million, respectively, related to the Hercules Term Loan.

**6. Commitments and Contingencies**

The Company is not party to any material pending legal proceedings. However, the Company may from time to time become involved in litigation relating to claims arising in the ordinary course of business.

*Operating lease*

The Company has an operating lease with BMR-34790 Ardentech Court LP, an affiliate of BMR Holdings and related party, for its office, research and development, and manufacturing facilities in Fremont, California. On June 6, 2017, the Company entered into the seventh amendment to the existing lease ( *Seventh Amendment* ), effective as of May 30, 2017. The Company entered into the eighth amendment to the existing lease ( *Eight Amendment* ), effective as of May 30, 2018.

Under the *Seventh Amendment*, the Company extended the term of the lease for the Company's headquarters in Fremont, California through August 31, 2024, with an option to further extend the lease for an additional 65 months, subject to certain terms and conditions. The Company has agreed to pay a monthly base rent of \$136,191 for the period commencing September 1, 2017, and ending on August 31, 2018, with an increase on September 1, 2018, and annual increases on September 1 of each subsequent year until the lease year beginning September 1, 2023. The *Seventh Amendment* also provides for rent abatements, subject to certain conditions, totaling \$275,552 and certain tenant improvements to be completed at the Landlord's expense (not to exceed \$975,000 or, under certain conditions, \$1,100,000). The Company will incur additional expense of approximately \$0.4 million under the lease in connection with roof repairs that will be treated as additional rent and paid over the term of the lease.

**Table of Contents**

The Eighth Amendment extended the deadline for the Company to cause certain tenant improvements to be completed at the landlord's expense from May 30, 2018 to September 30, 2018. No change to the financial statements resulted from the terms of the Eighth Amendment. For the three and six months ended June 30, 2018, the Company recorded rental expense under the related party operating lease of \$0.4 million and \$0.8 million, respectively. For the three and six months ended June 30, 2017, the Company recorded rental expense under the related party operating lease of \$0.2 million and \$0.4 million, respectively.

As of June 30, 2018, future minimum payments under the Company's non-cancelable related party operating lease for each year ending December 31 are as follows:

	<b>Total</b>	
	<i>(unaudited; in thousands)</i>	
Remaining of 2018	\$	833
2019		1,754
2020		1,807
2021		1,861
2022		1,914
2023 and thereafter		3,310
	\$	11,479

*Severance obligations*

The Company has entered into employment agreements with some of its executive officers. Generally, the terms of these agreements provide that, if the Company terminates the officer other than for cause, death, or disability, or if the officer terminates his or her employment with the Company for good cause, the officer shall be entitled to receive certain severance compensation and benefits as described in each such agreement.

On May 15, 2018, Georgia Erbez resigned as Chief Business Officer and Chief Financial Officer. Pursuant to the terms of a Separation Agreement entered into May 10, 2018, the Company agreed to pay severance totaling approximately \$201,000, including base salary and benefit continuation coverage, for the six months following the separation date. Accordingly, as of June 30, 2018, the Company has approximately \$152,000 of remaining severance related to this arrangement accrued and unpaid. In addition, 25% of the unvested portion of Ms. Erbez' equity awards at the time of her resignation were accelerated. Her vested options remain exercisable for a period of eighteen months following her resignation.

On May 8, 2017, Konstantinos Alataris resigned as President and Chief Executive Officer. Pursuant to the terms of a Separation Agreement, the Company agreed to pay severance totaling approximately \$252,000, including base salary and benefit continuation coverage, for six months following the separation date. As of June 30, 2018, the Company had no severance due to Dr. Alataris related to his separation agreement.

*Other commitments*

As of June 30, 2018, the Company has an equipment purchase commitment related to its pre-commercialization manufacturing activities aggregating approximately \$12.2 million. The terms of the purchase commitment are contingent upon performance of certain milestones.

## **7. Stockholders Equity**

On January 24, 2018, the Company amended its certificate of incorporation to increase the number of shares of common stock authorized for issuance from 100,000,000 to 250,000,000. On January 25, 2018, we effected a 1-for-20 reverse stock split of our outstanding common stock.

### ***Equity Line of Credit***

On October 20, 2017, the Company entered into a purchase agreement and a registration rights agreement with an accredited investor, Lincoln Park Capital Fund, LLC ( Lincoln Park ), providing for the purchase of up to \$35.0 million worth of the Company s common stock over the term of the purchase agreement (the Equity Line of Credit).

