

Zosano Pharma Corp
Form 10-Q
November 09, 2016
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, 2016

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)

Edgar Filing: Zosano Pharma Corp - Form 10-Q

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):

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 3, 2016, the registrant had a total of 16,815,997 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</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 Condensed Consolidated Financial Statements</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	26
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, 2016	December 31, 2015
	<i>(unaudited)</i>	
<u>ASSETS</u>		
Current assets:		
Cash and cash equivalents	\$ 19,178	\$ 6,646
Interest receivable	29	101
Short-term investments in marketable securities	3,878	30,287
Prepaid expenses and other current assets	412	237
Total current assets	23,497	37,271
Restricted cash	35	35
Property and equipment, net	6,107	7,660
Other long-term assets	388	371
Total assets	\$ 30,027	\$ 45,337
<u>LIABILITIES AND STOCKHOLDERS EQUITY</u>		
Current liabilities:		
Accounts payable	\$ 1,692	\$ 1,209
Accrued compensation	1,162	1,275
Secured promissory note, current portion (net of issuance cost and including accrued interest)	5,931	3,360
Other accrued liabilities	1,088	1,036
Total current liabilities	9,873	6,880
Deferred rent	51	45
Secured promissory note, net of issuance cost (including accrued interest)	8,095	11,910
Total liabilities	18,019	18,835
Commitments and contingencies		
Stockholders equity:		
Common stock, \$0.0001 par value; 100,000 shares authorized as of September 30, 2016 and December 31, 2015; 16,816 shares and 11,967 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	2	1

Edgar Filing: Zosano Pharma Corp - Form 10-Q

Additional paid-in capital	200,981	193,438
Accumulated deficit	(188,974)	(166,891)
Accumulated other comprehensive loss	(1)	(46)
Stockholders' equity	12,008	26,502
Total liabilities and stockholders' equity	\$ 30,027	\$ 45,337

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,	
	2016	2015	2016	2015
Revenue:				
License fees revenue	\$ -	\$ -	\$ -	\$ 170
Collaborative development support services	-	-	-	143
Total revenue	-	-	-	313
Operating expenses:				
Research and development	5,124	6,627	15,044	14,701
General and administrative	2,010	1,719	6,137	4,797
Total operating expenses	7,134	8,346	21,181	19,498
Loss from operations	(7,134)	(8,346)	(21,181)	(19,185)
Other income (expense):				
Interest expense, net	(314)	(314)	(951)	(1,247)
Other income	-	41	49	49
Warrant revaluation income	-	-	-	48
Loss on debt extinguishment	-	-	-	(446)
Net loss	(7,448)	(8,619)	(22,083)	(20,781)
Other comprehensive loss:				
Unrealized holding (loss) gain on marketable securities, net of tax effect	(3)	23	(1)	(15)
Comprehensive loss	\$ (7,451)	\$ (8,596)	\$ (22,084)	\$ (20,796)
Net loss per common share basic and diluted				
	\$ (0.52)	\$ (0.72)	\$ (1.73)	\$ (1.85)
Weighted-average shares used in computing net loss per common share basic and diluted				
	14,259	11,961	12,752	11,230

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, 2016 2015 (unaudited)	
Cash flows from operating activities:		
Net loss	\$ (22,083)	\$ (20,781)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation	1,866	1,835
Stock-based compensation	896	369
Loss on debt extinguishment	-	446
Gain on sale of equipment	(51)	-
Accretion of interest payment	241	184
Revaluation of warrants to fair value	-	(48)
Deferred rent	6	(58)
Change in operating assets and liabilities:		
Accounts and interest receivable	72	27
Prepaid expenses and other assets	(175)	915
Accounts payable	484	589
Accrued compensation and other accrued liabilities	(60)	(838)
Deferred revenue	-	(170)
Net cash flow used in operating activities	(18,804)	(17,530)
Cash flow from investing activities:		
Purchase of property and equipment	(325)	(191)
Proceeds from sales of property and equipment	63	-
Purchase of marketable securities	-	(42,606)
Proceeds from maturities of investments in marketable securities	26,332	3,480
Increase in investment	(18)	(25)
Net cash flow provided by (used in) investing activities	26,052	(39,342)
Cash flow from financing activities:		
Proceeds from initial public offering of securities, net of underwriting commissions and discounts	-	47,140
Payment of deferred offering costs	-	(1,359)
	-	14,475

Edgar Filing: Zosano Pharma Corp - Form 10-Q

Proceeds from a private placement concurrent with the initial public offering, net of private placement fee		
Proceeds from exercise of stock options and issuance of common stock	6	37
Proceeds from issuance of securities in private investment in public equity (PIPE), net of issuance costs	6,642	-
Proceeds from debt financing, net of issuance costs	-	11,705
Repayment of loan principal	(1,364)	(11,465)
Net cash flow provided by financing activities	5,284	60,533
Net increase in cash and cash equivalents	12,532	3,661
Cash and cash equivalents at beginning of period	6,646	1,214
Cash and cash equivalents at end of period	\$ 19,178	\$ 4,875
Supplemental cash flow information:		
Interest paid	\$ 902	\$ 3,290
Non-cash investing and financing activities:		
Conversion of debt to common stock	\$ -	\$ 7,407
Issuance of warrant in connection with debt financing	\$ -	\$ 212
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 Condensed Consolidated Financial Statements

September 30, 2016

1. Organization

The Company

Zosano Pharma Corporation and subsidiaries (the Company) is a clinical stage pharmaceutical company focusing on providing rapid symptom relief to patients using the Company's proprietary intracutaneous delivery system to administer drugs through the skin. The Company is focused on developing products that deliver established molecules with known safety and efficacy profiles primarily for treatment of central nervous system indications. Our intracutaneous technology offers rapid onset, consistent drug delivery, improved ease of use and room-temperature stability benefits that we believe would provide a potentially favorable alternative to using oral formulations or injections.

The Company was incorporated in Delaware as ZP Holdings, Inc. in January 2012 and changed its name to Zosano Pharma Corporation in June 2014. The Company was spun out of ALZA Corporation, a subsidiary of Johnson & Johnson, in October 2006, originally incorporated under the name The Macroflux Corporation, and changed its name to Zosano Pharma, Inc. in 2007, following the spin-off from Johnson & Johnson. In April 2012, in a transaction to recapitalize the business, a wholly-owned subsidiary of Zosano Pharma Corporation was merged into Zosano Pharma, Inc., whereby Zosano Pharma, Inc. was the surviving entity and became a wholly-owned subsidiary of Zosano Pharma Corporation. In June 2014, Zosano Pharma, Inc. changed its name to ZP Opco, Inc.

