

Zosano Pharma Corp
Form 10-Q
November 10, 2015
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 September 30, 2015

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	45-4488360 (I.R.S. Employer
incorporation or organization)	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 or smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Edgar Filing: Zosano Pharma Corp - Form 10-Q

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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 November 5, 2015, the registrant had a total of 11,966,958 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

	Page
<u>PART I. FINANCIAL INFORMATION</u>	3
Item 1. <u>Financial Statements (Unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets</u>	3
<u>Condensed Consolidated Statements of Operations and Comprehensive Loss</u>	4
<u>Condensed Consolidated Statements of Cash Flows</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	25
Item 4. <u>Controls and Procedures</u>	26
<u>PART II. OTHER INFORMATION</u>	28
Item 1. <u>Legal Proceedings</u>	28
Item 1A. <u>Risk Factors</u>	28
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
Item 3. <u>Defaults Upon Senior Securities</u>	28
Item 4. <u>Mine Safety Disclosures</u>	28
Item 5. <u>Other Information</u>	28
Item 6. <u>Exhibits</u>	28
<u>SIGNATURES</u>	29

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****ZOSANO PHARMA CORPORATION AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS***(In thousands, except par value)*

	September 30, 2015 (unaudited)	December 31, 2014
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 4,875	\$ 1,214
Accounts receivable		111
Interest receivable	84	
Short-term investments in marketable securities	34,098	
Prepaid expenses and other current assets	459	311
Total current assets	39,516	1,636
Restricted cash	35	35
Long-term investments in marketable securities	4,923	
Property and equipment, net	8,036	9,681
Other long-term assets	513	1,991
Total assets	\$ 53,023	\$ 13,343
<u>LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)</u>		
Current liabilities:		
Accounts payable	\$ 2,036	\$ 1,447
Accrued compensation	1,257	1,676
Deferred revenue		170
Related parties convertible notes (including accrued interest)		7,362
Secured promissory note, current portion (net of issuance cost and including accrued interest)	1,958	1,408
Freestanding warrant liability		300
Other accrued liabilities	573	992
Total current liabilities	5,824	13,355
Deferred rent	40	98
Secured promissory note, net of debt discount and issuance costs (including accrued interest)	13,264	2,530
Related party note payable (including accrued interest)		10,761

Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, \$0.0001 par value; 100,000 shares and 30,000 shares authorized as of September 30, 2015 and December 31, 2014, respectively; 11,967 shares and 5,165 shares issued and outstanding as of September 30, 2015 and December 31, 2014, respectively	1	1
Additional paid-in capital	193,154	125,062
Accumulated deficit	(159,245)	(138,464)
Accumulated other comprehensive loss	(15)	
Stockholders' equity (deficit)	33,895	(13,401)
Total liabilities and stockholders' equity (deficit)	\$ 53,023	\$ 13,343

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

Table of Contents**ZOSANO PHARMA CORPORATION AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS***(unaudited; in thousands, except per share amounts)*

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue:				
License fees revenue	\$	\$ 176	\$ 170	\$ 1,819
Collaborative development support services		198	143	662
Total revenue		374	313	2,481
Operating expenses:				
Cost of license fees revenue				100
Research and development	6,627	2,587	14,701	8,230
General and administrative	1,719	894	4,797	3,208
Total operating expenses	8,346	3,481	19,498	11,538
Loss from operations	(8,346)	(3,107)	(19,185)	(9,057)
Other income (expense):				
Interest expense, net	(314)	(579)	(1,247)	(1,261)
Other income (expense)	41	3	49	(143)
Warrant revaluation income			48	
Gain on debt forgiveness				497
Loss on debt extinguishment			(446)	
Net loss	\$ (8,619)	\$ (3,683)	\$ (20,781)	\$ (9,964)
Other comprehensive loss:				
Unrealized holding gain (loss) on marketable securities, net of tax effect	23		(15)	
Comprehensive loss	\$ (8,596)	\$ (3,683)	\$ (20,796)	\$ (9,964)
Net loss per common share basic and diluted	\$ (0.72)	\$ (0.72)	\$ (1.85)	\$ (1.95)
Weighted-average shares used in computing net loss per common share basic and diluted	11,961	5,138	11,230	5,121

