Mast Therapeutics, Inc.
Form 10-Q
May 06, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2016

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number 001-32157

Mast Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	84-1318182 (I.R.S. Employer Identification No.)
3611 Valley Centre Dr., Suite 500, San Diego, CA (Address of principal executive offices)	92130 (Zip Code)

(858) 552-0866

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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 x 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 x No ¨

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

Large accelerated filer ¨ Accelerated filer x

Non-accelerated filer ¨ 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 x

The number of shares outstanding of the registrant's common stock, $0.001 par value per share, as of May 4, 2016 was 192,836,367.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except for share and par value data)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$23,521	$23,052
Investment securities	13,568	17,929
Prepaid expenses and other current assets	1,160	1,271
Total current assets	38,249	42,252
Property and equipment, net	199	226
In-process research and development	8,549	8,549
Goodwill	3,007	3,007
Other assets	141	183
Total assets	$50,145	$54,217
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$2,453	$2,600
Accrued liabilities	7,793	8,152
Accrued compensation and payroll taxes	976	1,430
Debt facility	11,447	10,991
Total current liabilities	22,669	23,173
Long-term lease obligation	24	25
Debt facility, net of current portion	3,368	3,726
Deferred income tax liability	3,404	3,404
Total liabilities	29,465	30,328
Stockholders' equity:		
Common stock, $0.001 par value; 500,000,000 shares authorized; 192,836,367 and 163,614,297 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	193	164
Additional paid-in capital	306,662	298,715
Accumulated other comprehensive income/(loss)	5	(17)

Accumulated deficit	(286,180)	(274,973)
Total stockholders' equity	20,680	23,889
Total liabilities and stockholders' equity	$50,145	$54,217

See accompanying notes to unaudited condensed consolidated financial statements.

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except for share and per share data)

	Three Months Ended March 31,	
	2016	2015
Revenues	$—	$—
Operating expenses:		
Research and development	7,875	6,042
Selling, general and administrative	2,835	3,578
Depreciation and amortization	32	30
Total operating expenses	10,742	9,650
Loss from operations	(10,742)	(9,650)
Interest income	39	30
Interest expense	(519)	0
Other income, net	15	4
Net loss	$(11,207)	$(9,616)
Net loss per share - basic and diluted	$(0.06)	$(0.06)
Weighted average shares outstanding - basic and diluted	178,115,217	159,458,772
Comprehensive Income/(Loss):		
Net loss	$(11,207)	$(9,616)
Other comprehensive income	22	23
Comprehensive net loss	$(11,185)	$(9,593)

See accompanying notes to unaudited condensed consolidated financial statements.

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Three Months Ended March 31,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(11,207)	$(9,616)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	32	30
Share-based compensation expense related to employee stock options	659	1,066
Amortization of debt issuance costs and debt discount	169	—
Changes in assets and liabilities, net of effect of acquisitions:		
Decrease in prepaid expenses and other assets	153	438
(Decrease)/increase in accounts payable and accrued liabilities	(1,134)	733
Net cash used in operating activities	(11,328)	(7,349)
Cash flows from investing activities:		
Purchases of certificates of deposit	—	(5,296)
Proceeds from maturities of certificates of deposit	4,383	4,847
Purchases of property and equipment	(5)	(70)
Net cash provided by/(used in) investing activities	4,378	(519)
Cash flows from financing activities:		
Proceeds from sale of common stock	8,060	9
Payments for offering costs	(601)	(13)
Payments for capital lease	(2)	(2)
Costs paid in connection with debt facility	(38)	—
Net cash provided by/(used in) financing activities	7,419	(6)
Net increase/(decrease) in cash and cash equivalents	469	(7,874)
Cash and cash equivalents at beginning of period	23,052	35,808
Cash and cash equivalents at end of period	$23,521	$27,934

See accompanying notes to unaudited condensed consolidated financial statements.

Mast Therapeutics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Basis of Presentation

Mast Therapeutics, Inc., a Delaware corporation ("Mast Therapeutics," "we" or "our company"), prepared the unaudited interim condensed consolidated financial statements included in this report in accordance with United States generally accepted accounting principles ("U.S. GAAP") for interim financial information and the rules and regulations of the Securities and Exchange Commission ("SEC") related to quarterly reports on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for annual audited financial statements and should be read in conjunction with our audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 14, 2016 ("2015 Annual Report"). The condensed consolidated balance sheet as of December 31, 2015 included in this report has been derived from the audited consolidated financial statements included in the 2015 Annual Report. In the opinion of management, these condensed consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any future period, including the full year.

We are a biopharmaceutical company focused on developing clinical-stage therapies for serious or life-threatening diseases. We have devoted substantially all of our resources to research and development ("R&D") and acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue. Through our acquisition of SynthRx, Inc. ("SynthRx") in 2011, we acquired our Membrane Adhesion & Sealant Technology (MAST) platform, which includes proprietary poloxamer-related data and know-how derived from over two decades of clinical, nonclinical and manufacturing experience, and we are leveraging the MAST platform to develop vepoloxamer (also known as MST-188) for serious or life-threatening diseases and conditions typically characterized by impaired microvascular blood flow and damaged cell membranes. Through our acquisition of Aires Pharmaceuticals, Inc. ("Aires") in February 2014, we acquired AIR001, a sodium nitrite inhalation solution for intermittent inhalation via nebulization, which we are developing for the treatment of heart failure with preserved ejection fraction (HFpEF).

We have incurred significant operating losses since inception and have relied on our ability to fund our operations primarily though equity financings and a debt financing. For the year ended December 31, 2015 and the three months ended March 31, 2016, we incurred losses from operations of $39.4 million and $10.7 million, respectively, and our net cash used in operating activities was $32.9 million and $11.3 million, respectively. At March 31, 2016, our cash, cash equivalents and investment securities totaled $37.1 million and our working capital was $15.6 million. Our planned operating activities call for expenditures over the next 12 months to exceed our current cash, cash equivalents and investment securities balances and working capital. We intend to raise additional capital before the fourth quarter of 2016 through equity or debt financings and/or through collaborations, including licensing agreements. There can be no assurance that we will be successful in raising sufficient additional capital or that such capital, if available, will be on terms that are acceptable to us. Subject to limited exceptions, our debt facility (See Note 8, "Debt Facility") prohibits us from incurring indebtedness without the lender's prior written consent. Our anticipated operating

expenses and net losses and the uncertainties surrounding our ability to raise additional capital as needed raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and might realize significantly less than the values at which they are carried on our financial statements. If we have positive results from our Phase 3 clinical study of vepoloxamer in sickle cell disease, known as the EPIC study, but we are unable to raise sufficient additional capital before the fourth quarter of 2016, we anticipate that we would immediately reduce the scope of our planned operations, including by delaying or discontinuing investment in development and commercialization efforts for vepoloxamer in sickle cell disease and heart failure. In the event of negative results from the EPIC study and prepayment to our lender on July 31, 2016 of $10.0 million of the principal balance under our debt facility, we also plan to immediately and significantly reduce the scope of our operations. In either case, we expect that our cash, cash equivalents and investment securities as of March 31, 2016, would be sufficient to fund our operations, as reduced in scope, into the first quarter of 2017.

The accompanying condensed consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to our ability to continue as a going concern.

In addition, our business, operating results, financial condition, and growth prospects are subject to significant other risks and uncertainties, including failing to complete development of and obtain regulatory approval to commercialize our product candidates.

2. Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates and assumptions, including estimates related to R&D expenses, in-process research and development ("IPR&D"), goodwill, and share-based compensation expenses. We base our estimates on historical experience and various other relevant assumptions we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

3. Goodwill and IPR&D

At March 31, 2016 and December 31, 2015, our goodwill and IPR&D consisted of the following (in thousands):

Goodwill	$3,007
IPR&D	
Acquired IPR&D related to SynthRx acquisition	6,549
Acquired IPR&D related to Aires acquisition	2,000
Total goodwill and IPR&D	$11,556

Our goodwill represents the difference between the total purchase price for SynthRx and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed.

Our IPR&D consists of the estimated fair values of the vepoloxamer and AIR001 programs as of the dates we acquired SynthRx and Aires, respectively.

We test our goodwill and acquired IPR&D for impairment annually as of September 30, or, in the case of initially acquired IPR&D, on the first anniversary of the date we acquired it and subsequently on September 30, and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying value may be impaired. We performed a qualitative assessment of our goodwill and our acquired IPR&D as of September 30, 2015. We concluded that it is not more likely than not that the carrying value of our goodwill or our acquired IPR&D exceeds its fair value. Therefore, we concluded that no impairment charge is required.

4. Investment Securities

Investment securities are marketable equity or debt securities. All of our investment securities are "available-for-sale" securities and carried at fair value. Fair value for securities with short maturities and infrequent secondary market trades typically is determined by using a curve-based evaluation model that utilizes quoted prices for similar securities. The evaluation model takes into consideration the days to maturity, coupon rate and settlement date convention. Net unrealized gains or losses on these securities are included in accumulated other comprehensive loss, which is a separate component of stockholders' equity. Realized gains and realized losses are included in other income,

net while amortization of premiums and accretion of discounts are included in interest income. Interest and dividends on available-for-sale securities are included in interest income. We periodically evaluate our investment securities for impairment. If we determine that a decline in fair value of any investment security is other than temporary, then the cost basis would be written down to fair value and the decline in value would be charged to earnings.