The Company has two wholly owned subsidiaries as of September 30, 2016: 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 Pharmaceuticals USA (Asahi). The joint venture ceased operations in December 2013.

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 condensed consolidated balance sheet as of September 30, 2016, the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2016 and 2015, and the

condensed consolidated statements of cash flows for the nine months ended September, 2016 and 2015 are unaudited. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to state fairly the Company's financial position as of September 30, 2016, and the condensed consolidated results of operations for the three and nine months ended September 30, 2016 and 2015, and the condensed consolidated statement of cash flows for the nine months ended September 30, 2016 and 2015. The financial data and other information disclosed in these notes to the interim condensed consolidated financial statements as of September 30, 2016 and for the three and nine month periods ended September 30, 2016 and 2015 are also unaudited. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 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, 2015 included in the Company's annual report on Form 10-K filed with the Securities and Exchange Commission.

Table of Contents

Liquidity

The Company has incurred significant operating losses and had an accumulated deficit of \$189.0 million as of September 30, 2016. The Company has financed its operations primarily through sale of equity securities, debt financing and payments received under its former licensing and collaboration agreements with pharmaceutical companies. To date, none of the Company's product candidates have been approved for sale.

The Company will continue to require additional financing to develop its product candidates and fund operating losses. Management intends to seek funds through equity or debt financings, collaborative or other arrangements with corporate partners, or through other sources of financing. 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. There can be no assurance that the Company will be successful in raising capital, or that any needed financing will be available in the future at terms acceptable to the Company.

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, 2016, 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, 2015. Below are those policies with current period updates:

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 the Company's intracutaneous microneedle patch and applicator for the Company's clinical and nonclinical studies. In 2015, research and development costs also consisted of costs related to servicing the Company's collaborative development efforts with other pharmaceutical companies.

For the three months ended September 30, 2016, the Company incurred research and development costs of approximately \$3.3 million in connection with the Company's research and development efforts and approximately \$1.8 million in the manufacturing of the Company's microneedle patch system for development of the Company's product candidate. For the three months ended September 30, 2015, the Company incurred 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 candidate. For the nine months ended September 30, 2016, the Company incurred research and development costs of approximately \$8.6 million in connection with the Company's research and development efforts and approximately \$6.5 million in the manufacturing of the Company's microneedle patch system for development of the Company's product candidate. For the nine months ended September 30, 2015, the Company incurred research and development

Edgar Filing: Zosano Pharma Corp - Form 10-Q

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 candidate.

Table of Contents***Comprehensive Loss***

Comprehensive loss is comprised of net loss and the unrealized losses on the Company's marketable securities. Comprehensive loss is included in the Company's consolidated statements of operations and comprehensive loss for all periods presented.

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, warrants and options to purchase common stock are considered potential dilutive common stock equivalents. For the three and nine months ended September 30, 2016 and 2015, 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,	
	2016	2015
	(unaudited; in shares)	
Warrants to purchase common stock	9,672,379	72,379
Options to purchase common stock	1,372,808	956,951
	11,045,187	1,029,330

Recent Accounting Pronouncements

In March 2016, FASB issued ASU 2016-09, *Compensation - Stock Compensation: Improvements to Employee Share-Based Payment*. The new guidance simplifies several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2016. The Company is currently evaluating the impact of this accounting standard.

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. The amendments in this ASU replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information for credit loss estimates. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted as early as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact of this accounting standard.

Edgar Filing: Zosano Pharma Corp - Form 10-Q

In August 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments*. The amendment addresses eight specific cash flow issues with the objective of reducing diversity in practice. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the impact of this accounting standard.

Table of Contents**3. Cash, Cash Equivalents and Investments**

The following is a summary of the Company's cash, cash equivalents, and marketable securities investments for each of the periods presented:

	Amortized Cost	September 30, 2016 Gross Unrealized Gains		Gross Unrealized Losses	Estimated Fair Value
		<i>(unaudited; in thousands)</i>			
Cash in bank	\$ 11,934	\$ -		\$ -	\$ 11,934
Money market funds	7,244	-		-	7,244
Certificates of deposit (restricted)	35	-		-	35
Certificates of deposit	480	-		-	480
Corporate bonds	2,398	-		(1)	2,397
U.S. government agency bonds	1,001	-		-	1,001
	\$ 23,092	\$ -		\$ (1)	\$ 23,091

Classified as:

Cash and cash equivalent	\$ 19,178
Restricted cash	35
Short-term investments in marketable securities	3,878
	\$ 23,091

	Amortized Cost	December 31, 2015 Gross Unrealized Gains		Gross Unrealized Losses	Estimated Fair Value
		<i>(unaudited; in thousands)</i>			
Cash in bank	\$ 2,997	\$ -		\$ -	\$ 2,997
Money market funds	3,649	-		-	3,649
Certificates of deposit (restricted)	35	-		-	35
Certificates of deposit	5,040	-		(4)	5,036
Corporate bonds	11,749	-		(22)	11,727
U.S. government agency bonds	13,544	-		(20)	13,524
	\$ 37,014	\$ -		\$ (46)	\$ 36,968

Classified as:

Cash and cash equivalent	\$ 6,646
Restricted cash	35
Short-term investments in marketable securities	30,287

For the three and nine months ended September 30, 2016, there were no realized gains and losses on available-for-sale securities. As of September 30, 2016, the maximum contractual maturity of the Company's available-for-sale investments was within 2 months. The Company does not intend to sell the investments that are in an unrealized loss position, and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be at maturity. The Company has determined that the gross unrealized losses on its available-for-sale investments as of September 30, 2016 were temporary in nature.

Table of Contents**4. Fair Value of Financial 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, prepaid expenses and other current assets, accounts payable and accrued liabilities, 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. The carrying value of the Company's long-term notes payable approximates fair value because the interest rates approximate market rates that the Company could obtain for debt with similar terms and maturities.