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

Table of Contents

ZOSANO PHARMA CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited; in thousands)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (20,781)	\$ (9,964)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	1,835	2,278
Stock-based compensation	369	122
Gain on debt forgiveness		(497)
Loss on debt extinguishment	446	
Cost of debt subordination		141
Revaluation of warrants to fair value	(48)	(2)
Amortization of debt (premium) issuance costs	(9)	34
Accretion of interest	193	1,106
Deferred rent	(58)	(197)
Change in operating assets and liabilities:		
Accounts and interest receivable	27	(173)
Accounts receivable from joint venture partner		3,426
Prepaid expenses and other assets	915	(1,191)
Accounts payable	589	(2,003)
Accrued compensation and other accrued liabilities	(838)	(1,262)
Deferred revenue	(170)	(819)
Net cash flow used in operating activities	(17,530)	(9,001)
Cash flow from investing activities:		
Purchase of property and equipment	(191)	(1,079)
Decrease in restricted cash		30
Purchases of marketable securities	(42,606)	
Proceeds from maturities of investment in marketable securities	3,480	
(Increase) decrease in other investment	(25)	18
Net cash flow used in investing activities	(39,342)	(1,031)
Cash flow from financing activities:		
Proceeds from initial public offering of securities, net of underwriting discounts and commissions	47,140	
Payment of deferred offering costs	(1,359)	
Proceeds from a private placement concurrent with the initial public offering, net of private placement fee	14,475	

Edgar Filing: Zosano Pharma Corp - Form 10-Q

Proceeds from exercise of stock options and issuance of common stock	37	2
Proceeds from borrowing under related parties bridge notes		2,500
Proceeds from debt financing, net of issuance costs	11,705	3,920
Payment of loan principal and accrued interest	(11,465)	
Net cash flow provided by financing activities	60,533	6,422
Net increase (decrease) in cash and cash equivalents	3,661	(3,610)
Cash and cash equivalents at beginning of period	1,214	5,913
Cash and cash equivalents at end of period	\$ 4,875	\$ 2,303

Supplemental cash flow information:

Interest paid	\$ 3,290	\$
---------------	----------	----

Non-cash investing and financing activities:

Conversion of debt to common stock	\$ 7,407	\$
Issuance of common stock in connection with debt financing	\$	\$ 141
Issuance of warrant in connection with debt financing	\$ 212	\$ 115
Accrued deferred offering cost	\$	\$ 1,068
Reclassification of warrant liability to equity	\$ 252	\$

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

Table of Contents

Zosano Pharma Corporation and Subsidiaries

Notes to Unaudited Condensed Consolidated Financial Statements

September 30, 2015

1. Organization

The Company

Zosano Pharma Corporation and subsidiaries (the Company) is a clinical stage specialty pharmaceutical company that has developed a proprietary transdermal microneedle patch system to deliver drug formulations through the skin for the treatment of a variety of indications. The Company's microneedle patch system offers rapid onset, consistent drug delivery, improved ease of use and room-temperature stability, benefits which the Company believes often are unavailable using oral formulations or injections. The Company's microneedle patch system has the potential to deliver numerous medications for a wide variety of indications, in commercially attractive markets.

The Company has two wholly owned subsidiaries: ZP Opco, Inc. (Opco), through which the Company conducts its primary research and development activities, and ZP Group LLC, originally a joint venture with Asahi Kasei Pharma USA, which ceased operations in connection with the termination of the joint venture in December 2013. The Company operates in one business segment to develop human pharmaceutical products. Management uses one measurement of profitability and does not segregate its business for internal reporting.

Initial Public Offering and Concurrent Private Placement

On January 30, 2015, the Company completed its initial public offering, in which it sold 4,500,000 shares of its common stock at a price of \$11.00 per share, resulting in net proceeds of approximately \$44.2 million, after deducting underwriting discounts and commissions and other offering expenses. The common stock began trading on The NASDAQ Capital Market on January 27, 2015 under the ticker symbol ZSAN. Upon the closing of the Company's initial public offering, the principal and all unpaid and accrued interest on the related parties convertible notes outstanding as of January 30, 2015, totaling \$7.4 million, automatically converted into an aggregate of 792,182 shares of common stock at a price equal to 85% of the initial public offering price, resulting in the liability for such notes being reclassified to permanent equity. On February 27, 2015, the Company sold an additional 110,000 shares of its common stock at the initial public offering price of \$11.00 per share, pursuant to the underwriters' partial exercise of their over-allotment option, resulting in additional net proceeds of approximately \$1.1 million after deducting underwriting discounts and commissions.

Concurrently with the closing of its initial public offering on January 30, 2015, the Company issued and sold 1,363,636 shares of its common stock to Eli Lilly and Company (Lilly) in a private placement pursuant to a common stock purchase agreement dated November 21, 2014 between the Company and Lilly, and received net proceeds of \$14.5 million, after payment of a private placement fee.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and as required by Regulation S-X, Rule 10-01 for interim financial reporting. The preparation of the accompanying condensed consolidated financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements, and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

Unaudited Interim Financial Information

The accompanying interim condensed consolidated financial statements are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual audited

Table of Contents

consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair presentation of the financial positions and results of operations for the periods presented. The financial data and other information disclosed in these notes to the interim condensed consolidated financial statements are also unaudited. Since they are interim statements, the accompanying financial statements do not include all of the information and notes required by U.S. GAAP for complete financial statements. The results for the nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for the year ending December 31, 2015 or for any other interim period or for any future year. These financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2014 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014 as filed with the Securities and Exchange Commission.

