

Mast Therapeutics, Inc.
Form 10-Q
November 12, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

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)

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(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 No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or 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

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

The number of shares outstanding of the registrant's common stock, \$0.001 par value per share, as of November 9, 2015 was 163,614,297.

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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)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$32,207	\$35,808
Investment securities	17,706	21,481
Prepaid expenses and other current assets	1,536	1,114
Total current assets	51,449	58,403
Property and equipment, net	250	188
In-process research and development	8,549	8,549
Goodwill	3,007	3,007
Other assets	183	353
Total assets	\$63,438	\$70,500
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$2,931	\$1,370
Accrued liabilities	7,763	5,625
Accrued compensation and payroll taxes	1,289	1,443
Debt facility	1,537	—
Total current liabilities	13,520	8,438
Long-term lease obligation	24	—
Debt facility, net of current portion	12,951	—
Deferred income tax liability	3,404	3,404
Total liabilities	29,899	11,842
Stockholders' equity:		
Common stock, \$0.001 par value; 500,000,000 shares authorized; 163,614,297 and		
159,458,376 shares issued and outstanding at September 30, 2015 and December 31,		
2014, respectively	164	159
Additional paid-in capital	298,176	293,655
Accumulated other comprehensive loss	9	(25)

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Accumulated deficit	(264,810)	(235,131)
Total stockholders' equity	33,539	58,658
Total liabilities and stockholders' equity	\$63,438	\$70,500

See accompanying notes to unaudited condensed consolidated financial statements.

(1)

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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenues	\$—	\$—	\$—	\$—
Operating expenses:				
Research and development	7,330	5,402	21,106	14,503
Selling, general and administrative	2,460	2,455	8,448	7,091
Transaction-related expenses	—	2	—	271
Depreciation and amortization	38	25	105	60
Total operating expenses	9,828	7,884	29,659	21,925
Loss from operations	(9,828)	(7,884)	(29,659)	(21,925)
Interest income	32	18	94	50
Interest expense	(101)	—	(102)	—
Other (expense)/income, net	(15)	0	(12)	486
Net loss	\$(9,912)	\$(7,866)	\$(29,679)	\$(21,389)
Net loss per share - basic and diluted	\$(0.06)	\$(0.06)	\$(0.18)	\$(0.19)
Weighted average shares outstanding - basic and diluted	163,614,297	123,287,118	161,748,944	114,709,434
Comprehensive Income/(Loss):				
Net loss	\$(9,912)	\$(7,866)	\$(29,679)	\$(21,389)
Other comprehensive (loss)/income	(1)	(7)	34	(4)
Comprehensive net loss	\$(9,913)	\$(7,873)	\$(29,645)	\$(21,393)

See accompanying notes to unaudited condensed consolidated financial statements.

(2)

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$(29,679)	\$(21,389)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	105	60
Gain on bargain purchase	—	(486)
Share-based compensation expense	2,122	1,513
Amortization of debt issuance costs and debt discount	29	—
Changes in assets and liabilities, net of effect of acquisitions:		
(Increase)/decrease in prepaid expenses and other assets	(251)	61
Increase in accounts payable and accrued liabilities	3,536	1,611
Net cash used in operating activities	(24,138)	(18,630)
Cash flows from investing activities:		
Purchases of certificates of deposit	(8,235)	(12,463)
Proceeds from maturities of certificates of deposit	12,044	14,078
Purchases of property and equipment	(118)	(137)
Security deposit for new sublease	—	(130)
Cash obtained through acquisition	—	3,534
Net cash (used in)/provided by investing activities	3,691	4,882
Cash flows from financing activities:		
Proceeds from borrowings under term loan	15,000	—
Costs paid in connection with term loan	(160)	—
Proceeds from sale of common stock	2,140	14,766
Proceeds from exercise of warrants	—	0
Payments for capital lease	(5)	—
Payments for offering costs	(129)	(717)
Net cash provided by financing activities	16,846	14,049
Net (decrease)/increase in cash and cash equivalents	(3,601)	301
Cash and cash equivalents at beginning of period	35,808	25,681
Cash and cash equivalents at end of period	\$32,207	\$25,982

See accompanying notes to unaudited condensed consolidated financial statements.