The following tables set forth the fair value of the Company's financial instruments as of September 30, 2016 and December 31, 2015:

	Level I	September 30, 2016		Total
		Level II	Level III	
<i>(unaudited; in thousands)</i>				
Financial Instruments:				
Certificates of deposit (restricted cash)	\$ 35	\$ -	\$ -	\$ 35
Money market funds	7,244	-	-	7,244
Certificates of deposit	-	480	-	480
Corporate bonds	-	2,397	-	2,397
U.S. government agency bonds	-	1,001	-	1,001
Total financial instruments	\$ 7,279	\$ 3,878	\$ -	\$ 11,157

	Level I	December 31, 2015		Total
		Level II	Level III	
<i>(unaudited; in thousands)</i>				
Financial Instruments:				
Certificates of deposit (restricted cash)	\$ 35	\$ -	\$ -	\$ 35
Money market funds	3,649	-	-	3,649
Certificates of deposit	-	5,036	-	5,036
Corporate bonds	-	11,727	-	11,727
U.S. government agency bonds	-	13,524	-	13,524

Total financial instruments	\$ 3,684	\$ 30,287	\$ -	\$ 33,971
-----------------------------	----------	-----------	------	-----------

Table of Contents**5. Property and Equipment**

The following summarizes the Company's property and equipment as of September 30, 2016 and December 31, 2015:

	September 30, 2016 (unaudited)	December 31, 2015
	(in thousands)	
Property and Equipment:		
Laboratory and office equipment	\$ 1,093	\$ 1,112
Manufacturing equipment	10,798	10,730
Computer equipment and software	314	229
Leasehold improvements	15,542	15,534
Construction in progress	2,181	2,066
	29,928	29,671
Less: accumulated depreciation	(23,821)	(22,011)
	\$ 6,107	\$ 7,660

Depreciation and amortization expense was approximately \$0.6 million and \$0.6 million for the three months ended September 30, 2016 and 2015, respectively, and \$1.9 million and \$1.8 for the nine months ended September 30, 2016 and 2015, respectively.

6. Research and Development Collaboration and License Agreements***Former Collaboration Agreement with Novo Nordisk***

Pursuant to a collaboration agreement with Novo Nordisk dated January 31, 2014 related to the development of an intracutaneous presentation of select Novo Nordisk glucagon-like peptide-1 (GLP-1) analogues, the Company received a non-refundable upfront payment of \$1.0 million. The upfront payment was recorded as deferred revenue in the consolidated balance sheet and recognized as license fees revenue over the performance period that was consistent with the term of performance obligations under the specified feasibility study plan.

In July 2015, the Company announced that Novo Nordisk had notified the Company of its intention to discontinue the collaboration agreement. The termination became effective on October 27, 2015, and all technology rights licensed to Novo Nordisk related to the field of GLP-1 products reverted to the Company. As of June 30, 2015, the collaboration with Novo Nordisk was no longer a source of revenue or research and development expense for the Company.

For the three months ended September 30, 2015, the Company did not recognize any service revenue pursuant to the Novo Nordisk collaboration agreement. For the nine months ended September 30, 2015, the Company recognized \$46,000 as service revenue pursuant to the Novo Nordisk collaboration agreement.

7. Debt Financing

Conversion of Related Parties Convertible Promissory Notes

On January 30, 2015, upon the closing of the Company's initial public offering, the principal and all unpaid and accrued interest on the September 2013, and the February and December 2014 convertible promissory 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.

Previous Secured Financing with BMR

In connection with the recapitalization of the Company in April 2012, the Company renegotiated its lease agreement with its landlord, BioMed Realty Holdings, Inc. and affiliates (BMR Holdings), to include reduced rent obligations. In connection with the rent reduction, the Company issued a secured promissory note (the BMR Note) for the principal amount of approximately \$8.6 million to BMR Holdings in 2012, which was subsequently assigned to its affiliate BMV Direct SOTRS LP, one of our largest shareholders, and all previously accrued interest, unpaid rent, future rent obligations and other fees due to BMR Holdings were either rolled into the BMR Note or eliminated. In June 2015, the Company terminated the BMR Note by prepaying the outstanding principal and all accrued interest totaling \$11.4 million. As of June 30, 2015, the Company does not have any debt outstanding with BMR.

Table of Contents

For the three months ended September 30, 2015, the Company did not record any interest expense pursuant to the BMR Note and for the nine months ended September 30, 2015, the Company recorded \$0.6 million in interest expense pursuant to the BMR Note. No interest expense was recorded in 2016 in connection with the BMR Note.

Senior Secured Term Loan with Hercules

In June 2014, the Company entered into a loan and security agreement with Hercules Technology Growth Capital, Inc. (Hercules) which provided the Company \$4.0 million in debt financing. In June 2015, the Company entered into a first amendment to the loan and security agreement with Hercules to increase the aggregate principal amount of the loan to \$15.0 million (the Hercules Term Loan). Upon the execution of the first amendment to the loan and security agreement, the Company used approximately \$11.4 million of the Hercules Term Loan to prepay all amounts owing under the secured promissory note held by BMV Direct SOTRS LP, an affiliate of BioMed Realty Holdings, Inc.

The first amendment to the loan and security agreement with Hercules provides that the \$15.0 million principal balance will be subject to a 12-month interest-only period beginning July 1, 2015, followed by equal monthly installment payments of principal and interest, with all outstanding amounts due and payable on December 1, 2018. The outstanding principal balance bears interest at a variable rate of the greater of (i) 7.95%, or (ii) 7.95% plus the prime rate as quoted in the Wall Street Journal minus 5.25%. In addition, the Company will be obligated to pay a \$100,000 legacy end of term charge on the earlier of June 1, 2017 or the date the Company prepays the Hercules Term Loan and 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 subject to a prepayment charge of 1.0% of the then outstanding principal if prepaid prior to June 23, 2016, or 0.5% of the then outstanding principal if prepaid on or after June 23, 2016 but prior to June 23, 2017, with no prepayment charge if prepaid thereafter. 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.

In connection with the first amendment to the loan and security agreement with Hercules, the Company issued Hercules a warrant to purchase 40,705 shares of the Company's common stock at an exercise price of \$7.37 per share. The warrant was recorded at fair value on the date of issuance and treated as a debt discount which is being amortized to interest expense over the term of the loan using the effective interest method. (See Note 9 for a discussion of warrants to purchase common stock.)

The following is a summary of the Company's long-term debt, net of unamortized debt discount and issuance costs, as of September 30, 2016 and December 31, 2015:

	September 30, 2016	December 31, 2015
	<i>(unaudited)</i>	
	<i>(in thousands)</i>	
Principal amount	\$ 13,637	\$ 15,000
Less: unamortized debt issuance costs	(52)	(91)
unamortized fair value of free standing warrant	(95)	(163)
Plus: unamortized fair value debt premium	180	310
accrued terminal interest	266	111
accrued interest	90	103

Edgar Filing: Zosano Pharma Corp - Form 10-Q

Long-term debt, net of unamortized debt issuance cost and premium	\$	14,026	\$	15,270
-------------------------------------------------------------------	----	--------	----	--------

For the three and nine months ended September 30, 2016, the Company recorded total interest expense of \$0.3 million and \$1.0 million, respectively, related to the Hercules Term Loan. For the three and nine months ended September 30, 2015, the Company recorded total interest of \$0.3 million and \$0.6 million, respectively, in connection with the agreement with Hercules.