**Table of Contents**

Under the terms and subject to the conditions of the Equity Line of Credit, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase, up to \$35.0 million worth of shares of the Company's common stock. The Company's board of directors reserved 392,104 shares for issuance pursuant to the Equity Line of Credit (inclusive of commitment shares). On October 20, 2017, the Company issued 11,375 shares of its common stock, as initial commitment shares, to Lincoln Park with a fair value of \$15.30 which was recorded as deferred financing costs and is included within other current assets in the accompanying balance sheet as of June 30, 2018. The deferred financing costs are amortized as interest expense using the effective interest rate method over the term of the Equity Line of Credit as there is no guaranty that additional shares will be sold under the Equity Line of Credit. Additionally, the Company will issue, pro rata, up to an additional 11,375 shares of its common stock as additional commitment shares to Lincoln Park in connection with any additional purchases. Such future sales of common stock by the Company, if any, will be subject to certain limitations, and may occur from time to time, at the Company's option, over the 30-month period that commenced on November 21, 2017, the date that the registration statement was declared effective by the SEC, and the other conditions of the Equity Line of Credit were satisfied. No sales of common stock have been made under the Lincoln Park purchase agreement as of June 30, 2018.

***Public Offering March 2017***

On March 22, 2017, the Company completed a registered public offering of 977,500 shares of common stock at a price of \$30.00 per share, which included the exercise in full by the underwriters of their over-allotment option to purchase up to 127,500 additional shares of common stock. The total proceeds from the offering were \$26.6 million, net of underwriter's discounts and commissions and offering expenses.

***Public Offering April 2018***

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. We received gross proceeds of \$50.0 million and approximately \$45.6 million of net proceeds from this offering. The offering was made by the Company pursuant to a registration statement on Form S-1 previously filed with the SEC on December 22, 2017, as amended and declared effective by the SEC on March 28, 2018.

***Warrants***

Below is a table summarizing the warrants issued and outstanding for each of the periods presented:

	<b>Warrants</b>		<b>Warrants</b>		
	<b>Outstanding as of</b>	<b>Warrants</b>	<b>Warrants</b>	<b>Exercise</b>	<b>Expiration</b>
	<b>As of December 31,</b>	<b>Exercised</b>	<b>Expired</b>	<b>Price</b>	<b>Date</b>
	<b>2017</b>		<b>As of June 30, 2018</b>		
PIPE Financing - Series B	195,906		195,906	\$ 31.00	8/19/2021
Hercules - June 2014	1,583		1,583	\$ 176.80	1/27/2020
Hercules - June 2015	2,035		2,035	\$ 147.40	6/23/2020
Total	199,524		199,524		

As of June 30, 2018, the Company had 199,524 warrants outstanding classified as equity warrants. Each warrant grants the holder the right to purchase one share of common stock. Equity warrants are recorded at their relative fair



market value in the stockholders' equity section of the balance sheet. The Company's equity warrants can only be settled through the issuance of shares and do not have any anti-dilution or price reset provisions.

## **8. Stock-Based Compensation**

### ***The Amended and Restated 2014 Equity and Incentive Plan***

The Amended and Restated 2014 Equity and Incentive Plan (the "2014 Plan") provides for the issuance of (i) cash awards and (ii) equity-based awards, denominated in shares of the Company's common stock, including incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, unrestricted stock awards, performance share awards and dividend equivalent rights. Incentive stock options may be granted only to Company employees. Nonqualified stock options may be granted to Company employees, outside directors and consultants. As of June 30, 2018, the Company had reserved 1,348,173 shares of our common stock for issuance under our 2014 Plan, subject to automatic annual increases as set forth in the plan. Options and awards under the 2014 Plan may be granted for periods of up to ten years. Employee options granted by the Company generally vest over four years. Restricted stock awards granted to employees, directors and consultants can be subject to the same vesting conditions and the right of repurchase by the Company on unvested shares as determined by our board of directors. As of June 30, 2018, the Company had 179,475 shares available for grant under the 2014 Plan. For the six months ended June 30, 2018, the Company granted 131,000 stock option awards to non-employee Directors.