(3)

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, 2014, filed with the SEC on March 24, 2015 (“2014 Annual Report”). The condensed consolidated balance sheet as of December 31, 2014 included in this report has been derived from the audited consolidated financial statements included in the 2014 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 clinical-stage, biopharmaceutical company focused on developing 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 nebulizer, which we are developing for the treatment of heart failure with preserved ejection fraction (HFpEF).

Our business, operating results, financial condition, and growth prospects are subject to significant risks and uncertainties, including failing to obtain regulatory approval to commercialize our product candidates and failing to secure additional funding to complete development of and to successfully 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, and assumptions related to the probability of achieving milestones in connection with the potential prepayment obligation under our debt facility with Hercules. 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 and assumptions.

3. Acquisition of Aires

On February 27, 2014, we completed the acquisition of Aires in an all-stock transaction pursuant to the terms of an agreement and plan of merger, dated February 7, 2014, by and among us, AP Acquisition Sub, Inc., a wholly-owned subsidiary of ours, Aires, and a stockholders’ representative (the “Merger Agreement”). Aires was a clinical-stage company with its lead product candidate, AIR001 (sodium nitrite) inhalation solution, in Phase 2 studies in pulmonary hypertension. Aires survived the merger transaction as a wholly-owned subsidiary of ours.

Upon completion of the merger, we issued an aggregate of 1,049,706 unregistered shares of our common stock to former Aires stockholders and, in September 2014 after the six-month “holdback” period, we issued an aggregate of 4,053,996 additional unregistered shares of our common stock to former Aires stockholders, all in accordance with the merger agreement. There are no milestone or earn-out payments under the merger agreement; therefore, the total merger consideration was 5,103,702 shares.

We accounted for the acquisition of Aires in accordance with Accounting Standards Codification (“ASC”) Topic 805, Business Combinations (“ASC Topic 805”). The total purchase price of the acquisition was approximately \$3.3 million. We calculated the purchase price by first multiplying the total number of shares of our common stock issued by \$0.80, which was the closing

(4)

price per share of our common stock on February 27, 2014, the acquisition date. Then, we applied a discount factor to account for lack of market liquidity due to the restrictions on transfer of the securities for a period of six months following the acquisition in accordance with stockholder agreements we entered into with the former Aires stockholders and the fact that the shares are unregistered and we have no obligation to register them for resale.

Under the acquisition method of accounting, the total purchase price is allocated to Aires' net tangible and intangible assets and liabilities based on their estimated fair values as of the acquisition date. The table below summarizes the estimated fair values of Aires' net tangible and intangible assets and liabilities on the acquisition date (in thousands):

Cash and cash equivalents	\$3,534
Prepaid expenses and other assets	86
In-process research and development	2,000
Total assets:	5,620
Accounts payable and accrued liabilities	1,069
Deferred tax liability	795
Total liabilities:	1,864
Net assets acquired	\$3,756

The estimated fair value of the net assets acquired exceeds the purchase price by approximately \$0.5 million. Accordingly, we recognized the \$0.5 million excess as a bargain purchase gain in other (expense)/income net in our condensed consolidated statements of operations and comprehensive loss. We were able to realize a gain because Aires was in a distressed sale situation. Aires lacked sufficient capital to continue operations and was unable to secure additional capital in the timeframe it required.

Acquired In-Process Research and Development

Acquired IPR&D is the estimated fair value of the AIR001 program as of the acquisition date. We determined that the estimated fair value of the AIR001 program was \$2.0 million as of the acquisition date 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 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.

To calculate fair value of the AIR001 program under the MPEEM, we used probability-weighted, projected cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by clinical-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to AIR001 and then reduced by a contributory charge on requisite assets employed. Contributory assets included debt-free working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through a seven-year market exclusivity period. The resultant cash flows were then discounted to present value using a weighted-average cost of capital for companies with profiles substantially similar to that of Aires, which we believe represents the rate that market participants would use to value the assets. We compensated for the phase of development of the program by applying a probability factor to our estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, including the indication in which we will pursue development of AIR001, the time and resources needed to complete the development and regulatory approval of AIR001, estimates of revenue and operating profit related to the program considering its stage of development, the life

of the potential commercialized product, market penetration and competition, and risks associated with achieving commercialization, including delay or failure to obtain regulatory approvals to conduct clinical studies, failure of clinical studies, delay or failure to obtain required market clearances, and intellectual property litigation.