Our investment securities are under the custodianship of a major financial institution and consist of FDIC-insured certificates of deposit. We have classified all of our available-for-sale investment securities, including those with maturities beyond one year from the date of purchase, as current assets on our consolidated balance sheets because we consider them to be highly liquid and available for use, if needed, in current operations. As of March 31, 2016, $2.2 million, or approximately 17%, of our investment securities had contractual maturity dates of more than one year and less than or equal to 18 months and none had contractual maturity dates greater than 18 months.

At March 31, 2016 and December 31, 2015, our investment securities were as follows (in thousands):

	March 31, 2016	December 31, 2015
Fair value of investment securities	$13,568	$ 17,929
Cost basis of investment securities	13,563	17,946

	March 31, 2016	December 31, 2015
Net unrealized (gains)/losses on investment securities	$(5)	$ 17

5. Fair Value of Financial Instruments

Our cash equivalents are recorded at cost plus accrued interest, which approximates fair value. Our investment securities are carried at fair value. The fair value of financial assets and liabilities is measured under a framework that establishes "levels" which are defined as follows: (i) Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities; (ii) Level 2 fair value is determined from inputs, other than Level 1 inputs, 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, and (iii) Level 3 fair value is determined using the entity's own assumptions about the inputs that market participants would use in pricing an asset or liability.

The fair values at March 31, 2016 and December 31, 2015 of our cash equivalents and investment securities are summarized in the following table (in thousands):

		Fair Value Determined Under:		
	Total Fair Value	(Level 1)	(Level 2)	(Level 3)
At March 31, 2016:				
Cash equivalents	$15,214	$15,214	$—	$ —
Investment securities	$13,568	$—	$13,568	$ —
At December 31, 2015:				
Cash equivalents	$15,799	$15,799	$—	$ —
Investment securities	$17,929	$—	$17,929	$ —

We believe that our debt facility (see Note 8 "Debt Facility") bears interest at a rate that approximates prevailing market rates for instruments with similar characteristics and, accordingly, the carrying value of the debt facility approximates fair value. The fair value of our debt facility is determined under Level 2 in the fair value hierarchy.

6. Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets, which generally is three to five years. Leasehold improvements are amortized over the economic life of the asset or the lease term, whichever is shorter. Repairs and maintenance are expensed as incurred.

We lease certain office equipment under leases classified as capital leases. As of March 31, 2016, the total amount of leased equipment was $40,000 with interest rates ranging from 8% to 14% per annum. The equipment is being amortized over the life of the leases, which range from three to five years.

7. Accrued Liabilities

Accrued liabilities at March 31, 2016 and December 31, 2015 were as follows (in thousands):

	March 31, 2016	December 31, 2015
Accrued R&D agreements and study expenses	$7,355	$ 7,898
Other accrued liabilities	438	254
Total accrued liabilities	$7,793	$ 8,152

8. Debt Facility

Hercules Loan and Security Agreement

We have borrowed an aggregate of $15.0 million pursuant to a Loan and Security Agreement, dated August 11, 2015, with Hercules Technology III, L.P. and Hercules Capital, Inc. (formerly known as, Hercules Technology Growth Capital, Inc.) (together, “Hercules”), as amended by the First Amendment thereto dated September 28, 2015, the Second Amendment thereto dated December 31, 2015, and the Third Amendment thereto dated February 25, 2016, (collectively, the “Loan Agreement”). Pursuant to the terms and conditions of the Loan Agreement, we received the first advance of $5.0 million on August 11, 2015 and the second advance of $10.0 million (the “Second Advance”) on September 28, 2015.

Under the Loan Agreement, the Second Advance is required to be prepaid to Hercules on July 31, 2016, without any prepayment penalty, unless on or before such date, we demonstrate, to the reasonable satisfaction of Hercules, positive results in

our Phase 3 clinical study of vepoloxamer in patients with sickle cell disease, known as the EPIC study. Due to numerous factors, we are not able to predict with any reasonable certainty the probability of meeting this condition by July 31, 2016; therefore, we have classified the Second Advance as a current liability on the balance sheet.

The interest rate for the principal balance under the Loan Agreement is the greater of (i) 8.95% plus the prime rate as reported in The Wall Street Journal minus 3.25%, and (ii) 8.95%, determined on a daily basis. Monthly payments under the Loan Agreement are interest only until July 1, 2016, followed by equal monthly payments of principal and interest through the scheduled maturity date of January 1, 2019. The interest-only period will be extended to March 1, 2017 if we have demonstrated positive results in the EPIC study by July 1, 2016, we have not prepaid the Second Advance, and no event of default has occurred. If we demonstrate positive results in the EPIC study during the period from July 2, 2016 and July 31, 2016, inclusive, we have not prepaid the Second Advance and no event of default has occurred, then on July 1, 2016, we will be required to make a single payment against the principal balance of approximately $430,000 and, beginning August 1, 2016, we will resume making interest-only payments until March 1, 2017. If our interest-only payment period is extended to March 1, 2017, the maturity date would extend to October 1, 2019. An end of term charge of $712,500 will be due on the scheduled maturity date and is being accrued through interest expense using the effective interest method.

If we elect to prepay the principal balance under the Loan Agreement prior to maturity, a prepayment charge of 1%, 2% or 3%, of the then outstanding principal balance also will be due, depending upon when the prepayment occurs.

Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets, excluding our intellectual property but including the proceeds from the sale, licensing or disposition of our intellectual property. Our intellectual property is subject to customary negative covenants.

In connection with the Loan Agreement, we have paid facility charges of $150,000 and a commitment charge of $25,000. Such charges were accounted for as debt issuance costs and are being amortized to interest expense using the effective interest method through the scheduled maturity date.

In connection with the Loan Agreement, we entered into a Warrant Agreement with Hercules, dated August 11, 2015, as amended by the First Amendment thereto dated September 28, 2015 and the Second Amendment thereto dated February 25, 2016, pursuant to which Hercules has a right to purchase up to 2,272,727 shares of our common stock at an exercise price of $0.275 per share. Prior to the Second Amendment to Warrant Agreement, the Warrant Agreement, as amended by the First Amendment, provided Hercules a right to purchase up to 1,524,390 shares of our common stock at an exercise price of $0.41 per share.

The warrants issued to Hercules were valued using the Black-Scholes option pricing model with the following assumptions: volatility of 83%, expected term of five years, risk-free interest rate of 1.2% and a zero dividend yield. The warrant fair value of $0.4 million has been recorded as a debt discount and is being amortized through interest expense using the effective interest method through the scheduled maturity date. See Note 13 “Stockholders’ Equity” for further description of the terms of the warrants.

Summary of Carrying Value

The following table summarizes the components of the debt facility carrying value (in thousands):

	As of March 31, 2016	
	Short-term	Long-term
Potential prepayment to lender	$10,000	$ -

Principal payments to lender and end of term charge	1,328	4,384
Accrued interest	119	-
Debt issuance costs	-	(706)
Debt discount related to warrants	-	(310)
Carrying value	$11,447	$ 3,368

9. Share-Based Compensation Expense

Share-based compensation expense related to equity awards granted to our employees and non-employee directors for the three months ended March 31, 2016 and 2015 was as follows (in thousands):

	Three Months Ended March 31,	
	2016	2015
Selling, general and administrative expense	$424	$941
Research and development expense	235	125
Share-based compensation expense	$659	$1,066

During the three months ended March 31, 2016, the only equity awards granted to our employees and non-employee directors were stock option awards. The following table summarizes the equity award activity during such three-month period:

	Shares Underlying Option Awards	Weighted-Average Exercise Price
Outstanding at December 31, 2015	22,896,728	$ 0.78
Granted	7,833,059	$ 0.42
Exercised	—	$ —
Expired/forfeited	(526,662)	$ 1.18
Outstanding at March 31, 2016	30,203,125	$ 0.68

At March 31, 2016, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was $5.9 million, which is expected to be recognized over a weighted-average period of 3.0 years.

10. Net Loss Per Common Share

Basic and diluted net loss per common share was calculated by dividing the net loss for the three months ended March 31, 2016 and 2015 by the weighted-average number of common shares outstanding during those periods, respectively, without consideration for outstanding common stock equivalents because their effect would have been anti-dilutive. Common stock equivalents are included in the calculation of diluted earnings per common share only if their effect is dilutive. For the periods presented, our outstanding common stock equivalents consisted of options and warrants to purchase shares of our common stock. All common stock equivalents presented had an anti-dilutive impact due to losses reported in the applicable periods. The weighted-average number of those common stock equivalents outstanding for each of the periods presented is set forth in the table below:

	Three Months Ended March 31,	
	2016	2015
Options	30,322,614	20,763,600
Warrants	90,245,994	79,149,568

11. Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-09, Compensation – Stock Compensation ("ASU 2016-09"), which involves multiple aspects of the accounting for share-based transactions, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. For public companies, ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. Early adoption is permitted. We are in the process of evaluating the impact of this new guidance.

In February 2016, the FASB issued ASU No. 2016-02, Leases (ASC 842) ("ASU 2016-02"), ASU 2016-02 sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to classify leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. Accounting Standards Codification ("ASC") 842 supersedes the previous leases standard, ASC 840 Leases. The standard is effective on January 1, 2019, with early adoption permitted. We are in the process of evaluating the impact of this new guidance.