**Table of Contents**

The following table summarizes option and award activity, excluding inducement grants, for the six months ended June 30, 2018 (unaudited):

	Shares Available for Grant	Outstanding Number of Shares	Weighted- Average Exercise Price per Share	Weighted- Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at December 31, 2017	29,571	99,029	\$ 25.33		
Additional shares reserved	1,225,223		\$		
Options granted	(1,079,700)	1,079,700	\$ 4.28		
Options cancelled/forfeited/expired	6,248	(6,248)	\$ 23.03		
Shares expired under 2012 Plan	(1,867)		\$		
Balance at June 30, 2018	179,475	1,172,481	\$ 5.96	9.67	\$
Exercisable at June 30, 2018		81,371	\$ 18.34	8.73	\$
Vested or expected to vest at June 30, 2018		1,060,324	\$ 6.09	9.66	\$

The aggregate intrinsic value is calculated as the difference between the exercise price of the option and the estimated fair value of the Company's common stock for in-the-money options at June 30, 2018.

**Inducement Grants**

The Company has also awarded inducement grants to purchase common stock to new employees outside the existing equity compensation plans in accordance with Nasdaq listing rule 5635(c)(4). Such options vest at a rate of 25% of the shares on the first anniversary of the commencement of such employee's employment with the Company, and then one forty-eighth (1/48) of the shares monthly thereafter subject to such employee's continued service. The following table summarizes the Company's inducement grant stock option activities:

	Outstanding Number of Shares	Weighted- Average Exercise Price per Share	Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Balance at December 31, 2017	19,350	\$ 19.12		
Options granted		\$		
Options cancelled/forfeited/expired	(5,513)	\$ 15.40		
Balance at June 30, 2018	13,837	\$ 20.60	5.02	\$

Exercisable at June 30, 2018	9,165	\$	17.78	3.07	\$
Vested or expected to vest at June 30, 2018	13,430	\$	20.43	4.91	\$

The following summarizes the composition of stock options outstanding and exercisable within the approved stock options plans, which excludes inducement grants, as of June 30, 2018:

Exercise Price	Options Outstanding			Options Exercisable	
	Number of Shares	Weighted-Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
\$4.24 - \$4.24	946,064	9.79	\$ 4.24	39,504	\$ 4.24
\$4.24 - \$146.60	224,767	9.21	\$ 11.87	40,587	\$ 26.79
\$181.00 - \$181.00	100	6.81	\$ 181.00	83	\$ 181.00
\$182.60 - \$182.60	150	6.82	\$ 182.60	118	\$ 182.60
\$185.80 - \$185.80	1,400	6.89	\$ 185.80	1,079	\$ 185.80

**Table of Contents****Stock-Based Compensation Expense**

Total stock-based compensation expense recognized was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
	<i>(unaudited; in thousands)</i>		<i>(unaudited; in thousands)</i>	
Research and development	\$ 142	\$ 76	\$ 209	\$ 137
General and administrative	188	107	260	279
	\$ 330	\$ 183	\$ 469	\$ 416

As of June 30, 2018, the Company had \$3.8 million of total unrecognized stock-based compensation, net of estimated forfeitures, related to outstanding stock options that will be recognized over a weighted-average period of 3.7 years.

The Company's stock-based compensation expense for stock options is estimated at the grant date based on the award's fair value as calculated by the Black-Scholes option pricing model and is recognized as expense over the requisite service period. The Black-Scholes option pricing model requires various highly judgmental assumptions including expected volatility and expected term. The expected volatility is based on the historical stock volatilities of several of the Company's publicly listed peers over a period equal to the expected terms of the options as the Company does not have sufficient trading history to use the volatility of its own common stock. To estimate the expected term, the Company has opted to use the simplified method which is the use of the midpoint of the vesting term and the contractual term. If any of the assumptions used in the Black-Scholes option pricing model changes significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period. In addition, the Company estimates the forfeiture rate based on historical experience and its expectations regarding future pre-vesting termination behavior of employees. To the extent that the actual forfeiture rate is different from this estimate, stock-based compensation expense is adjusted accordingly.

The following table presents the weighted-average assumptions for the Black-Scholes option-pricing model used in determining the fair value of options granted:

	For the three months ended June 30,		For the six months ended June 30,	
	2018	2017	2018	2017
Dividend yield	0%	0%	0%	0%
Risk-free interest rate	2.74% - 3.11%	1.90%	2.74% - 3.11%	1.90% - 2.13%
Expected volatility	89%	89%	89%	89%
Expected term (years)	6.08	6.08	6.08	6.08