Deferred Income Tax Liability

The \$0.8 million recorded as deferred income tax liability resulting from the acquisition reflects the tax impact of the difference between the book basis and tax basis of acquired IPR&D. Such deferred income tax liability cannot be used to offset deferred tax assets when analyzing our valuation allowance as the acquired IPR&D is considered to have an indefinite life until we complete or abandon development of AIR001.

(5)

4. Goodwill and IPR&D

At September 30, 2015 and December 31, 2014, 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.

5. 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 (expense)/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 September 30, 2015, \$2.9 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 were greater than 18 months.

At September 30, 2015 and December 31, 2014, our investment securities were as follows (in thousands):

	September 30, 2015	December 31, 2014
Fair value of investment securities	\$ 17,706	\$ 21,481
Cost basis of investment securities	17,697	21,506
	September 30, 2015	December 31, 2014
Net unrealized gains/(losses) on investment securities	9	(25)

(6)

6. 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 September 30, 2015 and December 31, 2014 of our cash equivalents and investment securities are summarized in the following table (in thousands):

	Total Fair Value	Fair Value Determined Under:		
		(Level 1)	(Level 2)	(Level 3)
At September 30, 2015:				
Cash equivalents	\$ 16,018	\$ 16,018	\$ —	\$ —
Investment securities	\$ 17,706	\$ —	\$ 17,706	\$ —
At December 31, 2014:				
Cash equivalents	\$ 16,626	\$ 16,626	\$ —	\$ —
Investment securities	\$ 21,481	\$ —	\$ 21,481	\$ —

We believe that our 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.

7. 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 phone equipment under a lease agreement classified as a capital lease. The lease obligation is \$35,000 with an interest rate of 7.94% per annum and the lease expires in December 2019. The equipment is being amortized over five years.

8. Accrued Liabilities

Accrued liabilities at September 30, 2015 and December 31, 2014 were as follows (in thousands):

	September 30, 2015	December 31, 2014
Accrued R&D agreements and study expenses	\$ 7,306	\$ 5,383
Deferred rent	107	—
Other accrued liabilities	350	242
Total accrued liabilities	\$ 7,763	\$ 5,625

(7)

9. Debt Facility

Hercules Loan and Security Agreement

On August 11, 2015, we entered into a loan and security agreement (the “Loan Agreement”) with Hercules Technology III, L.P. and Hercules Technology Growth Capital, Inc. (together, “Hercules”), which provided for a \$15.0 million debt facility, and borrowed the first tranche of \$5.0 million (“Tranche 1”). On September 28, 2015, we entered into an amendment to the Loan Agreement (the “First Amendment”) and borrowed the second tranche of \$10.0 million (“Tranche 2”).

Under the Loan Agreement, as amended, if our vepoloxamer and AIR001 programs do not achieve certain clinical development milestones by December 31, 2015, and by April 30, 2016 we do not either (a) receive unrestricted and unencumbered net cash proceeds of at least \$15 million from either, or a combination of, upfront cash payments from one or more strategic corporate partnerships or one or more equity financings, or (b) demonstrate positive results in our Phase 3 “EPIC” study of vepoloxamer in sickle cell disease, we are required to prepay \$10 million of the outstanding principal due to Hercules on April 30, 2016.

The interest rate for the principal balance under the Loan Agreement, as amended, 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 amended Loan Agreement are interest only until June 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 September 1, 2016 if, on or before June 1, 2016, we have demonstrated positive results in the EPIC study and no event of default has occurred (the “First Interest Only Extension Condition”), and extended further to March 1, 2017 if we have satisfied the First Interest Only Extension Condition, have not prepaid Tranche 2, and no event of default has occurred. 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 amended 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. A prepayment charge will not be applied to our prepayment of Tranche 2 if such prepayment is required on April 30, 2016.

Our obligations under the amended 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 and First Amendment, we paid facility charges of \$112,500 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 and First Amendment, we issued warrants to Hercules which are exercisable for an aggregate of 1,524,390 shares of our common stock and at an exercise price of \$0.41 per share. The warrants were valued using the Black-Scholes option pricing model with the following assumptions: volatility of 77%, expected term of five years, risk-free interest rate of 1.5% 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 14 “Stockholders’ Equity – Outstanding Warrants,” 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. Short-term values represent amounts to be paid within the next twelve months.