In November 2015, the FASB issued ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes ("ASU 2015-17"). Currently deferred taxes for each tax jurisdiction are presented as a net current asset or liability and net noncurrent asset or

liability on the balance sheet. To simplify the presentation, the new guidance requires that all deferred tax assets and liabilities for each jurisdiction, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The new guidance becomes effective for public business entities in fiscal years beginning after December 15, 2016. We elected to early adopt this new standard prospectively for the year ended December 31, 2015 and it did not have a material impact on our financial statements.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). The amendments in ASU 2014-15 will require management to assess, at each annual and interim reporting period, the entity's ability to continue as a going concern and, if management identifies conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued, to disclose in the notes to the entity's financial statements the principal conditions or events that raised substantial doubt about the entity's ability to continue as a going concern, management's evaluation of their significance, and management's plans that alleviated or are intended to alleviate substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and early application is permitted. The amendments in ASU 2014-15 do not have any application to an entity's financial statements, but only to the related notes.

12. Supplemental Cash Flow Information

Non-cash investing and financing transactions presented separately from the condensed consolidated statements of cash flows for the three months ended March 31, 2016 and 2015 are as follows (in thousands):

	Three Months Ended March 31,	
	2016	2015
Cash paid for interest on debt facility	$288	$-
Supplemental disclosures of non-cash investing and financing activities:		
Warrants issued in connection with debt facility	$26	$-
Unrealized gain on investment securities	$(22)	$(23)
Purchases of property and equipment in accounts payable	$-	$2
Purchase of equipment under capital lease	$-	$33
Financing costs in accounts payable and accrued liabilities	$167	$19
Debt issuance costs in accounts payable and accrued liabilities	$10	$-

13. Stockholders' Equity

Underwritten Public Offering of Common Stock and Warrants

In February 2016, we completed an underwritten public offering with gross proceeds of $8.0 million from the sale and issuance of 29,090,910 units, each consisting of one share of our common stock and one warrant to purchase one share of our common stock. Net proceeds, after deducting underwriting discounts and commissions and other estimated offering expenses, were approximately $7.3 million. The warrants have an exercise price of $0.42 per share, are exercisable any time on or after August 17, 2016 and will expire on February 16, 2021.

"At the Market" Equity Offering Program

In February 2014, we entered into a sales agreement with Cowen and Company, LLC ("Cowen"), to sell shares of our common stock, with aggregate gross sales proceeds of up to $30.0 million, from time to time, through an "at the market," or ATM, equity offering program (the "2014 Sales Agreement"), under which Cowen acted as sales agent. In August 2015, we terminated the 2014 Sales Agreement upon entry into a new sales agreement with Cowen to sell shares of our common stock, with aggregate gross sales proceeds of up to $30.0 million, from time to time, through an ATM program. As of March 31, 2016, we had sold and issued an aggregate of 24,990,267 shares at a weighted-average sales price of $0.70 per share under the ATM programs for aggregate gross proceeds of $17.5 million and $16.6 million in net proceeds, after deducting sales agent commission and discounts and our other offering costs.

Shares Issuable to Former SynthRx Stockholders Upon Achievement of Milestones

In April 2011, we acquired SynthRx as a wholly-owned subsidiary through a merger transaction in exchange for shares of our common stock and rights to additional shares of our common stock upon achievement of specified milestones related to the development of MST-188 in sickle cell disease. We have issued an aggregate of 3,050,851 shares of our common stock to the

former SynthRx stockholders, 1,454,079 of which we repurchased in December 2012 for $0.001 per share pursuant to our exercise of a repurchase right under the merger agreement. We could issue up to an aggregate of 12,478,050 additional shares of our common stock to the former SynthRx stockholders if and when the development of MST-188 achieves the following milestones: (a) 3,839,400 shares upon acceptance for review by the U.S. Food and Drug Administration ("FDA") of a new drug application ("NDA") covering the use of purified poloxamer 188 for the treatment of sickle cell crisis in children and (b) 8,638,650 shares upon approval of such NDA by the FDA.

Warrants Issued to Hercules

In connection with the Loan Agreement, we entered into a Warrant Agreement with Hercules Technology III, L.P., dated August 11, 2015, as amended by the First Amendment thereto dated September 28, 2015 and the Second Amendment thereto dated February 25, 2016, pursuant to which Hercules has a right to purchase up to an aggregate of 2,272,727 shares of our common stock at an exercise price of $0.275 per share, at any time, or from time to time, through August 11, 2020. The Warrant Agreement, as amended, provides for adjustment to the exercise price and number of shares subject to Hercules' warrants in the event of a merger event, reclassification of our common stock, subdivision or combination of our common stock, or certain dividend payments. Upon exercise, the aggregate exercise price may be paid, at Hercules' election, in cash or on a net issuance basis, based upon the fair market value of our common stock at the time of exercise. If the fair market value of our common stock is greater than the exercise price of the warrants as of immediately before their expiration, to the extent the warrants are not previously exercised in full, the warrants shall be deemed automatically exercised on a net issuance basis as of immediately before their expiration.

Outstanding Warrants

At March 31, 2016, outstanding warrants to purchase shares of common stock are as follows:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
10,625,000	$ 1.100	November 2016
28,097,400	$ 0.650	June 2018
13,081,428	$ 0.010	November 2019
22,011,265	$ 0.750	November 2019
2,272,727	$ 0.275	August 2020
29,090,910	$ 0.420	February 2021
105,178,730		

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and accompanying notes appearing elsewhere in this report. For additional context with which to understand our financial condition and results of operations, see the discussion and analysis included in Part II, Item 7 of our annual report on Form 10-K for the year ended December 31, 2015, filed with the U.S. Securities and Exchange Commission, or SEC, on March 14, 2016, as well as the consolidated financial statements and accompanying notes contained therein. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including but not limited to those identified under "Forward Looking Statements" below and those discussed in Item 1A (Risk Factors) of Part II of this report and in Item 1A (Risk Factors) of Part I of our annual report on Form 10-K for the year ended December 31, 2015. Mast Therapeutics, our corporate logo, Aires Pharmaceuticals, Inc., VOICE Crisis Alert, and SynthRx are trademarks of our company. All trademarks, service marks or trade names appearing in this report are the property of their respective owners. Use or display by us of other parties' trademarks, service marks or trade names is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark or trade name owners.

Overview

We are a biopharmaceutical company developing clinical-stage therapies for serious or life-threatening diseases with significant unmet needs and we currently are focused on developing new therapies for sickle cell disease and heart failure. Our lead product candidate, vepoloxamer (also known as MST-188), is in Phase 3 clinical development for sickle cell disease and Phase 2 clinical development for heart failure with reduced ejection fraction. We are leveraging our Molecular Adhesion & Sealant Technology, or MAST, platform, derived from over two decades of clinical, nonclinical, and manufacturing experience with purified and non-purified poloxamers, to develop vepoloxamer, which has demonstrated multiple pharmacologic effects that may provide clinical benefit in a wide range of diseases and conditions typically characterized by impaired microvascular blood flow and/or damaged cell membranes. Our second product candidate, AIR001, a sodium nitrite solution for inhalation via nebulization, has demonstrated positive hemodynamic benefits in patients with heart failure with preserved ejection fraction, or HFpEF, and pulmonary hypertension, and currently is in Phase 2 clinical development for HFpEF.

We have devoted substantially all of our resources to research and development, or R&D, and to acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue and we have incurred significant annual operating losses since inception. We incurred a loss from operations of $10.7 million for the three months ended March 31, 2016. As of March 31, 2016, we had an accumulated deficit of $286.2 million. Our cash, cash equivalents, and investment securities were $37.1 million and our working capital was $15.6 million as of March 31, 2016.

Our development efforts have been funded primarily through the offering and sale of our equity securities from time to time and a debt facility under which we have a principal balance of $15.0 million. The process of developing and seeking regulatory approval for investigational new drug products and marketing such products, if approved, requires significant capital investment. We expect to continue to incur substantial operating losses for the next several years as we advance our product candidates through clinical development and, if successful, seek regulatory approval to market and sell them. Until such time as we obtain regulatory approval and are subsequently able to generate positive cash flow, we plan to continue to fund our operations with our current cash, cash equivalents and investment securities and by raising additional capital through equity or debt financings and/or through collaborations, including licensing arrangements. If we are not successful in raising sufficient additional capital as needed, we may be compelled to reduce the scope of our operations and planned capital expenditures and/or sell or license certain assets at inopportune

times, which could have a material and adverse effect on our ability to pursue our business strategy. As discussed below under "Management Outlook," we do not believe our cash, cash equivalents and investment securities as of March 31, 2016 will be sufficient to meet our currently planned operations for the next 12 months, and these circumstances raise substantial doubt about our ability to continue as a going concern. If we have positive results from our Phase 3 clinical study of vepoloxamer in sickle cell disease, known as the EPIC study, but we are unable to raise sufficient additional capital before the fourth quarter of 2016, we plan to reduce the scope of our operations, including by delaying or discontinuing investment in development and commercialization efforts for vepoloxamer in sickle cell disease and heart failure. In the event of negative results from the EPIC study and prepayment to our lender on July 31, 2016 of $10 million of the principal balance under our debt facility, as would be required by its terms, we also plan to immediately and significantly reduce the scope of our operations.

In February 2016, we completed enrollment in our 388-patient Phase 3 clinical study of vepoloxamer in sickle cell disease, known as the EPIC study, and we expect to report top-line data in the second quarter of 2016. Vepoloxamer also is currently being evaluated in a randomized, double-blind, placebo-controlled, multicenter Phase 2 study in patients with chronic heart failure. In addition, we continue to evaluate the opportunity for clinical development of vepoloxamer in ischemic stroke and our vepoloxamer pipeline includes a preclinical development program in resuscitation following major trauma (i.e., restoration of circulating blood volume and pressure). We obtained the MAST platform and vepoloxamer program through our acquisition of SynthRx, Inc. in April 2011.