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations included in our*

*Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the Securities and Exchange Commission, or SEC, on March 12, 2018, as amended. This discussion contains forward-looking statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Such forward looking statements involve risks and uncertainties. We use words such as may, continue, goal, would, could, might, project, anticipate, intend, forecast, designated, approximate, will, expect, anticipate, estimate, intend, plan, predict, potential, believe, should or negatives of these words and similar expressions and references to future periods to identify forward-looking statements. Although we believe the expectations reflected in these forward- looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. These statements appearing throughout this Quarterly Report on Form 10-Q are statements regarding our intent, belief, or current expectations, primarily regarding our operations. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. As a result of many factors, such as those set forth under Risk Factors under Item 1A of Part II below, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.*

## Table of Contents

### Overview

Zosano Pharma Corporation 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, we announced positive results from our ZOTRIP pivotal efficacy trial, or ZOTRIP trial, that evaluated M207, which is our proprietary formulation of zolmitriptan delivered via our ADAM technology, as an acute treatment for migraine. We are 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. We anticipate that many of our current and future development programs may enable us to utilize a regulatory pathway that would streamline clinical development and accelerate the path towards commercialization.

ADAM is our proprietary, investigational technology platform designed to offer rapid drug absorption into the bloodstream, which can result in an improved pharmacokinetic profile compared to original dosage forms. ADAM consists of an array of drug-coated titanium microprojections mounted on an adhesive backing that is pressed on to the skin using a reusable handheld applicator. The microprojections penetrate the stratum corneum, the outermost layer of skin of the epidermis, and allow the drug to be absorbed into very small blood vessels, microcapillaries, that connect to the larger blood vessels that transport the drug to the systemic circulation. We focus on developing products based on our ADAM technology for indications in which rapid onset, ease of use and stability offer significant therapeutic and practical advantages, for markets where there is a need for more effective therapies.

Our development efforts are focused on our product candidate, M207. M207 is our proprietary formulation of zolmitriptan delivered utilizing our ADAM technology. Zolmitriptan is one of a class of serotonin receptor agonists known as triptans and is used as an acute treatment for migraine. Migraine is a debilitating neurological disease, symptoms of which include moderate to severe headache pain, nausea and vomiting, and abnormal sensitivity to light and sound. The objective of M207 is to provide faster onset of efficacy and sustained freedom from migraine symptoms by delivering rapid absorption while avoiding the gastrointestinal tract. The United States Food and Drug Administration, or FDA, has indicated that one positive pivotal efficacy study, in addition to the required safety study, would be sufficient for approval of M207 for the treatment of migraine.

We have no product sales to date, and we will not have product sales unless and until we receive approval from the FDA or equivalent foreign regulatory bodies, to market and sell our product candidate. Accordingly, our success depends not only on the development, but also on our ability to finance the development of the product. We will require substantial additional funding to complete development and seek regulatory approval for these products. Additionally, we currently have no sales, marketing or distribution capabilities and thus our ability to market our products in the future will depend in part on our ability to develop such capabilities either alone or with collaboration partners.

### *M207 Clinical Trial and Long-Term Safety Study*

In November 2017, we announced the initiation of our long-term safety study for M207 as an acute treatment for migraine, with the enrollment of the first subject in the study. M207-ADAM is an open label study evaluating the safety of the 3.8 mg dose of zolmitriptan in migraine subjects who have historically experienced at least two migraines per month. Subjects are expected to treat a minimum of two migraines per month on average, with no maximum treatment limits. The study will evaluate at least 150 subjects for six months, and 50 subjects for a year at 31 sites in the U.S. The study is open-label, with investigator visits at months one, two, three, six, nine and twelve. The primary objective of our long-term safety study is to assess the safety of M207 during repeated use over six and twelve months. Other endpoints are electrocardiography and laboratory parameters, as well as percentage of headaches with

pain-free response.

In March 2018, we announced that the 100<sup>th</sup> subject had enrolled and received M207 in the long-term safety study. As of June 2018, 344 subjects have qualified and received study drug. Study subjects have treated more than 2,500 migraines since study initiation. We expect clinical completion by March 2019, when at least 50 of these subjects will complete one year in the study and have treated at least two migraines per month. As of the date of this filing, we have begun manufacturing of our registration batches in support of the NDA.

## **Table of Contents**

In April 2018, we closed an underwritten public offering pursuant to a registration statement on Form S-1 of 10,000,000 shares of our common stock sold at a price of \$5.00 per share. Net proceeds to us, after deducting underwriting discounts, commissions and reimbursable costs of approximately \$3.7 million and offering expenses of approximately \$0.7 million, were approximately \$45.6 million.