Table of Contents**8. Commitments and Contingencies**

The Company has an operating lease with BMR-34790 Ardentech Court LP, an affiliate of BMR Holdings, for its office, research and development, and manufacturing facilities in Fremont, California. In April 2012, the Company amended the lease agreement to reduce future rent obligations with a new lease term of seven years in exchange for a potential reduction of premises from a recapturable premises clause. In June 2015, the Company entered into another amendment to the lease, pursuant to which BMR-34790 Ardentech Court LP's option to recapture a specified portion of the leased premises (comprising approximately 29,348 square feet of the approximate total 55,588 square feet of leased premises) has been suspended. The Company had the option until December 31, 2015 to extend the term of the lease. The Company did not exercise this option and as a result, the terms of the previous amendment entered in April 2012 remain in effect.

For the three months ended September 30, 2016 and 2015, rental expense under operating leases was \$0.2 million and \$0.2 million, respectively. For the nine months ended September 30, 2016 and 2015, rental expense under operating leases was \$0.5 million and \$0.5 million, respectively.

As of September 30, 2016 future minimum payments under non-cancelable operating leases for each year ending December 31 are as follows:

	Total
	<i>(in thousands)</i>
2016	\$ 163
2017	632
2018	650
2019	164
	\$ 1,609

9. Stockholders Equity***Initial Public Offering***

On January 30, 2015, the Company completed an initial public offering (IPO) of its common stock on the NASDAQ Capital Market. The Company sold an aggregate of 4,500,000 shares of common stock under a registration statement on Form S-1, declared effective on January 27, 2015, at a public offering price of \$11.00 per share. Net proceeds to the Company were approximately \$44.2 million, after deducting underwriting commissions and expenses. On February 27, 2015, the underwriters exercised the overallotment option resulting in the Company's issuing an additional 110,000 shares of its common stock at \$11.00 per share, resulting in additional net proceeds of approximately \$1.1 million after underwriting discounts.

Concurrent Private Placement - January 2015

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 underwriting discounts. The closing of this

private placement took place concurrently with the Company's IPO. As of September 30, 2016, Lilly beneficially owned approximately 11% of the Company's outstanding common stock.

Private Investment in Public Equity (PIPE) - August 2016

On August 15, 2016, the Company entered into a Securities Purchase Agreement (Purchase Agreement) between the Company and certain purchasers, including members of the Company's Board of Directors and executive management, pursuant to which the Company sold and issued shares of common stock and warrants to purchase shares of common stock for aggregate gross proceeds of \$7.5 million. Costs related to the offering were \$0.9 million. Pursuant to the Purchase Agreement, the Company sold 4,800,000 common shares at \$1.32 per common share, the closing price per share on August 15, 2016, for gross proceeds of \$6.3 million. Additionally, 9,600,000 warrants were sold, at a price of \$0.125 per warrant, for gross proceeds of \$1.2 million. Each warrant grants the holder the right to purchase one share of our common stock. The Company granted 4,800,000 Series A Warrants and 4,800,000 Series B Warrants. Series A Warrants and Series B Warrants have a per share exercise price of \$1.45 and \$1.55, respectively, and will expire one year and one week and five years, respectively, from the date of issuance, August 19, 2016. Certain of our directors and executive officers purchased an aggregate of 275,454 shares of common stock and an aggregate of 550,908 warrants in this offering at the same price as the other investors.

Table of Contents

In connection with the PIPE transaction, the Company filed a registration statement, Form S-3, with the U.S. Securities and Exchange Commission, or SEC, registering for resale the shares of common stock and shares of common stock issuable upon exercise of the warrants. The registration statement was declared effective by the SEC on September 23, 2016.

Hercules Warrants

In connection with the Company's entry into the loan and security agreement with Hercules in June 2014, the Company issued Hercules a warrant to purchase \$280,000 worth of the Company's stock. The warrant was initially recorded on the Company's consolidated balance sheet at fair value on the date of issuance and treated as a debt discount that is being amortized to interest expense over the debt repayment period using the effective interest method. As a result of the pricing of the Company's IPO on January 27, 2015, and pursuant to the agreement the exercise price was fixed at \$8.84 per share, resulting in the warrant being exercisable for 31,674 shares (warrant amount of \$280,000 divided by \$8.84 per share) of the Company's common stock. Accordingly, management concluded that the requirements for equity classification had been met and effected a reclassification of the warrant liability of \$0.3 million to equity. The warrant is exercisable at any time, in whole or in part, until five years from the date of the Company's IPO. For the three and nine months ended September 30, 2015, the Company recorded other income of zero and \$48,000, respectively, related to the change in fair value of the warrant before equity reclassification, which was determined by using the Black-Scholes option valuation model with the following assumptions: expected term of 5.00 years; volatility of 89%; risk free interest rate of 1.32%; and no dividend yield.

In connection with the Company's entry into the first amendment to loan and security agreement with Hercules in June 2015, the Company issued Hercules a warrant to purchase 40,705 shares of the Company's common stock at an exercise price of \$7.37 per share. Hercules can exercise its purchase right under the warrant, in whole or in part, at any time until June 23, 2020. The warrant was recorded at fair value on the date of issuance and treated as a debt discount that is being amortized to interest expense over the term of the loan using the effective interest method. The Company classified the warrant to equity and recorded the fair value of the warrant of \$212,000 to additional paid-in capital in its consolidated balance sheet. The warrant fair value was determined by using the Black-Scholes option valuation model with the following assumptions: expected term of 5.00 years; volatility of 89%; risk free interest rate of 1.73% and no dividend yield.

10. Stock-Based Compensation

The Company has reserved 1.4 million shares of common stock for issuance under the Company's 2014 Equity and Incentive Plan (the 2014 Plan). In connection with the Company's IPO of its common stock in January 2015, the Company's board of directors terminated the Company's 2012 Stock Incentive Plan (the 2012 Plan) effective as of January 27, 2015 and no further awards may be issued under the 2012 Plan. However, the awards outstanding under the 2012 Plan at January 27, 2015 continue to be governed by the terms of the 2012 Plan.

On September 7, 2016, the Company awarded an inducement option grant to our Chief Business Officer to purchase 252,000 shares of our common stock at an exercise price of \$0.77 per share. This inducement option grant was issued outside of the existing equity compensation plans in accordance with NASDAQ listing rule 5635(c)(4).