Our second product candidate, AIR001, is in Phase 2 clinical development for HFpEF. In February 2016, we announced positive top-line results from a 30-patient, randomized, double-blind, placebo-controlled Phase 2a study of AIR001 in patients with HFpEF. The study met its pre-specified primary endpoint, with the AIR001 treatment group showing a statistically significant decrease in pulmonary capillary wedge pressure during exercise compared to the control group and AIR001 was generally well-tolerated. Another institution-sponsored Phase 2a clinical study of AIR001 in patients with HFpEF is ongoing. In addition, we are supporting a multicenter, randomized, double-blind, placebo-controlled crossover Phase 2 study of AIR001 in approximately 100 patients with HFpEF. The study, which is known as the Inorganic Nitrite Delivery to Improve Exercise Capacity in HFpEF (INDIE-HFpEF) study, is sponsored by Duke Research Institute as the Coordinating Center for the Heart Failure Clinical Research Network (HFN) and will be conducted at approximately 20 clinical centers in the U.S. that are part of the HFN. The study is expected to begin in the third quarter of 2016. We obtained the AIR001 program through our acquisition of Aires Pharmaceuticals, Inc. in February 2014.

Critical Accounting Policies and Significant Judgments and Estimates

Our discussion and analysis of our financial condition and results of operations included in this report is based upon consolidated financial statements and condensed consolidated financial statements that we have prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make a number of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses in these financial statements and accompanying notes. On an ongoing basis, we evaluate these estimates and assumptions, including those related to determination of the fair value of goodwill and acquired in-process research and development, or IPR&D, and recognition of R&D expenses and share-based compensation. We base our estimates on historical information, when available, and assumptions believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

We believe the following accounting estimates are those that can have a material impact on our financial condition or operating performance and involve substantial subjectivity and judgment in the application of our accounting policies to account for highly uncertain matters or the susceptibility of such matters to change. The following is not intended to be a comprehensive discussion of all of our significant accounting policies. See the notes accompanying our consolidated financial statements appearing in our most recent annual report on Form 10-K for a summary of all of our significant accounting policies and other disclosures required by U.S. GAAP.

Accrued Research and Development Expenses. As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. Many of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The majority of our accrued expenses relate to R&D services and related expenses. Examples of estimated accrued R&D expenses include:

- fees paid to contract research organizations, or CROs, in connection with clinical studies;
- fees paid to investigative sites and investigators in connection with clinical studies;
- fees paid to contract manufacturing organizations, or CMOs, in connection with process development activities and production of nonclinical and clinical trial material;

- fees paid to vendors in connection with nonclinical development activities; and
- fees paid to consultants for regulatory-related advisory and data management services.

We base our accrued expenses related to CROs and CMOs on our estimates of the services received and efforts expended pursuant to purchase orders or contracts with multiple service providers that we engage to conduct and manage our clinical studies and manufacture our clinical trial material on our behalf. The financial terms of our arrangements with our CROs and CMOs are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful completion of specified process development activities or the successful enrollment of patients and the completion of clinical study milestones. In accruing these service fees, we estimate, as applicable, the time period over which services will be performed (e.g., enrollment of patients, activation of clinical sites, etc.). If the actual timing varies from our estimate, we adjust the accrual accordingly. In addition, there may be instances in which payments made to service providers will exceed the level of services provided and result in a prepayment of R&D expense, which we report as an asset. The actual costs and timing of clinical studies and research-related manufacturing are uncertain and subject to change depending on a number of factors. Differences between actual costs of these services and the estimated costs that we have accrued in a prior period are recorded in the subsequent period in which the actual costs become known to us. Historically, these differences have not resulted in material adjustments, but such differences may occur in the future and have a material impact on our consolidated results of operations or financial position.

Business Combinations. We account for business combinations, such as our acquisitions of SynthRx in April 2011 and Aires Pharmaceuticals in February 2014, in accordance with Accounting Standards Codification, or ASC, Topic 805, Business Combinations, which requires the purchase price to be measured at fair value. When the purchase consideration consists entirely of shares of our common stock, we calculate the purchase price by determining the fair value, as of the acquisition date, of shares issued in connection with the closing of the acquisition and, if the transaction involves contingent consideration based on achievement of milestones or earn-out events, the probability-weighted fair value, as of the acquisition date, of shares issuable upon the occurrence of future events or conditions pursuant to the terms of the agreement governing the business combination. If the transaction involves such contingent consideration, our calculation of the purchase price involves probability inputs that are highly judgmental due to the inherent unpredictability of drug development, particularly by development-stage companies such as ours. We recognize estimated fair values of the tangible assets and intangible assets acquired, including IPR&D, and liabilities assumed as of the acquisition date, and we record as goodwill any amount of the fair value of the tangible and intangible assets acquired and liabilities assumed in excess of the purchase price.

Goodwill and Acquired IPR&D. In accordance with ASC Topic 350, Intangibles – Goodwill and Other, or ASC Topic 350, our goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying value may be impaired. We perform our annual impairment testing as of September 30 of each year, or, in the case of initially acquired IPR&D, on the first anniversary of the date we acquired it and subsequently on September 30. Pursuant to Accounting Standards Update, or ASU, No. 2011-08, Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment, and No. 2012-02, Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment, we have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that our goodwill or our acquired IPR&D is impaired. If we choose to first assess qualitative factors and we determine that it is not more likely than not that goodwill or acquired IPR&D is impaired, we are not required to take further action to test for impairment. We also have the option to bypass the qualitative assessment and perform only the quantitative impairment test, which we may choose to do in some periods but not in others.

If we perform a quantitative assessment of goodwill, we utilize the two-step approach prescribed under ASC Topic 350. Step 1 requires a comparison of the carrying value of a reporting unit, including goodwill, to its estimated fair value. We test for impairment at the entity level because we operate on the basis of a single reporting unit. If our carrying value exceeds our fair value, we then perform Step 2 to measure the amount of impairment loss, if any. In Step 2, we estimate the fair value of our individual assets, including identifiable intangible assets, and liabilities to determine the implied fair value of goodwill. We then compare the carrying value of our goodwill to its implied fair value. The excess of the carrying value of goodwill over its implied fair value, if any, is recorded as an impairment charge.

If we perform a quantitative assessment of IPR&D, we calculate the estimated fair value of acquired IPR&D by using the Multi-Period Excess Earnings Method, or MPEEM, which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset’s projected incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life.

Our determinations as to whether, and, if so, the extent to which, goodwill and acquired IPR&D become impaired are highly judgmental and based on significant assumptions regarding our projected future financial condition and operating results, changes in the manner of our use of the acquired assets, development of our acquired assets or our overall business strategy, and regulatory, market and economic environment and trends.

Share-based Compensation Expenses. We account for share-based compensation awards granted to employees, including non-employee members of our board of directors, in accordance with ASC Topic 718, Compensation — Stock Compensation. Compensation expense for all share-based awards is based on the estimated fair value of the award on its date of grant and recognized on a straight-line basis over its vesting period. As share-based compensation expense is based on awards ultimately expected to vest, it is reduced for estimated forfeitures. We estimate forfeitures at the time of grant based on the expected forfeiture rate for our unvested stock options, which is based in large part on our historical forfeiture rates, but also on assumptions believed to be reasonable under the circumstances. We revise our estimates in subsequent periods if actual forfeitures differ from those estimates. Although share-based compensation expense can be significant to our consolidated financial statements, it does not involve the payment of any cash by us.

We estimate the grant date fair value of a stock option award using the Black-Scholes option-pricing model, or Black-Scholes model. In determining the grant date fair value of a stock option award under the Black-Scholes model, we must make a number of assumptions, including the term of the award, the volatility of the price of our common stock over the term of the award, and the risk-free interest rate. Changes in these or other assumptions could have a material impact on the compensation expense we recognize.

Results of Operations – Overview

We operate our business and evaluate our company on the basis of a single reportable segment, which is the business of developing therapies for serious or life-threatening diseases.

Revenue

We have not generated any revenue from product sales to date, and we do not expect to generate revenue from product sales until such time, if any, that we have obtained approval from a regulatory agency to sell one or more of our product candidates, which we cannot predict with certainty will occur. If we enter into any licensing or other collaborative arrangements regarding our development programs, we may recognize revenue from those arrangements prior to commercial sale of any products.

Operating Expenses

Research and Development Expenses. We maintain and evaluate our R&D expenses by the type of cost incurred rather than by project. We do this primarily because we outsource a substantial portion of our work and our R&D personnel and consultants work across multiple programs rather than dedicating their time to one particular program. We categorize our R&D expenses as external clinical study fees and expenses, external nonclinical study fees and expenses, personnel costs and share-based compensation expense. The major components of our external clinical study fees and expenses are fees and expenses related to CROs and clinical study investigative sites and investigators. The major components of our external nonclinical study fees and expenses are fees and expenses related to preclinical studies and other nonclinical testing, research-related manufacturing, quality assurance and regulatory affairs services, and preparation of a new drug application, or NDA, for vepoloxamer. Research-related manufacturing expenses include costs associated with producing and/or purchasing active pharmaceutical ingredient (API), conducting process development activities, producing clinical trial material, producing material for stability testing to support regulatory filings, related labeling, testing and release, packaging and storing services and related consulting fees. Impairment losses on R&D-related manufacturing equipment are also considered research-related manufacturing expenses. Personnel costs relate to employee salaries, benefits and related costs.