We will need additional financing for manufacturing, operations, and commercialization of M207, if approved. While we are pursuing clinical development and regulatory approval of our M207 product candidate through commercialization, we remain open to opportunities with potential strategic partners to ensure our product candidate has the best chance of commercial success.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ( U.S. GAAP ). The preparation of our financial statements in conformity with U.S. GAAP requires our management to make estimates and assumptions that affect the amounts and disclosures reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates. Our management believes judgment is involved in determining revenue recognition, the fair value-based measurement of stock-based compensation, and accruals. Our management evaluates estimates and assumptions as facts and circumstances dictate. As future events and their effects cannot be determined with precision, actual results could differ from these estimates and assumptions, and those differences could be material to the financial statements. If our assumptions change, we may need to revise our estimates, or take other corrective actions, either of which may also have a material adverse effect on our results of operations, liquidity and financial condition.

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012. Emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

There have been no significant and material changes in our critical accounting policies and use of estimates during the six months ended June 30, 2018, as compared to those disclosed in Part II, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Significant Judgments and Estimates in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC.

## **Financial Operations Overview**

As of June 30, 2018, we had an accumulated deficit of \$242.9 million. We have incurred significant losses and expect to incur significant losses in the foreseeable future as we advance M207 into later stages of development, and if approved, commercialization. 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 net proceeds of the offering were approximately \$45.6 million. We plan to use the net proceeds from this offering to complete the long-term safety study of M207 and for working capital and general corporate purposes. We believe the completion of this public offering will allow us to continue executing on the timely filing of our NDA for M207, which we expect will occur in the fourth quarter of 2019.

We expect our research and development expenses to increase significantly as we continue to advance M207 through clinical development. Because of the numerous risks and uncertainties associated with our technology and drug



development, we are unable to predict the timing or amount of expenses incurred or when, or if, we will be able to achieve commercialization, revenue or profitability.

***Research and development expenses***

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our proprietary product candidates. We recognize all research and development expenses as they are incurred.

Research and development expenses consist of:

production costs which include, but are not limited to, employee-related expenses, including salaries, benefits and stock-based compensation expense, and fees paid to conduct nonclinical studies, drug formulation, and cost of consumables used in nonclinical and clinical trials;

expenses related to the purchase of active pharmaceutical ingredients and raw materials for the production of product candidates based on our ADAM technology, including fees paid to contract manufacturing organizations ( CMOs );

## **Table of Contents**

fees paid to contract research organizations ( CROs ), clinical consultants, clinical trial sites and vendors, including institutional review boards ( IRBs ), in conjunction with implementing and monitoring our clinical trials and acquiring and evaluating clinical trial data, including all related fees, such as for investigator grants, subject screening fees, laboratory work and statistical compilation and analysis;

fees paid to conduct clinical studies, drug formulation, and cost of consumables used in nonclinical and clinical trials;

other consulting fees paid to third parties; and

allocation of certain shared costs, such as facilities-related costs and information technology ( IT ) support services.

For the immediate future, our research and development efforts and resources will be focused primarily on advancing our product candidate M207 through clinical development.

We cannot forecast with any degree of certainty if any of our product candidates will be subject to future collaborations or how such arrangements would affect our development plans or capital requirements. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

### ***General and administrative expenses***

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development.

### ***Other income and expenses***

*Interest expense, net.* Interest expense, net of interest income, consists primarily of interest costs related to our debt and the amortization of debt discount and issuance costs. Interest expense for the six months ended June 30, 2018 reflects accrued and paid interest related to our secured term loan facility ( Hercules Term Loan ) with Hercules Capital, Inc. ( Hercules ), and the related amortization of debt discount and issuance costs.

*Other income, net.* Other income, net of other expense, consists of certain miscellaneous income or expenses that are not included in other categories of the condensed statements of operations. (See explanations under the subheading, Results of Operations).

## **Results of Operations**

### ***Comparison of the three months ended June 30, 2018 and 2017***

#### ***Research and development expenses***

	Three months ended June 30,		Change	
	2018	2017	Amount	%

(In thousands)

Research and development	\$ 6,533	\$ 4,363	\$ 2,170	50%
--------------------------	----------	----------	----------	-----

Research and development expenses increased approximately \$2.2 million, or 50%, for the three months ended June 30, 2018, as compared to the same period in 2017. The increase in research and development expense was primarily attributable to an increase in clinical trial costs of \$1.8 million related to the M207 long-term safety study and to an additional increase of \$0.3 million in costs for clinical supplies for materials to support production of registration batches.