Table of Contents

The following table summarizes option and award activity during the nine months ended September 30, 2016:

	Shares Available for Grant	Shares Subject to Outstanding Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
Options at December 31, 2015	858,606	972,951	\$ 2.35	7.40	
Options granted	(792,463)	792,463	\$ 1.92		
Options exercised	-	(145,892)	\$ 1.53		
Options cancelled/forfeited	246,714	(246,714)	\$ 2.76		
Restricted stock units granted	(9,478)	-	\$ -		
Shares expired under 2012 Plan	(21,314)	-	\$ -		
Balance at September 30, 2016	282,065	1,372,808	\$ 2.12	8.47	\$ 5
Exercisable at September 30, 2016		299,911	\$ 2.09	5.22	\$ -
Vested and expected to vest at September 30, 2016		1,293,252	\$ 2.14	8.40	\$ 4

The aggregate intrinsic values of options outstanding and exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the closing market value of the Company's common stock as reported on NASDAQ as of September 30, 2016.

The following summarizes the composition of stock options outstanding and exercisable as of September 30, 2016 (unaudited):

Exercise Price	Options Outstanding and Exercisable	
	Number of Shares	Weighted-Average Remaining Contractual Life (in years)
\$0.77 - \$1.40	503,050	1.06
\$2.04 - \$2.57	805,457	2.38
\$4.52 - \$9.05	33,301	5.05
\$9.13 - \$9.29	31,000	9.27

1,372,808

On March 29, 2016, the Board of Directors of the Company approved the grant of certain performance-based stock options to employees of the Company for a total of 164,500 option shares with an aggregate grant date fair value of approximately \$0.3 million. As of September 30, 2016, a total of 58,125 of such options vested upon achievement of certain specified performance conditions. The Company accounts for these performance-based stock options in accordance with the provisions under ASC 718 and recognized compensation expense when the performance conditions are considered probable of achievement.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized was as follows:

	Three Months Ended September 30,		Nine Months Ended	
	2016	2015	September 30,	2015
	<i>(unaudited; in thousands)</i>		<i>(unaudited; in thousands)</i>	
Research and development	\$ 76	\$ 103	\$ 351	\$ 166
General and administrative	154	63	545	203
Total stock-based compensation expense	\$ 230	\$ 166	\$ 896	\$ 369

As of September 30, 2016, the Company had \$2.4 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 3.41 years.

Table of Contents

The Company uses the Black-Scholes model for valuing its options and awards granted to employees and non-employees. Stock-based compensation in connection with non-employee grants was immaterial for the three and nine months ended September 30, 2016 and 2015. The following table illustrates the input assumptions used to value employee stock option grants for the three and nine months ended September 30, 2016 and 2015 (unaudited):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Dividend yield	0%	0%	0%	0%
Risk-free interest rate	1.26%	1.07% - 1.73%	1.06 - 1.97%	1.07% - 2.01%
Expected volatility	89%	89%	89%	89%
Expected term (years)	6.08	6.08	6.08	6.08

11. Restructuring and Severance

In January 2016, the Company terminated the employment of its Chief Executive Officer (CEO). Pursuant to the terms of his employment agreement, the Company was obligated to its former CEO for certain severance payments, continuation of benefits, and acceleration of vesting of the remaining outstanding unvested stock options. For the three months ended March 31, 2016, the Company had recorded a liability and an expense of \$0.4 million for postemployment severance and benefits and a stock-based compensation expense of approximately \$16,000 related to the acceleration of vesting of the former CEO's stock options. For the nine months ended September 30, 2016, the Company had paid \$0.4 million of the postemployment severance and benefits, with \$7,500 remaining included within accrued compensation on the condensed consolidated balance sheet.

In March 2016, the Company consolidated its operations with the primary focus on continued development of M207 (previously known as ZP-Triptan). In accordance with ASC 420, Exit or Disposal Cost Obligations, the aggregate restructuring charges of approximately \$0.5 million represent one-time termination benefits, comprised principally of severance, benefit continuation costs and outplacement services. For the three months ended March 31, 2016, the Company had recorded \$0.5 million as a liability and an expense and a stock-based compensation expense of approximately \$5,000 on the acceleration of vesting of certain stock options related to the elimination of certain senior positions in connection with the workforce reduction. For the nine months ended September 30, 2016, the Company paid approximately \$0.5 million, with approximately \$31,000 remaining included within accrued compensation on the condensed consolidated balance sheet.

12. Going Concern

The accompanying condensed consolidated financial statements have been prepared in conformity with U.S. GAAP, which contemplate continuation of the Company as a going concern. As of September 30, 2016, the Company has an accumulated deficit of \$189.0 million as well as negative cash flows from operating activities. Presently, the Company does not have sufficient cash resources to meet its plans in the next twelve months following September 30, 2016. The Company will continue to require substantial funds to continue research and development, including clinical trials of its product candidate. Management's plans in order to meet its operating cash flow requirements include financing activities such as private placements of its common stock, preferred stock offerings, issuances of debt and convertible debt instruments and collaborative or other arrangements with corporate sources.

These factors raise substantial doubt regarding the Company's ability to continue as a going concern. There are no assurances that such additional funding will be achieved and that the Company will succeed in its future operations. The Company's inability to obtain required funding in the near future or its inability to obtain funding on favorable terms will have a material adverse effect on its operations and strategic development plan for future growth. If the Company cannot successfully raise additional capital and implement its strategic development plan, its liquidity, financial condition and business prospects will be materially and adversely affected, and the Company may have to cease operations.

Table of Contents

13. Subsequent Event

On October 12, 2016, we received a deficiency letter from the Listing Qualifications Department of The NASDAQ Stock Market notifying us that, for the preceding 30 consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on The NASDAQ Global Market pursuant to NASDAQ Listing Rule 5550(a)(2). In accordance with NASDAQ Listing Rule 5810(c)(3)(A), the Company has been provided an initial period of 180 calendar days, or until April 10, 2017, to regain compliance with the Rule. If, at any time before April 10, 2017, the bid price for the Company's common stock closes at \$1.00 or more for a minimum of 10 consecutive business days as required under Listing Rule 5810(c)(3)(A), the Staff will provide written notification to the Company that it complies with the Rule.

If the Company does not regain compliance with the Rule by April 10, 2017, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and will need to provide written notice to the Staff of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split if necessary.

Table of Contents

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, 2015, filed with the Securities and Exchange Commission, or SEC, on March 29, 2016. 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.

Overview

Zosano Pharma is a clinical stage company focusing on providing rapid symptom relief to patients using known therapeutics, specifically for central nervous system indications, with well-established safety and efficacy, but altering their delivery profile using the Company's proprietary intracutaneous delivery system, which we believe may offer rapid and consistent drug delivery and improved ease of use over current means of administration.