	As of September 30, 2015	
	Short-term	Long-term
Obligations to lender	\$2,104	\$ 13,608
Accrued interest	45	-
Debt issuance costs	(426)	(458)
Debt discount related to warrants	(186)	(199)
Carrying value	\$ 1,537	\$ 12,951

(8)

10. Share-Based Compensation Expense

Share-based compensation expense related to equity awards granted to our employees and non-employee directors for the three and nine months ended September 30, 2015 and 2014 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Selling, general and administrative expense	\$375	\$465	\$1,687	\$1,152
Research and development expense	169	224	435	361
Share-based compensation expense	\$544	\$689	\$2,122	\$1,513

During the nine months ended September 30, 2015, 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 nine-month period:

	Shares	
	Underlying	Weighted-Average
	Option	Exercise
	Awards	Price
Outstanding at December 31, 2014	13,616,137	\$ 1.00
Granted	12,547,752	\$ 0.55
Exercised	—	\$ —
Expired/forfeited	(3,708,082)	\$ 0.66
Outstanding at September 30, 2015	22,455,807	\$ 0.81

At September 30, 2015, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was \$4.8 million, which is expected to be recognized over a weighted-average period of 3.0 years.

11. Net Loss Per Common Share

Basic and diluted net loss per common share was calculated by dividing the net loss for the three and nine months ended September 30, 2015 and 2014 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Options	22,453,351	13,824,355	21,128,025	11,129,739
Warrants	76,356,327	44,424,075	77,345,043	44,518,635

12. Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (“ASU”) No. 2015-03, Simplifying the Presentation of Debt Issuance Costs (“ASU 2015-03”). The new standard requires debt issuance costs to be presented on the balance sheet as a direct reduction of the carrying value of the associated debt liability, consistent with the presentation of debt discounts. The recognition and measurement requirements will not change as a result of this guidance. ASU 2015-03 is effective for the annual reporting periods beginning after December 15, 2015 and requires a retrospective application. The Company elected to early adopt this guidance and it did not have a material impact on the Company’s financial statements.

(9)

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.

13. Supplemental Cash Flow Information

Non-cash investing and financing transactions presented separately from the condensed consolidated statements of cash flows for the nine months ended September 30, 2015 and 2014 are as follows (in thousands):

	Nine Months Ended September 30, 2015 2014	
Supplemental disclosures of non-cash investing and financing activities:		
Issuance of common stock for acquisitions	\$-	\$3,270
Assumptions of liabilities in acquisitions	\$-	\$1,069
Fair value of warrants issued in connection with debt facility	\$393	\$-
Unrealized (gain)/loss on investment securities	\$(34)	\$4
Purchases of property and equipment in accounts payable	\$31	\$-
Purchase of equipment under capital lease	\$35	\$-
Debt facility costs in accounts payable and accrued liabilities	\$33	\$-

14. Stockholders' Equity

Underwritten Public Offering of Common Stock, Pre-funded Warrants and Warrants

In November 2014, we completed an underwritten public offering of 30,941,102 shares of our common stock, 13,081,428 "pre-funded" warrants exercisable for up to 13,081,428 shares of our common stock, and 22,011,265 warrants exercisable for up to 22,011,265 shares of our common stock. These securities were offered and sold to the underwriters and the public in units with each Series A unit consisting of one share of our common stock and one-half

(0.5) of a warrant and each Series B unit consisting of one pre-funded warrant and one-half (0.5) of a warrant. Each whole warrant is exercisable for one share of our common stock. We sold an aggregate of 30,941,102 Series A units and 13,081,428 Series B units. The gross proceeds from this financing were \$21.0 million and, after deducting underwriting discounts and commissions and other offering expenses, our net proceeds were \$19.7 million. We may receive up to \$0.1 million and \$16.5 million of additional proceeds from the exercise of the pre-funded warrants and warrants, respectively, issued in the offering. The exercise price of the pre-funded warrants is \$0.01 per share and exercise price of the warrants is \$0.75 per share. Subject to certain beneficial ownership limitations, the pre-funded warrants and warrants are exercisable at any time on or before November 12, 2019.