A general understanding of drug development is critical to understanding our results of operations and, particularly, our R&D expenses. Drug development in the United States and most countries throughout the world is a process that includes several steps defined by the U.S. Food and Drug Administration, or FDA, and similar regulatory authorities in foreign countries. The FDA approval processes relating to new drug products differ depending on the nature of the particular product candidate for which approval is sought. With respect to any product candidate with active ingredients not previously approved by the FDA, a prospective drug product manufacturer is required to submit a NDA that includes complete reports of pre-clinical, clinical and laboratory studies and extensive manufacturing information to demonstrate the product candidate’s safety and effectiveness. Generally, an NDA must be supported by at least phase 1, 2 and 3 clinical studies, with each study typically more expensive and lengthy than the previous study.

Future expenditures on R&D programs are subject to many uncertainties, including the number of clinical studies required to be conducted for each development program and whether we will develop a product candidate with a partner or independently. At this time, due to such uncertainties and the risks inherent in drug product development and the associated regulatory process, we cannot estimate with any reasonable certainty the duration of or costs to complete our R&D programs, or whether or when or to what extent revenues will be generated from the commercialization and sale of any of our product candidates. The duration and costs of our R&D programs, in particular, the duration and costs associated with clinical studies and research-related manufacturing, can vary significantly as a result of a variety of factors, including:

- the number of clinical and nonclinical studies necessary to demonstrate the safety and efficacy of a product candidate in a particular indication;
- the number of patients who participate in each clinical study;
- the number and location of sites included and the rate of site approval in each clinical study;
- the rate of patient enrollment and ratio of randomized to evaluable patients in each clinical study;
- the duration of patient treatment and follow-up;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the time and cost to manufacture clinical trial material and commercial product, including process development and scale-up activities, and to conduct stability studies, which can last several years;
- the availability and cost of comparative agents used in clinical studies;
- the timing and terms of any collaborative or other strategic arrangements that we may establish; and
- the cost, requirements, timing of and the ability to secure regulatory approvals.

We regularly evaluate the prospects of our R&D programs, including in response to available scientific, nonclinical and clinical data, our assessments of a product candidate's market potential and our available resources, and make determinations as to which programs to pursue and how much funding to direct to each one.

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses consist primarily of salaries, benefits and related costs for personnel in executive, finance and accounting, legal and marketing functions, and professional and consulting fees for accounting, legal, investor relations, business development, commercial strategy and research, human resources and information technology services. Other SG&A expenses include facility lease and insurance costs and in-licensing costs for third-party intellectual property, if any.

Interest Income. Interest income includes interest earned on our cash, cash equivalent and investment security balances.

Interest Expense. Interest expense consists of interest payments made and interest expense related to debt issuance costs and debt discount under our debt facility and interest expense associated with payments under capital leases of equipment.

Other (Expense)/Income, Net. Other (expense)/income, net includes unrealized and realized gains and losses from foreign currency transactions and other non-operating gains and losses.

Comparison of Three Months Ended March 31, 2016 and 2015

Revenue. We recognized no revenue for the three months ended March 31, 2016 and 2015.

R&D Expenses. Our most significant R&D expenses for the three months ended March 31, 2016 were external costs associated with the EPIC study, our Phase 2 study of vepoloxamer in heart failure, research-related manufacturing for vepoloxamer and costs related to preparing our vepoloxamer NDA. These expenses consisted primarily of CRO and CMO expenses, clinical study and regulatory-related consulting expenses, and study site expenses, which include start-up costs as well as patient costs. The following table summarizes our consolidated R&D expenses by type for each of the periods listed and their respective percent of our total R&D expenses for such periods (in thousands, except for percentages):

	Three Months Ended March 31,					
	2016	%		2015	%	
External clinical study fees and expenses	$4,054	52	%	$3,507	58	%
External nonclinical study fees and expenses	2,459	31	%	1,516	25	%
Personnel costs	1,127	14	%	895	15	%
Share-based compensation expense	235	3	%	124	2	%
Total	$7,875	100	%	$6,042	100	%

R&D expenses increased by $1.9 million, or approximately 30.4%, to $7.9 million for the three months ended March 31, 2016, compared to $6.0 million for the same period in 2015. This increase was due primarily to a $0.9 million increase in external nonclinical study fees and expenses, a $0.5 million increase in external clinical study fees and

expenses and a $0.3 million increase in personnel costs and share-based compensation expense.

The $0.9 million increase in external nonclinical study fees and expenses was due primarily to an increase of $0.5 million in external costs related to preparing our vepoloxamer NDA and an increase of $0.5 million in research-related manufacturing costs for vepoloxamer, offset by a decrease of $0.1 million in research-related manufacturing costs for AIR001. The $0.5 million increase in external clinical study fees and expenses was due primarily to an increase of $0.5 million in costs for our Phase 2 study of vepoloxamer in heart failure and an increase of $0.3 million in costs for the EPIC study, offset by a decrease of $0.3 million in costs for the Phase 2 study of vepoloxamer in acute limb ischemia, or ALI, which we discontinued and began to wind-down in the third quarter of 2015.

SG&A Expenses. SG&A expenses decreased by $0.8 million, or approximately 20.8%, to $2.8 million for the three months ended March 31, 2016, compared to $3.6 million for the same period in 2015. SG&A expenses in the three months ended March 31, 2015 included $0.4 million of severance expenses and $0.3 million of share-based compensation expense resulting from the termination of employment of our former president and chief operating officer in February 2015 and the acceleration of stock option vesting pursuant to the terms of his option agreements.

Interest Expense. Interest expense for the three months ended March 31, 2016 was $519,000, $518,000 of which was related to our debt facility. There was no interest expense in the three months ended March 31, 2015.

Net Loss. Net loss was $11.2 million, or $0.06 per share, for the three months ended March 31, 2016, compared to net loss of $9.6 million, or $0.06 per share, for the same period in 2015.

Liquidity and Capital Resources

We have a history of annual losses from operations and we anticipate that we will continue to incur losses for at least the next several years. For the three months ended March 31, 2016, we incurred a loss from operations of $10.7 million. Our cash, cash equivalents and investment securities were $37.1 million and our working capital was $15.6 million as of March 31, 2016.

We historically have funded our operations principally through proceeds from sales of our equity securities. In February 2016, we completed an underwritten public offering with gross proceeds of $8.0 million from the sale and issuance of 29,090,910 units, each consisting of one share of our common stock and one warrant to purchase one share of our common stock. Net proceeds, after deducting underwriting discounts and commissions and other estimated offering expenses, were approximately $7.3 million. The warrants have an exercise price of $0.42 per share, are exercisable any time on or after August 17, 2016, subject to certain beneficial ownership limitations, and will expire on February 16, 2021.

We may receive up to $11.7 million, $18.3 million, $0.1 million, $16.5 million and $12.2 million of additional net proceeds from the exercise of warrants issued in the underwritten public offerings we completed in November 2011, June 2013, November 2014 and February 2016, respectively. However, the timing of the exercise and extent to which any of these warrants are exercised before they expire are beyond our control and depend on a number of factors, including certain beneficial ownership limitations and the market price of our common stock. The exercise prices of these warrants are $1.10, $0.65, $0.01, $0.75 and $0.42 per share, respectively. In comparison, the closing sale price of our common stock on May 4, 2016 was $0.33 per share and we do not expect the holders of the warrants to exercise them unless and until our common stock trades at or above the exercise price of their warrants. In addition, if at the time of exercise there is not an effective registration statement available for the issuance of the shares subject to the warrants, they may be exercised on a “cashless” net issuance basis, in which case we would not receive any proceeds from the exercise of these warrants.

In February 2014, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, to sell shares of our common stock, with aggregate gross sales proceeds of up to $30.0 million, from time to time, through an “at the market,” or ATM, equity offering program, under which Cowen acts as sales agent. We refer to that agreement as the 2014 Sales Agreement. In August 2015, we terminated the 2014 Sales Agreement upon entry into a new sales agreement with Cowen to sell shares of our common stock, with aggregate gross sales proceeds of up to $30.0 million, from time to time, through an ATM program. As of March 31, 2016, we had sold and issued an aggregate of 24,990,267 shares at a weighted-average sales price of $0.70 per share under the ATM programs for aggregate gross proceeds of $17.5 million and $16.6 million in aggregate net proceeds, after deducting sales agent commission and discounts and our other offering costs.