The focus of our development efforts is on our product candidate M207. M207 is our proprietary formulation of zolmitriptan, one of a class of serotonin receptor agonists known as triptans, used for the treatment of 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. Our M207 intracutaneous microneedle patch is applied to an individual's upper arm to deliver zolmitriptan to the central nervous system, with the objective of providing rapid onset relief from migraine symptoms.

Recent Developments

Following is a summary of selected recent developments affecting our business that have occurred since December 31, 2015.

In March 2016, we announced the decision to prioritize our clinical development effort on M207 and to suspend further development related to our other candidates, Daily B104 and Weekly B206 (previously known as Daily ZP-PTH and Weekly ZP-PTH, respectively) and D107 (previously known as ZP-Glucagon), until such time that we can appropriately fund such development through strategic partnerships or additional financing. As a result of this decision, we streamlined our organization to effectively use our funds for this purpose. The workforce reduction is expected to reduce our expenses by approximately \$2.0 million, net of

severance costs, for the fiscal year, 2016.

In July 2016, we announced the dosing of the first subject in the M207 pivotal efficacy trial, known as Zotrip study. The Zotrip trial is a multicenter, double-blinded, randomized, placebo-controlled trial comparing three doses of M207 (1.0 mg, 1.9 mg, and 3.8 mg) to placebo for the treatment of a single migraine attack.

Table of Contents

On November 8, 2016, we announced that we had achieved sufficient patient enrollment in the Zotrip trial to reach the goal of approximately 360 randomized patients, and subsequently we closed enrollment. We are on track to announce results of the Zotrip trial in the first quarter of 2017.

M207 Clinical Trials

The ongoing Zotrip pivotal efficacy trial is a multicenter, double-blind, randomized, placebo-controlled trial comparing three doses of M207 (1.0 mg, 1.9 mg, and 3.8 mg) to placebo for the treatment of a single migraine attack. We expect to enroll enough subjects to randomize approximately three hundred sixty subjects in the Zotrip trial at 36 centers across the United States. Subjects are recruited into the Zotrip trial if they have a history of at least one year of episodic, acute migraines with or without aura. Upon recruitment, subjects undergo a screening and run-in period to ensure they meet the key eligibility criterion of 2-8 migraine attacks per month, documented using an electronic diary. Successfully screened subjects are then randomized into the treatment/dosing period and have 8 weeks to confirm and administer blinded treatment for a single migraine attack.

Based on the Company's discussions with the FDA and the FDA's October 2014 Draft Guidance "Migraine: Developing Drugs for Acute Treatment," the co-primary endpoints of this study are:

- (i) pain freedom at 2 hours post-dosing, and
- (ii) freedom from each subject's most bothersome symptom at 2 hours post-dosing.

Furthermore, the FDA has indicated that a single, positive, pivotal efficacy study, in addition to a safety study, will be sufficient data to file for regulatory approval under the 505(b)(2) pathway. The Company intends to conduct the safety study after completion of the Zotrip trial.

The planned safety study, will follow after the completion of the efficacy study upon confirming the commercial dose selection. We will require additional financing to initiate this safety study. According to FDA guidance, the safety study is designed to enroll a total of 250 subjects, who historically had experienced two to eight migraines per month, with the goal of retaining 150 subjects who have completed at least six months of follow up and 50 subjects who have completed 12 months of follow up. The safety study is planned to be an open-label study with investigator visits at months one, three, six, nine and twelve to record adverse events. The primary objective of the safety study is to measure adverse events and local tolerability during repeated administration. Other endpoints are electrocardiography, and laboratory parameters, as well as percentage of headaches with pain-free response.

While we are considering 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 will receive 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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or 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, accruals and warrant valuations. 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 consolidated 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 condensed consolidated statements of operations and comprehensive loss, liquidity and financial condition.

Table of Contents

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. 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 three and nine months ended September 30, 2016, 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, 2015 filed with the Securities and Exchange Commission.

Financial Operations Overview

As of September 30, 2016, we had an accumulated deficit of approximately \$189.0 million. We have incurred significant losses and expect to incur significant and increasing losses in the foreseeable future as we advance our product candidates into later stages of development and, if approved, commercialization.

We expect our research and development expenses and manufacturing expenses related to clinical trials to increase significantly as we continue to advance our product candidates 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 profitability.

Revenue

Our revenue to date has been generated primarily from non-refundable license fee payments and reimbursements for research and development expenses under our former collaboration and license agreements with strategic partners. Our collaboration agreements with Lilly and Novo Nordisk have been terminated. We cannot assure you that we will receive additional collaboration revenue in the future.

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 costs 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 our intracutaneous microneedle patch system, including fees paid to contract manufacturing organizations or CMOs;

fees paid to contract research organizations, or CROs, clinical consultants, clinical trial sites and vendors, including institutional review boards, or 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, patient 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;

Table of Contents

other consulting fees paid to third parties; and

allocation of certain shared costs, such as facilities-related costs and 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 are actively seeking opportunities to enter into collaborations with strategic partners to further the clinical and commercial development of our other product candidates, such as Daily B104, Weekly B206 and D107.

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 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 three and nine months ended September 30, 2016 reflects accrued and paid interest related to the term loan with Hercules Technology Growth Capital, Inc., or Hercules, and the related amortization of debt discount and issuance costs. Interest expense for the nine months ended September 30, 2015 reflects accrued interest on the secured promissory note payable to BMV Direct SOTRS LP, one of our largest stockholders, as well as on the term loan with Hercules and the related amortization of debt discount and issuance costs. Interest expense for the nine months ended September 30, 2015, also includes interest accrued on our related parties' convertible promissory notes.

Other income (expense) and warrant revaluation income. Other income or expense consists of certain miscellaneous income or expenses that are not included in other categories of the consolidated statement of operations. For the nine months ended September 30, 2016, other income consists primarily of a \$51,000 gain from the sale of equipment. For the nine months ended September 30, 2015, the Company recorded warrant revaluation income of \$48,000 that resulted from the re-measurement of our common stock warrant liability issued in connection with the Hercules loan. We recorded changes to the fair value of the common stock warrants as income or loss at each balance sheet date until they were reclassified to permanent equity in the first quarter 2015. As such, there was no income or expense recorded for the three months ended September 30, 2015.

Results of Operations

Comparison of the three months ended September 30, 2016 and 2015

Revenue

Edgar Filing: Zosano Pharma Corp - Form 10-Q

Due to the completion of the feasibility study and conclusion of work under the collaboration agreement with Novo Nordisk which was terminated in 2015, there were no revenues for the three months ended September 30, 2016 and 2015.