“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 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 million, from time to time, through an ATM program. As of September 30, 2015, we had sold and issued an aggregate of 24,859,107 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

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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.

Outstanding Warrants

At September 30, 2015, outstanding warrants to purchase shares of common stock are as follows:

Shares Underlying		
Outstanding Warrants	Exercise Price	Expiration Date
2,046,139	\$ 2.750	January 2016
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
1,524,390	\$ 0.410	August 2020
77,385,622		

Warrants Issued to Hercules

In connection with the Loan Agreement, on August 11, 2015, we entered into a Warrant Agreement with Hercules Technology III, L.P. and, in connection with the First Amendment, on September 28, 2015, we entered into a First Amendment to Warrant Agreement with Hercules Technology III, L.P. (together, the “Amended Warrant Agreement”). The Amended Warrant Agreement provides Hercules with a right to purchase an aggregate of 1,524,390 shares of our common stock at an exercise price of \$0.41 per share, at any time, or from time to time, through August 11, 2020. The exercise price and the number of shares underlying the warrants subject to the Amended Warrant Agreement are subject to adjustment 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.

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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, 2014, filed with the U.S. Securities and Exchange Commission, or SEC, on March 24, 2015, 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 our quarterly report on Form 10-Q filed with the SEC on August 12, 2015. Mast Therapeutics, our corporate logo, Aires Pharmaceuticals, Inc., 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 clinical-stage, biopharmaceutical company developing novel therapies for serious or life-threatening diseases with significant unmet needs. 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 (also known as MST-188), our lead drug candidate. Vepoloxamer 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. We currently are developing vepoloxamer for the treatment of sickle cell disease, heart failure, and stroke. We also are developing AIR001, a sodium nitrite solution for intermittent inhalation via nebulizer. AIR001 has demonstrated positive hemodynamic effects in patients with pulmonary hypertension and we are developing it for the treatment of heart failure with preserved ejection fraction, or 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 \$29.7 million for the nine months ended September 30, 2015. As of September 30, 2015, we had an accumulated deficit of \$264.8 million. Our cash, cash equivalents, and investment securities were \$49.9 million as of September 30, 2015.

We continue to focus our resources primarily on the development of vepoloxamer. Enrolling subjects in EPIC, our pivotal Phase 3 study of vepoloxamer in patients with sickle cell disease, is one of our top priorities. We also initiated a Phase 2 study of vepoloxamer in patients with chronic heart failure in October 2015. In addition, we continue to pursue the opportunity for clinical development of vepoloxamer in ischemic stroke. Our vepoloxamer pipeline also includes a preclinical development program in resuscitation following major trauma (i.e., restoration of circulating blood volume and pressure).

Our second product candidate, AIR001, is being tested in two institution-sponsored Phase 2a clinical studies in patients with HFpEF. We obtained the AIR001 program through our acquisition of Aires Pharmaceuticals, Inc. in February 2014. If data from the Phase 2a studies are positive, we expect to conduct a Phase 2b proof-of-concept study in HFpEF patients.

Acquisition of Aires Pharmaceuticals

In February 2014, we acquired Aires Pharmaceuticals, Inc. in a merger transaction, which resulted in Aires becoming our wholly-owned subsidiary. Upon completion of the merger, we issued an aggregate of 1,049,706 unregistered shares of our common stock to former Aires stockholders and, in September 2014, following a six-month “holdback” period, we issued an aggregate of 4,053,996 additional unregistered shares of our common stock to former Aires stockholders, all in accordance with the merger agreement. There are no milestone or earn-out payments under the merger agreement. Accordingly, the total merger consideration was 5,103,702 shares.

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

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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 and assumptions related to the probability of achieving milestones in connection with the potential prepayment obligation under our debt facility with Hercules. 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.

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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 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.

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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, and quality assurance and regulatory affairs services. 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 new drug application, or 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 market research functions, and professional and consulting fees for accounting, legal, investor relations, business development, market research, human resources and information technology services. Other SG&A expenses include facility lease and insurance costs.

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Transaction-Related Expenses. Transaction-related expenses consist of legal, accounting, financial and business development advisory fees associated with the evaluation of potential acquisition targets and execution of acquisition transactions, including our acquisitions of Aires and SynthRx.