We have borrowed $15.0 million under a debt facility and have received proceeds of approximately $14.8 million, net of fees. The debt facility is governed by a loan and security agreement, as amended, among our company, Hercules Technology III, L.P., and Hercules Capital, Inc. (formerly known as Hercules Technology Growth Capital, Inc.), together referred to as Hercules. Under the loan and security agreement, as amended, we are required to prepay $10 million of the principal balance to Hercules on July 31, 2016 unless on or before such date we demonstrate, to the reasonable satisfaction of Hercules, positive results in the EPIC study. To date, we have been making interest-only payments to Hercules. However, our first principal payment of approximately $430,000 is due on July 1, 2016, unless we demonstrate positive results in the EPIC study on or before such date and no event of default has occurred, in which case our first principal payment will not be due until March 1, 2017. If we do not have EPIC results before July

1, but demonstrate positive results in EPIC between July 2 and July 31, 2016, inclusive, and no event of default has occurred, then on July 1, 2016, we will be required to make a single principal payment of approximately $430,000, but then resume making interest-only payments until March 1, 2017. See Note 8, “Debt Facility,” of the Notes to the Condensed Consolidated Financial Statements in this report for additional information regarding our debt facility with Hercules. Our obligations under our agreement with Hercules are secured by substantially all of our assets other than our intellectual property, but including proceeds from the sale, licensing or other disposition of our intellectual property. Our intellectual property is subject to negative covenants, which, among other things, prohibit us from selling, transferring, assigning, mortgaging, pledging, leasing, granting a security interest in or otherwise encumbering our intellectual property, subject to limited exceptions. The agreement includes a number of other restrictive covenants that may limit our ability to raise capital through other debt or equity financing. The debt facility also includes events of default, the occurrence and continuation of which would provide Hercules with the right to exercise remedies against us and the collateral securing our indebtedness, which include declaring payment of all or any part of the debt, together with an end of term charge of $712,500 and a prepayment charge of 1%, 2% or 3% of the then outstanding principal balance, immediately due and payable. These events of default include, among other things, our failure to pay any amount due on the due date, our breach or default in the performance of any covenant under the debt facility, our insolvency, the attachment, seizure, or filing of a levy against our assets or a judgment entered against us in an amount greater than $250,000, the occurrence of any default under certain other indebtedness, and, subject to limited exceptions, the occurrence of an event or circumstance that would reasonably be expected to have a material adverse effect on our

business, operations, assets or financial condition, our ability to repay our indebtedness in accordance with the terms of the credit facility, or on the collateral securing our indebtedness.

For a discussion of our liquidity and capital resources outlook, see “Management Outlook” below.

Operating activities. Net cash used in operating activities was $11.3 million for the three months ended March 31, 2016 and consisted primarily of a net loss of $11.2 million adjusted for non-cash items, including share-based compensation expenses of $0.7 million and amortization of debt issuance costs and debt discount of $0.2 million, and a net decrease of $1.0 million due to changes in assets and liabilities. Net cash used in operating activities was $7.3 million for the three months ended March 31, 2015 and consisted primarily of a net loss of $9.6 million adjusted for non-cash items, including share-based compensation expenses of $1.1 million and a net increase of $1.2 million due to changes in assets and liabilities.

Investing activities. Net cash provided by investing activities was $4.4 million for the three months ended March 31, 2016 compared to net cash used in investing activities of $0.5 million for the same period in 2015. Net cash provided by investing activities for the three months ended March 31, 2016 was primarily due to $4.4 million in proceeds from the maturity of certificates of deposit. Net cash used in investing activities for the three months ended March 31, 2015 was primarily due to $5.3 million used to purchase certificates of deposit, offset by $4.8 million in proceeds from the maturity of certificates of deposit.

Financing activities. Net cash provided by financing activities for the three months ended March 31, 2016 was $7.4 million, primarily a result of net proceeds of $7.3 million from the sale of units consisting of shares of our common stock and warrants to purchase our common stock in February 2016. Net cash used in financing activities for the three months ended March 31, 2015 was negligible.

Contractual Obligations

The following is a summary of our long-term contractual obligations as of March 31, 2016 (in thousands):

	Total	Less than 1 year	1 - 3 years (1)	3 - 5 years (2)	More than 5 years
Long-term debt obligation with Hercules (3)	$16,790	$11,520	$5,270	$ -	$ -
Capital lease obligations	37	8	29	-	-
Operating lease obligations	2,133	303	1,592	238	-
Total	$18,960	$11,831	$6,891	$238	$ -

(1) Payments to be made in the years ending December 31, 2017, 2018 and 2019.
(2) Payments to be made in the year ending December 31, 2020.
(3) $10.0 million of the principal balance of our debt facility will be due to Hercules on July 31, 2016 unless on or before such date we demonstrate positive results in the EPIC study. Because we are unable to predict with any reasonable certainty the probability of meeting this condition, this obligation is shown as due in 2016. Otherwise, the scheduled maturity date of the $15.0 million debt facility is January 1, 2019. The maturity date may be extended to October 1, 2019 if we demonstrate positive results in the EPIC study by July 31, 2016. See Note 8, “Debt Facility,” of the Notes to the Condensed Consolidated Financial Statements in this report for additional

information.

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Management Outlook

If results from the EPIC study are positive and we believe they will support an NDA submission for vepoloxamer in sickle cell disease, we expect our operating expenses for the remaining nine months of 2016 will be approximately $30.0 to $33.0 million, excluding share-based compensation expense. Based on our projected capital needs, which assume positive results from the EPIC study, our current cash, cash equivalents and investment securities and working capital will not be sufficient to fund our operations for the next 12 months. We intend to raise additional capital before the fourth quarter of 2016 through equity or debt financings and/or through collaborations, including licensing arrangements, to pursue our current business strategy and planned operations. If we have positive results from the EPIC study, but we are unable to raise sufficient additional capital before the fourth quarter of 2016, we anticipate that we would immediately reduce the scope of our planned operations, including by delaying or discontinuing investment in development and commercialization efforts for vepoloxamer in sickle cell disease and heart failure. In the event of negative results in the EPIC study and prepayment to Hercules on July 31, 2016 of $10.0 million of the principal balance under our debt facility, we also plan to immediately and significantly reduce the scope of our planned operations. In either case, we expect that our cash, cash equivalents and investment securities as of March 31, 2016, would be sufficient to fund our operations, as reduced in scope, into the first quarter of 2017. Whether results in the EPIC study are positive or negative, adequate additional capital may not be available to us on acceptable terms, on a timely basis, or at all. These uncertainties raise substantial doubt about our ability to continue as a going concern.

Our estimate of operating expenses for the remaining nine months of 2016 and of the period of time through which our current financial resources will be adequate to support our operations are forward-looking statements based on significant assumptions, including that results from the EPIC study are positive and we determine they will support an NDA submission. We could utilize our financial resources sooner than we currently expect. Forward-looking statements involve a number of risks and uncertainties and actual results could differ materially if the assumptions on which we have based our forward-looking statements prove to be wrong. Factors that will affect our 2016 operating expenses and future capital requirements include, but are not limited to:

- the results from the EPIC study;
- feedback from the FDA regarding the content and process for submission of an NDA for vepoloxamer, including whether the FDA will require a second Phase 3 study or other clinical or nonclinical studies to demonstrate substantial evidence of effectiveness of vepoloxamer for the treatment of sickle cell crisis, such as greater statistical significance or magnitude of clinical relevance, or to provide additional safety and tolerability data, or whether the FDA will require the starting material for vepoloxamer to be manufactured consistent with cGMP requirements applicable to API or that we have control over excipient-grade cGMP conditions under which it currently is manufactured;
- our ability to secure adequate supply of API and finished drug product from our CMOs to meet market demand and manage our costs related to commercial manufacture of our products, should any of our product candidates obtain regulatory approval;
- the design, initiation, scope, rate of progress, results and timing of our clinical and nonclinical studies of our product candidates;
- the successful completion of our development programs and our ability to manage costs associated with clinical and nonclinical development of our product candidates, including research-related manufacturing activities;
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our ability to obtain and maintain regulatory approvals of our product candidates, the scope of regulatory approval we pursue, and the extent to which we do so independently or through collaborations;

- the extent to which we increase our workforce, including in connection with establishing a commercial infrastructure to support independent commercialization of vepoloxamer in the U.S. and EU, if approved;
- our ability to obtain and maintain effective patent coverage or other market exclusivity protections for our products, if approved, and to operate our business without infringing upon the intellectual property rights of others;
- the extent of commercial success of any of our product candidates for which we receive regulatory approval; and
- the extent to which we seek to expand our product pipeline through acquisitions and execute on transactions intended to do so.

Vepoloxamer

We are focusing our resources primarily on development of vepoloxamer. In February 2016, we completed patient enrollment in the EPIC study and we expect to report top-line data in the second quarter of 2016. If results are positive and, based on subsequent discussions with the FDA we determine to submit an NDA for vepoloxamer for the treatment of vaso-occlusive crisis in patients with sickle cell disease utilizing the FDA's rolling review process, we plan to begin submitting portions of the NDA in the fourth quarter of 2016 and complete our submission in the first quarter of 2017. We currently are planning for a six-month review period following the FDA's filing decision (or approximately eight months from the date we complete the NDA submission), based on an assumption of receiving priority review designation. If vepoloxamer is approved on this timeline, we anticipate commercial launch in the U.S. by the end of 2017. We plan to build a commercial infrastructure to support U.S. launch, including a sales force of approximately 30 representatives, in 2017. In order to take advantage of vepoloxamer's potential to be the first and only approved therapy to shorten the duration of a vaso-occlusive crisis, we are conducting and plan to continue to conduct during 2016 other commercial-readiness activities, including medical communications, brand development and other market preparation activities.

To support our NDA submission, we are conducting other studies in parallel with EPIC: an open-label, multicenter EPIC extension study known as EPIC-E to expand our existing safety database regarding repeat exposure to vepoloxamer; a sub-study of patients who participated in EPIC at selected U.S. study sites to investigate the effect of vepoloxamer on tissue oxygenation during sickle cell crisis; and a clinical pharmacokinetics study of vepoloxamer in approximately 40 individuals with varying degrees of renal insufficiency. The special population study will further enhance the safety database for vepoloxamer and help guide dosage adjustments for renally impaired patients. We intend to continue enrolling these studies as we prepare our NDA submission for vepoloxamer in sickle cell disease.