Table of Contents***Research and development expenses***

	Three Months Ended September 30,		Change	
	2016	2015	Amount	%
	<i>(In thousands)</i>			

Research and development	\$ 5,124	\$ 6,627	\$ (1,503)	-23%
--------------------------	----------	----------	------------	------

Research and development expenses decreased approximately \$1.5 million, or 23%, for the three months ended September 30, 2016 as compared to the same period in 2015. The decision to suspend development of product candidates, Daily B104, Weekly B206 and D107, resulted in a decrease of approximately \$4.3 million primarily related to production costs for the manufacturing of clinical trial material for those product candidates.

The focus of our development efforts on product candidate M207, beginning March 2016, resulted in an increase of approximately \$2.9 million primarily related to CRO costs.

General and administrative expenses

	Three Months Ended September 30,		Change	
	2016	2015	Amount	%
	<i>(In thousands)</i>			

General and administrative	\$ 2,010	\$ 1,719	\$ 291	17%
----------------------------	----------	----------	--------	-----

General and administrative expenses increased approximately \$0.3 million, or 17%, for the three months ended September 30, 2016 as compared to the same period in 2015. General and administrative expenses increased approximately \$0.4 million due primarily to increases in stock based compensation related to performance grants, legal and consulting costs. These increases were partially offset by a decrease of approximately \$0.1 million in personnel costs.

Other income (expense)

	Three Months Ended September 30,		Change	
	2016	2015	Amount	%
	<i>(In thousands)</i>			

Interest expense, net	\$ (314)	\$ (314)	\$ -	0%
-----------------------	----------	----------	------	----

Other income	-	41	(41)	-100%
--------------	---	----	------	-------

Interest expense, net, was unchanged for the three months ended September 30, 2016 as compared to the same period in 2015.

Other income decreased approximately \$41,000 for the three months ended September 30, 2016 as compared to the same period in 2015. The decrease was primarily related to a non-recurring reimbursement on an insurance claim in 2015.

*Comparison of the nine months ended September 30, 2016 and 2015***Revenue**

	Nine Months Ended September 30,		Change	
	2016	2015	Amount	%
	<i>(In thousands)</i>			
Revenue				
License fee revenue	\$ -	\$ 170	\$ (170)	-100%
Collaborative development support services	-	143	(143)	-100%
Total revenue	\$ -	\$ 313	\$ (313)	-100%

Table of Contents

Total revenue decreased \$0.3 million, or 100%, for the nine months ended September 30, 2016 as compared to the same period in 2015. The decrease was due to the completion of feasibility study and conclusion of work under the collaboration agreement with Novo Nordisk which was terminated in 2015.

Research and development expenses

	Nine Months Ended		Change	
	September 30,		Amount	%
	2016	2015		
	<i>(In thousands)</i>			

Research and development	\$ 15,044	\$ 14,701	\$ 343	2%
--------------------------	-----------	-----------	--------	----

Research and development expenses increased approximately \$0.3 million, or 2%, for the nine months ended September 30, 2016 as compared to the same period in 2015. The increase was primarily due to the initiation of clinical development of M207. Product costs for M207 increased approximately \$7.8 million, primarily for manufacturing personnel costs in connection with the production of clinical trial materials, CRO costs, M207 efficacy study start-up costs and certain preclinical studies related to the submission of M207's IND application. New asset development costs also increased \$0.8 million.

Increases was offset by a decrease of approximately \$8.2 million for manufacturing production and product-related studies as a result of our decision to suspend development of product candidates, Daily B104, Weekly B206 and D107.

General and administrative expenses

	Nine Months Ended		Change	
	September 30,		Amount	%
	2016	2015		
	<i>(In thousands)</i>			

General and administrative	\$ 6,137	\$ 4,797	\$ 1,340	28%
----------------------------	----------	----------	----------	-----

General and administrative expenses increased approximately \$1.3 million, or 28%, for the nine months ended September 30, 2016 as compared to the same period in 2015. This increase was primarily due to approximately \$0.4 million in non-recurring charges related to the reduction in force in March 2016, increased stock based compensation expense of approximately \$0.3 million partially related to performance awards that vested in the second quarter of 2016 upon reaching pivotal clinical trial goals, an increase of approximately \$0.3 million related to insurance and infrastructure expenses, and approximately \$0.2 million in outside services and contractors.

Other expenses

	Nine Months Ended		Change	
	September 30,		Amount	%
	2016	2015		
	<i>(In thousands)</i>			

Edgar Filing: Zosano Pharma Corp - Form 10-Q

Interest expense, net	\$ (951)	\$ (1,247)	\$ 296	-24%
Other income	49	49	-	0%
Warrant revaluation income	-	48	(48)	-100%
Loss on debt extinguishment	-	(446)	446	-100%

Interest expense, net, decreased approximately \$0.3 million, or 24%, for the nine months ended September 30, 2016 as compared to the same period in 2015. The decrease in interest expense was primarily due to savings from the restructuring of our term loan with Hercules in June 2015 at a lower interest rate.

Table of Contents

Other income was unchanged for the periods presented. For the nine months ended September 30, 2016, other income consists primarily of a gain of approximately \$51,000 recorded from sale of equipment, and for the nine months ended September 30, 2015, other income consists of a non-recurring reimbursement on an insurance claim.

For the nine months ended September 30, 2015, we recorded warrant revaluation income, which resulted from the re-measurement of the fair value of our common stock warrant liability issued in connection with the Hercules term loan in June 2014.

Loss on debt extinguishment was related to the restructuring and consolidation of our outstanding debt in June 2015. The amended Hercules Term Loan had substantially different terms than the original loan, and the original debt was considered extinguished. We accounted for the extinguishment based on relative fair value of the loan and recorded a loss on debt extinguishment of \$0.4 million in the three months ended June 30, 2015.

Liquidity and Capital Resources

We have incurred operating losses and negative cash flows from operating activities since inception, and as of September 30, 2016, had an accumulated deficit of \$189.0 million. We expect to incur additional losses in the future as we continue our research and development, clinical and pre-commercialization manufacturing activities for our product candidates.