Interest Expense. Interest expense consists of interest payments made on the principal balance under our debt facility with Hercules and interest expense associated with payments under capital leases of equipment.

Other (Expense)/Income, Net. Other (expense)/income, net includes the bargain purchase gain related to the acquisition of Aires in 2014, as well as unrealized and realized gains and losses from foreign currency transactions and other non-operating gains and losses.

Comparison of Three Months Ended September 30, 2015 and 2014

Revenue. We recognized no revenue for the three months ended September 30, 2015 and 2014.

R&D Expenses. Our R&D expenses for the three months ended September 30, 2015 consisted primarily of external costs associated with the EPIC study, our Phase 2 study of vepoloxamer in heart failure and research-related manufacturing for vepoloxamer and AIR001. These expenses consisted primarily of CRO and CMO expenses, clinical study-related consulting 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			
	September 30,			
	2015	%	2014	%
External clinical study fees and expenses	\$3,362	46 %	\$3,168	59 %
External nonclinical study fees and expenses	2,785	38 %	962	18 %
Personnel costs	1,014	14 %	1,048	19 %
Share-based compensation expense	169	2 %	224	4 %
Total	\$7,330	100 %	\$5,402	100 %

R&D expenses increased by \$1.9 million, or approximately 35.7%, to \$7.3 million for the three months ended September 30, 2015, compared to \$5.4 million for the same period in 2014. This increase was due primarily to a \$1.8 million increase in external nonclinical study fees and expenses and a \$0.2 million increase in external clinical study fees and expenses, offset by a \$0.1 million decrease in personnel costs and share-based compensation expense.

The \$1.8 million increase in external nonclinical study fees and expenses was due primarily to an increase in research-related manufacturing costs for vepoloxamer. The \$0.2 million increase in external clinical study fees and expenses was due primarily to an increase of \$0.4 million in costs for our Phase 2 study of vepoloxamer in heart failure, offset by a decrease of \$0.2 million in costs for the Phase 2 study of vepoloxamer in acute limb ischemia, or ALI, which we discontinued and began to wind-down during the three months ended September 2015.

SG&A Expenses. SG&A expenses of \$2.5 million for the three months ended September 30, 2015 were consistent with the same period in 2014.

Transaction-Related Expenses. There were no transaction-related expenses for the three months ended September 30, 2015. Transaction-related expenses for the three months ended September 30, 2014 were negligible.

Interest Expense. Interest expense for the three months ended September 30, 2015 was \$101,000. There was no interest expense in the three months ended September 30, 2014.

Net Loss. Net loss was \$9.9 million, or \$0.06 per share, for the three months ended September 30, 2015, compared to net loss of \$7.9 million, or \$0.06 per share, for the same period in 2014.

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Comparison of Nine Months Ended September 30, 2015 and 2014

Revenue. We recognized no revenue for the nine months ended September 30, 2015 and 2014.

R&D Expenses. Our R&D expenses for the nine months ended September 30, 2015 consisted primarily of external costs associated with the EPIC study, our Phase 2 study of vepoloxamer in ALI, our Phase 2 study of vepoloxamer in heart failure and research-related manufacturing for vepoloxamer and AIR001. These expenses consisted primarily of CRO and CMO expenses, clinical study-related consulting 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):

	Nine Months Ended September 30,			
	2015	%	2014	%
External clinical study fees and expenses	\$10,573	50 %	\$8,397	58 %
External nonclinical study fees and expenses	7,177	34 %	3,058	21 %
Personnel costs	2,921	14 %	2,687	19 %
Share-based compensation expense	435	2 %	361	2 %
Total	\$21,106	100%	\$14,503	100%

R&D expenses increased by \$6.6 million, or approximately 45.5%, to \$21.1 million for the nine months ended September 30, 2015, compared to \$14.5 million for the same period in 2014. This increase was due primarily to a \$4.1 million increase in external nonclinical study fees and expenses, a \$2.2 million increase in external clinical study fees and expenses and a \$0.2 million increase in personnel expenses.