Vepoloxamer also is in Phase 2 clinical development for the treatment of heart failure. Our ongoing randomized, double-blind, placebo-controlled, multicenter Phase 2 study in which we plan to enroll approximately 150 patients, is evaluating a new formulation of vepoloxamer for the treatment of patients with chronic heart failure. As of May 5, 2016, we had opened a total of 10 study sites in the U.S. and Australia. Pending positive data from the EPIC study, we plan to open additional study sites within and outside of the U.S. Although predicting the rate and timing of enrollment for any clinical study including this study is subject to a number of significant assumptions and completion of the study may differ materially, we expect to complete patient enrollment in the first quarter of 2018.

We also are evaluating vepoloxamer's potential in stroke. Based on nonclinical study data we announced in 2015, as well as published data from third party studies of poloxamer 188, we believe, and several medical experts in the field have agreed, that sufficient data now exists to support clinical development of vepoloxamer in stroke. We continue to assess the opportunity and believe it is a Phase 2-ready program. However, we do not plan to commence clinical development in stroke prior to analysis of results from the EPIC study.

Further, we are conducting or plan to conduct a number of other ex vivo, nonclinical in vivo and in vitro studies of vepoloxamer to further understand its pharmacologic effects and support our intellectual property positions.

AIR001

AIR001 is in Phase 2 clinical development for the treatment of patients with HFpEF. Since acquiring the program in 2014, we have supported two investigator-sponsored Phase 2a studies of AIR001 in patients with HFpEF, one of which is ongoing and the other reported positive top-line results in February 2016, as discussed above. In addition, as discussed above, we are supporting the Heart Failure Clinical Research Network's (HFN) INDIE-HFpEF study, a multicenter, randomized, double-blind, placebo-controlled crossover Phase 2 study of AIR001 in approximately 100 patients with HFpEF. The study is expected to begin in the third quarter of 2016. We have entered into an agreement

with Duke Research Institute, the HFN's Coordinating Center, to provide the test materials, nebulizers, regulatory and technical support for the study, as well as approximately $3.0 million in financial support at specified milestones over the course of the study. We expect to pay the majority of such amount in 2017.

In parallel with our independent development of vepoloxamer and AIR001, from time to time, we evaluate opportunities for strategic collaborations, including with respect to country-specific development and regulatory or commercial expertise that would enhance the value of our programs.

As discussed above, based on our projected capital needs, which assume positive results from the EPIC study, we do not believe our current cash, cash equivalents and investment securities as of March 31, 2016 will be sufficient to meet our currently planned operations for the next 12 months and for the foreseeable future we must rely on equity and/or debt financings or collaborations such as licensing agreements to raise additional capital as and when needed. These circumstances raise substantial doubt about our ability to continue as a going concern. We intend to raise additional capital before the fourth quarter of 2016 through equity or debt financings and/or through collaborations, including licensing arrangements, to pursue our current business strategy and planned operations. Subject to limited exceptions, our loan and security agreement with Hercules prohibits us from incurring indebtedness without Hercules' prior written consent. If we have positive results from the EPIC study but are unable to raise sufficient additional capital

before the fourth quarter of 2016, we anticipate that we would immediately reduce the scope of our planned operations, including by delaying or discontinuing investment in development and commercialization efforts for vepoloxamer in sickle cell disease and heart failure. In the event of negative results in the EPIC study and prepayment to Hercules on July 31, 2016 of $10.0 million of the principal balance under our debt facility, we also plan to immediately and significantly reduce the scope of our operations. In either case, we expect that our cash, cash equivalents and investment securities as of March 31, 2016, would be sufficient to fund our operations, as reduced in scope, into the first quarter of 2017. If we implement significant cost saving measures, it could delay our ability to seek approval for vepoloxamer in sickle cell disease even if EPIC results are positive, and our ability to commercialize vepoloxamer for sickle cell crisis, if approved, and could adversely affect our ability meet future market demand.

We may utilize our current financial resources sooner than we currently expect if we incur unanticipated expenses or the assumptions on which we've based our forecasts and contingency plans prove to be wrong. If we are unable to raise sufficient additional capital as needed and we reduce the scope of our operations, we may also be compelled to repay all of our outstanding debt to Hercules and sell certain assets, including intellectual property assets, which would have a further material and adverse effect on our financial condition and ability to pursue our business strategy.

Recent Accounting Pronouncements

See Note 11, "Recent Accounting Pronouncements," of the Notes to the Condensed Consolidated Financial Statements (Unaudited) in this report for a discussion of recent accounting pronouncements and their effect, if any, on us.

Forward Looking Statements

This report, particularly in Part I, Item 2, "Management's Discussion and Analysis of Financial Condition and Results of Operations," includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements we make regarding our business strategy, expectations and plans, our objectives for future operations and our future financial position. When used in this report, the words "believe," "may," "could," "would," "will," "estimate," "continue," "anticipate," "plan," "intend," "expect," "indicat expressions are intended to identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements we make regarding activities, timing and costs related to developing and seeking regulatory approval for our product candidates, including the nature, cost, and timing of initiation, completion and announcement of results of clinical studies and nonclinical testing, the indications in which we plan to pursue development of our product candidates, our plans regarding commercialization of our product candidates, if approved, our plans regarding partnering or other collaborative arrangements and for raising additional capital to support our operations, and our belief that our cash, cash equivalents and investment securities would be sufficient to fund a reduced level of operations into the first quarter of 2017. The foregoing is not an exclusive list of all forward-looking statements we make.

We have based the forward-looking statements we make on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. The forward-looking statements we make are subject to known and unknown risks and uncertainties that could cause our actual results, performance or achievements to be materially different from any result, performance or achievement expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to the following:

- negative results in the EPIC study;

- an event of default under our loan and security agreement with Hercules requiring us to repay all principal balance and accumulated interest and certain additional charges immediately, or our failure to demonstrate positive results in the EPIC study, which would require us to prepay $10.0 million of the principal balance on July 31, 2016;
- our ability to obtain additional capital before the fourth quarter of 2016, or at all;
- the feedback from the FDA regarding the content and process for submission of an NDA for vepoloxamer as a treatment for sickle cell crisis, including whether the FDA will require a second Phase 3 study or other clinical or nonclinical studies to demonstrate substantial evidence of effectiveness of vepoloxamer for the treatment of sickle cell crisis, or to provide additional safety and tolerability data, or whether the FDA will allow starting material for vepoloxamer to be manufactured consistent with cGMP requirements applicable to API or that we have control over excipient-grade cGMP conditions under which it currently is manufactured;
- our ability, or that of a future partner, to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates;

- our ability to establish effective sales and marketing capabilities and to timely launch our vepoloxamer product if approved for treatment of sickle cell crisis;
- delays in the commencement or completion of clinical studies or manufacturing and regulatory activities necessary to obtain regulatory approval to commercialize our product candidates, including vepoloxamer;
- suspension or termination of a clinical study, including due to patient safety concerns or capital constraints;
- our ability to successfully execute clinical studies, including timely enrollment, and the ability of our product candidates to demonstrate acceptable safety and efficacy in clinical studies;
- our ability to secure adequate and timely supply of API and finished drug product from our CMOs for clinical studies of our product candidates or, if approved, to meet market demand;
- the satisfactory performance of third parties, including CROs, on whom we rely significantly to conduct or assist in the conduct of our nonclinical testing, clinical studies and other aspects of our development programs;
- the potential for us to delay, scale back, or discontinue development of a product candidate, partner it at inopportune times, or pursue less expensive but higher-risk and/or lower-return development paths if we are unable to raise sufficient additional capital as needed;
- the potential for the FDA, or another regulatory agency, to require additional nonclinical or clinical studies of vepoloxamer or AIR001 prior to our initiation of a Phase 2 clinical study in any new indication;
- the potential that, even if clinical studies of a product candidate in one indication are successful, clinical studies in another indication may not be successful;
- the potential for unsuccessful nonclinical or clinical studies in one indication or jurisdiction, or by a future partner that may be outside of our control, to adversely affect opportunities for a product candidate in other indications or jurisdictions;
- the potential that we may enter into one or more collaborative arrangements, including partnering or licensing arrangements, for a product candidate, and the terms of any such arrangements;
- the extent to which we increase our workforce and our ability to attract and retain qualified personnel and manage growth;
- the extent of market acceptance of our product candidates, if we receive regulatory approval, and available alternative treatments;
- our ability to obtain and maintain effective patent coverage or other market exclusivity protections for our products and technologies without infringing the proprietary rights of others;
- claims against us for infringing the proprietary rights of third parties;
- healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent commercial success;
- undesirable side effects that our product candidates or products may cause;
- potential product liability exposure and, if successful claims are brought against us, liability for a product or product candidate;
- the extent to which we acquire new technologies and/or product candidates and our ability to integrate them successfully into our operations;
- our ability to maintain compliance with NYSE MKT continued listing standards and to maintain the listing of our common stock on the NYSE MKT equities market or another national securities exchange; and
- the other factors that are described in Item 1A (Risk Factors) of Part II of this report and our annual report on Form 10-K filed with the SEC on March 14, 2016.