***General and administrative expenses***

	Three months ended June 30,		Change	
	2018	2017	Amount	%

(In thousands)

General and administrative	\$ 2,272	\$ 2,188	\$ 84	4%
----------------------------	----------	----------	-------	----

**Table of Contents**

General and administrative expenses increased approximately \$0.1 million, or 4%, for the three months ended June 30, 2018 as compared to the same period in 2017. Increases in expenses were primarily due to increase in rent for our corporate headquarters.

**Other income (expenses)**

	<b>Three months ended June 30,</b>		<b>Change</b>	
	<b>2018</b>	<b>2017</b>	<b>Amount</b>	<b>%</b>
	<i>(In thousands)</i>			
Interest expense, net	\$ (33)	\$ (207)	\$ 174	84%
Other income, net	16	12	4	(33%)

Interest expense, net decreased approximately \$0.2 million, or 84%, for the three months ended June 30, 2018, as compared to the same period in 2017. Interest expense is primarily attributable to the Hercules Term Loan. The decrease in interest expense is attributable to the lower interest costs resulting from the lower loan principal balance during the three months ended June 30, 2018 as compared to the same period in 2017.

**Comparison of the six months ended June 30, 2018 and 2017****Research and development expenses**

	<b>Six months ended June 30,</b>		<b>Change</b>	
	<b>2018</b>	<b>2017</b>	<b>Amount</b>	<b>%</b>
	<i>(In thousands)</i>			
Research and development	\$ 12,339	\$ 8,989	\$ 3,350	37%

Research and development expenses increased approximately \$3.3 million, or 37%, for the six months ended June 30, 2018, as compared to the same period in 2017. The increase in research and development expense was primarily attributable to an increase in clinical trial costs of \$2.6 million related to the long-term safety study and to an additional increase \$0.7 million attributed to an increase related to the production of our registration batches.

**General and administrative expenses**

	<b>Six months ended June 30,</b>		<b>Change</b>	
	<b>2018</b>	<b>2017</b>	<b>Amount</b>	<b>%</b>
	<i>(In thousands)</i>			
General and administrative	\$ 4,532	\$ 4,310	\$ 222	5%

General and administrative expenses increased approximately \$0.2 million or 5% for the six months ended June 30, 2018 as compared to the same period in 2017. Increases in expenses were primarily due to increase in building rent and franchise taxes.

**Other income (expenses)**

	<b>Six months ended June 30,</b>		<b>Change</b>	
	<b>2018</b>	<b>2017</b>	<b>Amount</b>	<b>%</b>
	<i>(In thousands)</i>			
Interest expense, net	\$ (174)	\$ (454)	\$ 280	62%
Other income, net	17	10	7	(70%)

Interest expense, net decreased approximately \$0.3 million, or 62%, for the six months ended June 30, 2018, as compared to the same period in 2017. Interest expense is primarily attributable to the Hercules Term Loan. The decrease in interest expense is attributable to the lower interest costs resulting from the lower loan principal balance during the six months ended June 30, 2018 as compared to the same period in 2017.

### **Liquidity and Capital Resources**

Since our inception in October 2006, we have funded our operations primarily through a combination of equity offerings, secured and unsecured borrowings from private investors, bank credit facilities, and licensing and service revenue from our license and collaboration agreements. We have incurred recurring operating losses and negative cash flows from operating activities since inception, and as of June 30, 2018, had an accumulated deficit of \$242.9 million. We expect to incur additional losses in the future to conduct research and development of our M207 product candidate and to conduct pre-commercialization manufacturing activities. As of June 30, 2018, we had approximately \$37.6 million in cash, cash equivalents, and investments.

## Table of Contents

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. As of June 30, 2018, the Company has an equipment purchase commitment related to its pre-commercialization activities aggregating approximately \$12.2 million. Upon execution of the purchase order, the Company made an initial payment of \$1.5 million which was recorded in construction-in-progress. The terms of the purchase commitment are contingent upon performance of certain milestones.

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 Form 10-Q.

On October 20, 2017, we entered into a purchase agreement ( Lincoln Park Purchase Agreement ) with Lincoln Park Capital, LLC ( Lincoln Park ). Under the terms and subject to the conditions of the Lincoln Park Purchase Agreement, we have the right, but not the obligation, to sell to Lincoln Park up to \$35.0 million worth of shares of our common stock. See Note 7 to the accompanying condensed financial statements for additional information on the Lincoln Park Purchase Agreement. No sales of common stock have been made under the Lincoln Park purchase agreement as of June 30, 2018.