From our inception in October 2006 to our initial public offering in January 2015, we have funded our operations primarily through private placements of our preferred stock, secured and unsecured borrowings from private investors, bank credit facilities, and licensing and service revenue from our license and collaboration agreements. On January 30, 2015, we completed our IPO, in which we issued 4,500,000 shares of our 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 payment of offering expenses. Concurrent with the closing of our IPO on January 30, 2015, we issued and sold an additional 1,363,636 shares of our common stock to Lilly in a separate private placement for net proceeds of \$14.5 million, after deducting a private placement fee. On February 27, 2015, we issued and sold an additional 110,000 shares of our common stock at a price of \$11.00 per share pursuant to the partial exercise of the overallotment option granted to the underwriters in our initial public offering, resulting in net proceeds to us of approximately \$1.1 million after deducting underwriting discounts and commissions. On August 19, 2016, we completed a Private Investment in Public Equity (PIPE) offering and issued an aggregate 4,800,000 shares of common stock and warrants to purchase 9,600,000 shares of common stock for net proceeds of \$6.6 million.

As of September 30, 2016, we had approximately \$23.1 million in cash, cash equivalents and marketable securities. We anticipate that we will not be able to satisfy our cash requirements over the next twelve months and shall be required to seek additional financing to enable us to complete all development activities necessary for NDA filing.

We will continue to require additional financing to develop our product candidates and fund operating losses. We will seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. 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;

Edgar Filing: Zosano Pharma Corp - Form 10-Q

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 emergence of competing technologies and other adverse market developments;

Table of Contents

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

if approved, the resources we devote to marketing, commercializing our product candidates; and the costs associated with being a public company.

If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of 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.

The following table shows a summary of our cash flows for the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
	2016	2015
	<i>(In thousands)</i>	
Net cash (used in) provided by:		
Operating activities	\$ (18,804)	\$ (17,530)
Investing activities	26,052	(39,342)
Financing activities	5,284	60,533
Net increase (decrease) in cash and cash equivalents	\$ 12,532	\$ 3,661

Operating Cash Flow: Net cash used in operating activities was approximately \$18.8 million and \$17.5 million for the nine months ended September 30, 2016 and 2015, respectively. Net cash used during the first nine months of 2016 was primarily due to personnel costs related to manufacturing M207 clinical trial materials, preclinical study costs, certain termination benefits paid to a former executive, cost associated with our workforce reduction in March 2016 and professional fees and administrative expenses incurred in the course of our continuing operations. Net cash used during the first nine months of 2015 was primarily the result of clinical and non-clinical costs, personnel costs related to the hiring of key personnel with critical manufacturing know-how to ramp up our production of clinical trial materials in preparation of our planned clinical trials, professional fees and administrative expenses incurred in the course of our continuing operations.

Investing Cash Flow: Net cash provided by investing activities was approximately \$26.1 million for the nine months ended September 30, 2016, as compared to net cash used in investing activities of approximately \$39.3 million for the same period in 2015. Net cash provided by investing activities during the first nine months of 2016 was primarily the result of the maturity of certain marketable securities in our investment portfolio. Net cash used in investing activities during the first nine months of 2015 was primarily due to the purchase of \$42.6 million of marketable securities for investment, partially offset by the maturities of \$3.5 million of our investment in marketable securities.

Financing Cash Flow: Net cash provided by financing activities was approximately \$5.3 million and \$60.5 million for the nine months ended September 30, 2016 and 2015, respectively. Net cash generated by financing activities during first nine months of 2016 was due to net proceeds of \$6.6 million from the PIPE offering, which was completed in August 2016. Financing proceeds were offset by principal payments on the Hercules Loan of \$1.4 million. Net cash generated by financing activities during first nine months of 2015 included approximately \$60.0 million of net proceeds from our initial public offering of securities and concurrent private placement with Lilly.

Contractual Obligations and Commitments

Our primary contractual obligations as of September 30, 2016 consist of operating leases of approximately \$1.6 million and long-term debt obligations of approximately \$15.9 million (including end of term payments and periodic interest payments). Operating leases represent our future minimum rental commitments under our operating leases. Long-term debt obligations include our secured term loan facility with Hercules.

Table of Contents

Recent Accounting Pronouncements

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation: Improvements to Employee Share-Based Payment. The new guidance simplifies several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2016. The Company is currently evaluating the impact of this accounting standard.

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments. The amendments in this ASU replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information for credit loss estimates. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted as early as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently evaluating the impact of this accounting standard.

In August 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments*. The amendment addresses eight specific cash flow issues with the objective of reducing diversity in practice. The new standard is effective for fiscal years, including interim periods within those fiscal years, beginning after December 15, 2017. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the impact of this accounting standard.

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. We had cash and cash equivalents of \$19.2 million as of September 30, 2016, which consisted of bank deposits and money market funds. We also had \$3.9 million of investments in short-term marketable securities as of September 30, 2016, which consisted of certificates of deposit, corporate notes and bonds, and U.S. government agency bonds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Any interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, a hypothetical immediate 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Edgar Filing: Zosano Pharma Corp - Form 10-Q

Our management, with the participation of our Chief Executive Officer and our Interim Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2016. 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.

Table of Contents

Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, our Chief Executive Officer and Interim Chief Financial 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 and Interim Chief Financial 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 September 30, 2016 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.

Table of Contents

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, 2015 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 nine months ended September 30, 2016. You should consider carefully the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2015 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.

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

On January 30, 2015, we consummated the closing of our initial public offering, (IPO), of common stock pursuant to our Registration Statement on Form S-1 (File No. 333-196983), as amended, which was declared effective by the Securities and Exchange Commission, or SEC, on January 26, 2015.

As of September 30, 2016, we have used all net proceeds of the IPO to fund M207, Daily B104, and D107 product candidates, to service our debt obligation with Hercules, to expand and enhance our manufacturing capabilities, and for working capital and other general corporate purposes.

Item 3. Defaults Upon Senior Securities

Not Applicable.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

A list of exhibits is set forth on the Exhibit Index immediately following the signature page of this Quarterly Report on Form 10-Q, and is incorporated herein by reference.

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: November 9, 2016

Zosano Pharma Corporation

(Registrant)

/s/ Konstantinos Alataris
Konstantinos Alataris, Ph.D.
Chief Executive Officer and President

/s/ Georgia Erbez
Georgia Erbez
Interim Chief Financial Officer and
Chief Business Officer

Table of Contents**EXHIBIT INDEX**

Exhibit number	Description
4.1	Form of Series A warrant (included as exhibit to Securities Purchase Agreement)
4.2	Form of Series B warrant (included as exhibit to Securities Purchase Agreement)
10.1	Securities Purchase Agreement (Incorporate by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on August 15, 2016)
10.2	Erbez Employment Agreement (Incorporated by reference to Exhibit 10.1 to the registrant's Current Report on Form 8-K filed with the Commission on September 7, 2016)
31.1	Certification of Principal Executive 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
31.2	Certification of 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
32.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. 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.*