Consolidation

The consolidated financial statements include the accounts of Zosano Pharma Corporation, ZP Opco, Inc., and ZP Group LLC post-termination of the joint venture. Intercompany balances and transactions have been eliminated in consolidation.

Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the nine months ended September 30, 2015, as compared to the significant accounting policies described in Note 2 of the Notes to Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2014, except for the following updates:

Investments in Marketable Securities

The Company classifies its investments in marketable securities as available-for-sale. Investments with maturities between three and twelve (12) months are considered short-term investments. Investments with maturities greater than 12 months are considered long-term investments. The Company's investments classified as available-for-sale are recorded at fair value based upon quoted market prices at period end. Unrealized gains and losses that are deemed temporary in nature are recorded in accumulated other comprehensive income (loss) as a separate component of stockholders' equity (deficit). A decline in the fair value of any security below cost that is deemed other than temporary results in a charge to earnings and the corresponding establishment of a new cost basis for the security. Premiums and discounts are amortized (accreted) over the life of the corresponding security as an adjustment to its yield. Dividend and interest income are recognized when earned. Realized gains and losses are included in earnings and are derived using the specific identification method for determining the cost of investments sold.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting, printing and filing fees totaling approximately \$1.8 million related to the initial public offering were capitalized and offset against proceeds from the initial public offering upon the closing of the offering in January 2015. As of December 31, 2014, approximately \$1.5 million of expenses related to the initial public offering had been deferred as other long-term assets in the Company's consolidated balance sheet.

Research and Development Expenses

Research and development costs are charged to expense as incurred and consist of costs related to (i) servicing the Company's collaborative development efforts with other pharmaceutical companies, (ii) furthering the Company's

research and development efforts, and (iii) designing and manufacturing the Company's transdermal microneedle patch and applicator for the Company's clinical and nonclinical studies.

For the three months ended September 30, 2015, the Company incurred no research and development costs in support of the Company's collaborative development services, approximately \$3.0 million in connection with the Company's research and development efforts, and approximately \$3.6 million in the manufacturing of the Company's microneedle patch system for the development of the Company's product candidates. For the three months ended September 30, 2014, the Company incurred research and development costs of approximately \$0.1 million in support of

Table of Contents

the Company's collaborative development services to Novo Nordisk A/S (Novo Nordisk), approximately \$1.0 million in connection with the Company's research and development efforts and approximately \$1.5 million in the manufacturing of the Company's microneedle patch system for the development of the Company's product candidates.

For the nine months ended September 30, 2015, the Company incurred research and development costs of approximately \$0.1 million in support of the Company's collaborative development services, approximately \$6.3 million in connection with the Company's research and development efforts, and approximately \$8.3 million in the manufacturing of the Company's microneedle patch system for the development of the Company's product candidates. For the nine months ended September 30, 2014, the Company incurred research and development costs of approximately \$0.4 million in support of the Company's collaborative development services to Novo Nordisk, approximately \$3.6 million in connection with the Company's research and development efforts and approximately \$4.3 million in the manufacturing of the Company's microneedle patch system for the development of the Company's product candidates.

Net Loss Per Common Share

Basic net income (loss) per common share is calculated by dividing the net income (loss) by the weighted-average number of common shares outstanding during the period, without consideration for potential dilutive common stock equivalents. Diluted net income (loss) per common share is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. For purposes of this calculation, convertible promissory notes, warrants and options to purchase common stock are considered potential dilutive common stock equivalents. For the three and nine months ended September 30, 2015 and 2014, 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:

	September 30,	
	2015	2014
	(unaudited; in shares)	
Warrants to purchase common stock	72,379	31,674
Options to purchase common stock	956,951	527,619
	1,029,330	559,293

Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2015-03, *Simplifying the Presentation of Debt Issuance Costs*. The update changes the presentation of debt issuance costs in financial statements. ASU 2015-03 requires an entity to present such costs in the balance sheet as a direct deduction from the related debt liability rather than an asset. Amortization of the costs will continue to be reported as interest expense. ASU 2015-03 is effective for annual reporting periods beginning after December 15, 2015 with early adoption permitted. The Company elected to adopt ASU 2015-03 as of June 30, 2015 and the adoption has no impact on the Company's financial position or results of operations.

Table of Contents

3. Cash, Cash Equivalents and Investments

The following is a summary of the Company&