The Company has financed its operations primarily through the sale of equity securities, debt financing and payments received under licensing and collaboration agreements with pharmaceutical companies. To date, none of the Company's product candidates have been approved by the FDA 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 equity or debt financing, collaboration or other arrangements with corporate partners, and/or other sources of financing. Management plans to meet its operating cash flow requirements include 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 resources. 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.

We will continue to require additional financing to develop our product candidates and fund operating losses. Our plans to meet our operating cash flow requirements include financing activities such as private placements of our common stock, preferred stock offerings, issuances of debt and convertible debt instruments and collaborative or other arrangements with corporate sources. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including, but not limited to:

the scope, progress, expansion, costs, and results of our clinical trials;

the scope, progress, expansion, and costs of manufacturing our product candidates;

the timing of and costs involved in obtaining regulatory approvals;

the type, number, costs, and results of the product candidate development programs which we are pursuing or may choose to pursue in the future;

our ability to establish and maintain development partnering arrangements;

the timing, receipt and amount of contingent, royalty, and other payments from any of our future development partners;

the emergence of competing technologies and other adverse market developments;

the costs of maintaining, expanding, and protecting our intellectual property portfolio, including potential litigation costs and liabilities;

the resources we devote to marketing, and if approved, commercializing our product candidates;

our ability to draw funds from our loan and security agreement; and

the costs associated with being a public company.

**Table of Contents**

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate our development programs and clinical trials. We may also be required to sell or license to others technologies or clinical product candidates or programs that we would prefer to develop and commercialize ourselves.

There are no assurances that such additional funding will be achieved and that we will succeed in our future operations. Adequate additional funding may not be available to us on acceptable terms or at all. Our inability to obtain required funding in the near future or our inability to obtain funding on favorable terms will have a material adverse effect on our operations and strategic development plan for future growth. If we cannot successfully raise additional capital and implement our strategic development plan, our liquidity, financial condition and business prospects will be materially and adversely affected, and we may have to cease operations.

The following table shows a summary of our cash flows for the six months ended June 30, 2018 and 2017:

	<b>Six Months Ended June 30,</b>	
	<b>2018</b>	<b>2017</b>
	<i>(In thousands)</i>	
Net cash (used in) provided by:		
Operating activities	\$ (14,128)	\$ (14,125)
Investing activities	(23,846)	(7,674)
Financing activities	42,520	27,955
<b>Net increase in cash and cash equivalents</b>	<b>\$ 4,546</b>	<b>\$ 6,156</b>

*Operating Cash Flow:* Net cash used in operating activities was approximately \$14.1 million for the six months ended June 30, 2018 and 2017. Net cash used during the first six months of 2018 was primarily due to clinical trial costs for the M207 long-term safety study production and support, in addition to other research and development and administrative expenses incurred in the course of our continuing operations. Net cash used during the first six months of 2017 was primarily due to the closing costs of the ZOTRIP study and professional fees and administrative expenses incurred in the course of our continuing operations.

*Investing Cash Flow:* Net cash used in investing activities was approximately \$23.8 million and \$7.7 million for the six months ending June 30, 2018 and 2017, respectively. Net cash used in investing activities during the first six months of 2018 was primarily the result of the purchase of certain marketable securities. Net cash used in investing activities during the first six months of 2017 was primarily due to the purchase of investments in marketable securities.

*Financing Cash Flow:* Net cash provided by financing activities was approximately \$42.5 million and \$28.0 million for the six months ended June 30, 2018 and 2017, respectively. Net cash provided by financing activities for the first six months of 2018 was primarily due to proceeds from a registered public offering of \$45.6, net of underwriter's discounts, commissions, and offering expenses. Net cash generated by financing activities for the first six months of 2017 was primarily due to proceeds from a registered public offering of \$26.6 million, net of underwriter's discounts, commissions, and offering expenses and to warrant exercises to purchase 136,301 shares common stock for proceeds of \$4.0 million. The increase was partially offset by payments on the Hercules Term Loan of approximately \$2.8 million.

**Contractual Obligations and Commitments**



Our primary contractual obligations as of June 30, 2018, consist of operating leases of approximately \$11.5 million and short-term debt obligations of approximately \$3.6 million (including end of term payments and periodic interest payments). Operating leases represent our future minimum rental commitments under our operating leases through August 2024. See Note 6 to the accompanying condensed financial statements for a discussion of the related party operating lease for our headquarters. Debt obligations include the Hercules Term Loan, maturing in December 2018. See Note 5 to the accompanying condensed financial statements for a discussion of the Hercules Term Loan. As of June 30, 2018, the Company has an equipment purchase commitment related to its pre-commercialization activities aggregating approximately \$12.2 million. Upon execution of the purchase order, the Company made an initial payment of \$1.5 million which was recorded in construction-in-progress. The terms of the purchase commitment are contingent upon performance of certain milestones.