The \$4.1 million increase in external nonclinical study fees and expenses was due primarily to a \$3.8 million increase in research-related manufacturing costs for vepoloxamer and a \$0.3 million increase in research-related manufacturing costs for AIR001. The \$2.2 million increase in external clinical study fees and expenses was due primarily to increases of \$2.7 million in EPIC study costs and \$0.4 million in costs for our Phase 2 study of vepoloxamer in heart failure, offset by decreases of \$0.5 million in clinical study costs related to Aires' pre-acquisition clinical studies of AIR001 in pulmonary arterial hypertension and \$0.5 million in costs for the Phase 2 study of vepoloxamer in ALI, which we discontinued and began to wind-down during the three months ended September 30, 2015.

SG&A Expenses. SG&A expenses increased by \$1.3 million, or approximately 19.1%, to \$8.4 million for the nine months ended September 30, 2015, compared to \$7.1 million for the same period in 2014. This increase was due primarily to a \$0.7 million increase in personnel costs and a \$0.5 million increase in professional and consulting fees. Personnel costs for the nine months ended September 30, 2015 include \$0.4 million of severance expense 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.

Transaction-Related Expenses. There were no transaction-related expenses for the nine months ended September 30, 2015. Transaction-related expenses of \$0.3 million for the nine months ended September 30, 2014 consisted primarily of legal fees associated with the acquisition of Aires.

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Interest Expense. Interest expense for the nine months ended September 30, 2015 was \$102,000. There was no interest expense in the nine months ended September 30, 2014.

Other (Expense)/Income, Net. Other (expense)/income, net for the nine months ended September 30, 2015 was negligible. Other (expense)/income, net for the nine months ended September 30, 2014 consisted primarily of a \$0.5 million bargain purchase gain associated with the acquisition of Aires.

Net Loss. Net loss was \$29.7 million, or \$0.18 per share, for the nine months ended September 30, 2015, compared to net loss of \$21.4 million, or \$0.19 per share, for the same period in 2014.

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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 nine months ended September 30, 2015, we incurred a loss from operations of \$29.7 million. Our cash, cash equivalents and investment securities were \$49.9 million as of September 30, 2015.

We historically have funded our operations principally through proceeds from sales of our equity securities. In November 2014, we completed an underwritten public offering with gross proceeds of \$21.0 million from the sale and issuance of units consisting of shares of our common stock and warrants to purchase our common stock at an exercise price of \$0.75 per share and units consisting of “pre-funded” warrants to purchase shares of our common stock at an exercise price of \$0.01 per share and warrants to purchase shares of our common stock at an exercise price of \$0.75 per share. We issued and sold an aggregate of 30,941,102 shares of our common stock, 13,081,428 pre-funded warrants exercisable for up to 13,081,428 shares, and 22,011,265 warrants exercisable for up to 22,011,265 shares. Net proceeds, after deducting underwriting discounts and commissions and other offering expenses, were \$19.7 million. The pre-funded warrants and the warrants are exercisable at any time on or before November 12, 2019, subject to certain beneficial ownership limitations.

We may receive up to \$5.6 million, \$11.7 million, \$18.3 million, \$0.1 million and \$16.5 million of additional net proceeds from the exercise of warrants issued in the registered direct equity financings we completed in January 2011 and the underwritten public offerings we completed in November 2011, June 2013 and November 2014, 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 \$2.75, \$1.10, \$0.65, \$0.01 and \$0.75 per share, respectively. In comparison, the closing sale price of our common stock on September 30, 2015 was \$0.58 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 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 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 million, from time to time, through an ATM program. As of September 30, 2015, we had sold and issued an aggregate of 24,859,107 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.

We have borrowed \$15 million under a debt facility and have received proceeds of approximately \$14.8 million, net of fees. We borrowed the first tranche of \$5.0 million in August 2015 upon entry into a loan and security agreement with Hercules Technology III, L.P. and Hercules Technology Growth Capital, Inc., together referred to as Hercules, and we borrowed the second tranche of \$10.0 million in September 2015 upon entry into an amendment to that agreement. If we do not satisfy specific financial and/or clinical development conditions, as described in Note 9, “Debt Facility,” of the Notes to the Condensed Consolidated Financial Statements (Unaudited) in this report, we will be required to prepay \$10 million of the principal balance of the loan on April 30, 2016. 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 other customary restrictive covenants that may limit our ability

to raise capital through other debt or equity financing.