Except as required by law, we do not intend to update the forward-looking statements discussed in this report publicly or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. In light of these risks and uncertainties and our assumptions, actual results may differ materially and adversely from expectations indicated or implied by the forward-looking statements contained in this report and in any documents incorporated in this report. Accordingly, you are cautioned not to place undue reliance on such forward-looking statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Pursuant to Item 305(c) of Regulation S-K, we are not required to provide disclosures under this item until after December 31, 2016.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of March 31, 2016. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of March 31, 2016 these disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarterly period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in various claims and legal proceedings. Regardless of outcome, litigation and other legal and administrative proceedings can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material pending litigation or other material legal proceeding.

Item 1A. Risk Factors

Investment in our securities involves a high degree of risk and uncertainty. Our business, operating results, growth prospects and financial condition are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge investors to consider carefully the risks described below, together with those described in Item 1A of Part I of our annual report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 14, 2016, and all of the information in this report and our other public filings, before making investment decisions regarding our securities. Each of these risk factors, as well as additional risks not presently known to us or that we currently deem immaterial, could adversely affect our business, operating results, growth prospects or financial condition, as well as the trading price of our common stock, in which case you may lose all or part of your investment.

The risk factors set forth below contain material changes to the risk factors previously disclosed and included in our annual report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 14, 2016.

We have incurred net losses since our inception, we expect our operating expenses to continue to exceed revenue for the foreseeable future, and we may never generate revenue sufficient to achieve profitability. In addition, we do not believe our cash, cash equivalents and investment securities as of March 31, 2016 will be sufficient to fund our operations for the next 12 months and we may not be able to raise additional capital as and when needed, which uncertainties raise substantial doubt regarding our ability to continue as a going concern.

We are a clinical-stage biopharmaceutical company and have not generated sustainable revenue from operations or been profitable since inception, and we may never achieve profitability. We have devoted our resources to acquiring and developing proprietary product candidates, but such product candidates cannot be marketed until the regulatory process is completed and governmental approvals have been obtained. For the year ended December 31, 2015 and the three months ended March 31, 2016, we incurred losses

from operations of $39.4 million and $10.7 million, respectively, and our net cash used in operating activities was $32.9 million and $11.3 million, respectively. At March 31, 2016, we had an accumulated deficit of $286.2 million, our cash, cash equivalents and investment securities were $37.1 million, and our working capital was $15.6 million. We expect to continue to incur substantial operating losses for the next several years as we advance our product candidates through clinical studies and other development activities and seek approval from the FDA and regulatory authorities outside of the U.S. to commercialize them. Accordingly, there is no current source of revenue from operations, much less profits, to sustain our present activities. Further, no revenue from operations will likely be available until, and unless, one of our product candidates is approved by the FDA or another regulatory agency and successfully marketed, or we enter into an arrangement that provides for licensing revenue or other partnering-related funding, outcomes which we may not achieve. If we obtain FDA approval of vepoloxamer in sickle cell disease, we may incur significant sales, marketing, and external manufacturing expenses, as well as continued research and development expenses. In addition, if by July 31, 2016, we have not demonstrated, to the reasonable satisfaction of Hercules, positive results from the EPIC study, we will be required to prepay to Hercules $10.0 million of the principal balance under our debt facility on July 31, 2016.

As more fully discussed in Note 1 to the condensed consolidated financial statements included in this report and Part I, Item 2 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of this report, based on our anticipated operating expenses and current limited capital resources, we plan to raise additional capital before the fourth quarter of 2016 through equity or debt financings and/or through collaborations, including licensing arrangements, to fund our operations. However, our anticipated operating expenses and net losses and the uncertainties surrounding our ability to raise additional capital as needed raise substantial doubt about our ability to continue as a going concern. The condensed consolidated financial statements included in this report have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. However, if we are not successful in raising sufficient additional capital as needed, we may be compelled to reduce the scope of our operations and planned capital expenditures and/or sell or license certain assets at inopportune times, which could have a material and adverse effect on our ability to pursue our business strategy and our future financial condition.

Our management plans to take actions to raise additional capital to fund cash requirements after results of the EPIC study are known. However, there is no assurance that we will be able to obtain additional capital on favorable terms, or at all, or to successfully reduce costs in such a way that would continue to allow us to operate our business. If we are compelled to reduce the scope of our operations because we are unable to raise adequate additional capital as needed, which may be the case even if EPIC results are positive, our cost saving measures may delay our ability to seek approval for vepoloxamer in sickle cell disease and/or to commercialize vepoloxamer for sickle cell crisis, if approved, and could adversely affect our ability to meet future market demand, which could have a material negative impact on our future financial condition and results of operations.

We cannot predict the extent of our future operating losses and accumulated deficit, and we may never generate sufficient revenues to achieve or sustain profitability. To become and remain profitable, we must succeed in developing and obtaining required regulatory approvals and commercializing our product candidates. This will require us to succeed in a range of challenging activities, including all of the activities described in our annual report on Form 10-K for the year ended December 31, 2015. We may never succeed in these activities, and we may never obtain the FDA’s or another regulatory authority’s approval to market our product candidates or otherwise generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

We have significant goodwill and IPR&D and impairment of goodwill and IPR&D may have a significant adverse impact on our future financial condition and results of operations.

Our goodwill and IPR&D assets, which resulted from our acquisitions of SynthRx and Aires Pharmaceuticals in 2011 and 2014, respectively, represent a significant portion of our total assets. As of March 31, 2016, we had goodwill and IPR&D of approximately $11.6 million, representing approximately 23% of our total assets. These intangible assets are subject to an impairment analysis whenever an event or change in circumstances indicates the carrying amount of such an asset may not be recoverable. We test our goodwill and IPR&D for impairment annually, or more frequently if an event or change in circumstances indicates that the asset may be impaired. If an impairment exists, we would be required to record an impairment charge with respect to the impaired asset to our consolidated statements of operations and comprehensive loss. A significant impairment charge could have a material negative impact on our financial condition and results of operations.

Events giving rise to impairment are difficult to predict and are an inherent risk in the pharmaceutical industry. Some of the potential risks that could result in impairment of our goodwill and IPR&D include negative clinical study results, adverse regulatory developments, delay or failure to obtain regulatory approval, additional development costs, changes in the manner of our use or development of vepoloxamer or AIR001, competition, earlier than expected loss of exclusivity, pricing pressures, higher operating costs, changes in tax laws, and other market and economic environment changes or trends. All of our goodwill and approximately $6.5 million of our IPR&D, or approximately 83% of our total goodwill and IPR&D, relate to the fair value of our vepoloxamer program in sickle cell disease as of the date we acquired SynthRx. If, for example, results from the EPIC study are negative or, based on pre-NDA discussions with the FDA, we determine that additional development costs will be necessary to obtain regulatory approval, we may re-evaluate our goodwill and IPR&D and be required to incur a significant non-cash impairment charge, which could materially adversely affect our financial condition and results of operations.

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

None other than as previously described in a current report on Form 8-K filed with the SEC.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

An Exhibit Index has been attached as part of this report and is incorporated herein by reference.

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.

Mast Therapeutics, Inc.

Date: May 6, 2016 By: /s/ Brian M. Culley
Brian M. Culley

Chief Executive Officer

(Principal Executive Officer)

Date: May 6, 2016 By: /s/ Brandi L. Roberts
Brandi L. Roberts

Chief Financial Officer and Senior Vice President

(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit No.	Description	Filed Herewith	Incorporated by Reference		
			Form	File/Film No.	Date Filed
4.1	Form of Warrant Agreement entered into on February 16, 2016 between the registrant and American Stock Transfer & Trust Company, LLC		Form 8-K	001-32157-161407765	02/11/16
4.2	Form of Warrant Certificate for warrants to acquire common stock of the registrant issued by the registrant on February 16, 2016		Form 8-K	001-32157-161407765	02/11/16
4.3	Second Amendment to Warrant Agreement, dated as of February 25, 2016, between the registrant and Hercules Technology III, L.P.		Form 8-K	001-32157-161468225	02/29/16
10.1	Third Amendment to Loan and Security Agreement, dated as of February 25, 2016, among the registrant, Hercules Technology III, L.P. and Hercules Technology Growth Capital, Inc.		Form 8-K	001-32157-161468225	02/29/16
10.2#	Executive Severance Agreement, dated March 23, 2016, between the registrant and Brian M. Culley		Form 8-K	001-32157-161530105	03/25/16
10.3#	Executive Severance Agreement, dated March 23, 2016, between the registrant and Brandi L. Roberts		Form 8-K	001-32157-161530105	03/25/16
10.4#	Executive Severance Agreement, dated March 23, 2016, between the registrant and R. Martin Emanuele		Form 8-K	001-32157-161530105	03/25/16
10.5#	Executive Severance Agreement, dated March 23, 2016, between the registrant and Edwin L. Parsley	X			
10.6#	Executive Severance Agreement, dated March 23, 2016, between the registrant and Gregory D. Gorgas	X			
10.7#	Executive Severance Agreement, dated March 31, 2016, between the registrant and Shana Hood	X			
10.8#	2016 Executive Incentive Plan			001-32157-161555255	04/05/16

			Form 8-K
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a)	X	
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a)	X	
32.1±	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X	
101.INS	XBRL Instance Document	X	
101.SCH	XBRL Taxonomy Extension Schema Document	X	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X	

			Incorporated by Reference		
				File/Film	Date
Exhibit No.	Description	Filed Herewith	Form	No.	Filed
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X			

#Indicates management contract or compensatory plan

±These certifications are being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation by reference language in such filing.