### **Recent Accounting Pronouncements**

See Note 2 to the accompanying condensed financial statements for the Recent Accounting Pronouncements.

## **Table of Contents**

### **Off-Balance Sheet Arrangements**

We currently have no off-balance sheet arrangements, such as structured finance, special purpose entities or variable interest entities.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risks in the ordinary course of our business. Financial instruments which potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents, as well as investments in short-term marketable securities. We had cash and cash equivalents of \$16.2 million as of June 30, 2018, which consisted of bank deposits and money market funds.

Our cash and cash equivalents are held for working capital purposes. Cash balances are insured by the Federal Deposit Insurance Corporation ( FDIC ) up to regulatory limits, and we are exposed to credit risk when our cash balances exceed FDIC insurance limits. Our total cash and cash equivalent balances exceed the maximum amounts insured by the FDIC.

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. We hold interest-earning instruments, which carry a degree of interest rate risk. In addition, the interest rate on our outstanding term loan is variable. To date, fluctuations in interest income and expense have not been significant. However, fluctuations in market interest rates in the future could have a material impact on our financial condition and results of operations.

### **Item 4. Controls and Procedures**

#### ***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation of our Chief Executive Officer, who is currently our principal executive and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2018. The term disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms.

Based on the evaluation of our disclosure controls and procedures as of June 30, 2018, our Chief Executive Officer concluded that, as of such date, our disclosure controls and procedures are designed to, and are effective to, provide assurance at a reasonable level that the information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer, as appropriate, to allow timely decisions regarding required disclosures.

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal controls over financial reporting during the quarter ended June 30, 2018, identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**PART II. OTHER INFORMATION**

**Item 1. Legal Proceedings**

We are not party to any material pending legal proceedings. However, we may from time to time become involved in litigation relating to claims arising in the ordinary course of our business.

**Item 1A. Risk Factors**

Investing in our common stock involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2017 includes a detailed discussion of our risk factors under the heading Part I, Item 1A Risk Factors. There have been no material changes from such risk factors during the six months ended June 30, 2018. You should consider carefully the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2017, and all other information contained in or incorporated by reference in this Quarterly Report on Form 10-Q before making an investment decision. If any of the risks discussed in the Annual Report on Form 10-K actually occur, they may materially harm our business, financial condition, operating results, cash flows or growth prospects. As a result, the market price of our common stock could decline, and you could lose all or part of your investment. Additional risks and uncertainties that are not yet identified or that we think are immaterial may also materially harm our business, financial condition, operating results, cash flows or growth prospects and could result in a complete loss of your investment.

**Table of Contents**

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not Applicable.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

<b>Exhibit number</b>	<b>Description</b>
10.1	<u>Separation Agreement, dated May 10, 2018, between Zosano Pharma Corporation and Georgia Erbez (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on May 15, 2018).</u>
10.2	<u>Zosano Pharma Corporation Amended and Restated 2014 Equity and Incentive Plan, as amended on May 31, 2018 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on June 5, 2018).</u>
10.3	<u>Employment Letter Agreement, dated as of June 7, 2018 between Zosano Pharma Corporation and John Walker (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on June 12, 2018).</u>
10.4	<u>Eighth Amendment to Lease entered into as of May 30, 2018 by and between Zosano Pharma Corporation and BMR-34790 Ardentech Court LP.</u>
10.5	<u>Purchase Order by and between Zosano Pharma Corporation and Harro Hoflinger Packaging System (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on August, 6, 2018)</u>
31.1	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
32.1*	<u>Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C.</u>

Edgar Filing: Zosano Pharma Corp - Form 10-Q

Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

101.INS	XBRL Instance Document XBRL
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

*Filed herewith*

\* *Exhibit 32.1 is being furnished and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liability of that section, nor shall such exhibit be deemed to be incorporated by reference in any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise specifically stated in such filing.*

Table of Contents

**SIGNATURES**

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 thereunto duly authorized.

Dated: August 9, 2018

**Zosano Pharma Corporation**

(Registrant)

/s/ John Walker  
**John Walker**  
**Chief Executive Officer**