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

Operating activities. Net cash used in operating activities was \$24.1 million for the nine months ended September 30, 2015 and consisted primarily of a net loss of \$29.7 million adjusted for non-cash items, including share-based compensation expenses of \$2.1 million and a net increase of \$3.3 million due to changes in assets and liabilities. Net cash used in operating activities was \$18.6 million for the nine months ended September 30, 2014 and consisted primarily of a net loss of \$21.4 million adjusted for non-cash items, including share-based compensation expenses of \$1.5 million and a net increase of \$1.7 million due to changes in assets and liabilities, offset by a gain on bargain purchase of \$0.5 million.

Investing activities. Net cash provided by investing activities was \$3.7 million for the nine months ended September 30, 2015 compared to net cash provided by investing activities of \$4.9 million for the same period in 2014. Net proceeds from the maturity of certificates of deposit, offset by the purchase of new certificates of deposit were \$3.8 million for the nine months ended September 30, 2015 compared to \$1.6 million for the same period in 2014. In the nine months ended September 30, 2014, we obtained \$3.5 million of cash through our acquisition of Aires.

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Financing activities. Net cash provided by financing activities was \$16.8 million for the nine months ended September 30, 2015, primarily consisting of the net proceeds of \$14.8 million under our debt facility with Hercules and \$2.0 million from sales of our shares of common stock through our ATM program. Net cash provided by financing activities was \$14.0 million for the nine months ended September 30, 2014, representing the net proceeds from sales of our shares of common stock through our ATM program.

Management Outlook

We anticipate that our cash, cash equivalents and investment securities as of September 30, 2015 will be sufficient to fund our operations for at least the next 12 months; provided that we are not required to prepay \$10 million of the principal balance under our debt facility with Hercules on April 30, 2016. We expect our operating expenses for the last three months of 2015 will be approximately \$9 million to \$10 million, excluding share-based compensation expense.

Our estimate of our operating expenses for the remaining three months of 2015 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 and 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 operating expenses and future capital requirements include, but are not limited to:

- the design, initiation, scope, rate of progress, results and timing of our clinical and nonclinical studies of our product candidates, including the EPIC study;
- 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;
- 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;
- our ability to manage timelines and costs related to commercial manufacture of our products, should any of our product candidates obtain regulatory approval;
- the extent to which we increase our workforce, including in connection with establishing or acquiring sales and distribution capabilities;
- our ability to protect our intellectual property and 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. Enrolling subjects in the EPIC study is one of our top priorities. We expect to enroll 388 subjects into EPIC and have enrolled more than 80% of those subjects. In addition, we have more than 75 EPIC study sites open in 12 countries, reflecting broad international support for the study among the physician community. However, we experienced slower than predicted enrollment in October, requiring us to update our anticipated timeline for announcement of top-line data. Although predicting the rate of enrollment and timing of availability of data for any clinical study, including EPIC, is subject to a number of significant assumptions and completion of the study and timing of data may differ materially, we expect to announce top-line results in the second quarter of 2016.

In addition to EPIC, we are conducting other activities to evaluate vepoloxamer's potential in sickle cell disease, including enrolling patients participating in EPIC at selected U.S. study sites in a sub-study to investigate and quantify the effect of vepoloxamer on tissue oxygenation using non-invasive methods. Further, during the second quarter of 2015, we initiated an open-label, multicenter extension study called EPIC-E to expand our existing safety database regarding repeat exposure to vepoloxamer. The study is enrolling patients who have completed the EPIC study and are hospitalized for subsequent vaso-occlusive crisis. To further enhance the safety database for our new drug application and help guide dosage adjustments for special populations, we also plan to initiate a clinical study of vepoloxamer in approximately 40 patients with varying degrees of renal impairment.

We also are advancing our other vepoloxamer programs. In October 2015, we initiated a randomized, double-blind, placebo-controlled, multicenter Phase 2 study of vepoloxamer in ambulatory patients with chronic heart failure. Approximately 150 patients will be randomized into one of three approximately 50-patient study arms and receive one of two dose levels of a new formulation of vepoloxamer, which we designed to be more suitable for heart failure patients, or the placebo control. The study will evaluate the safety and efficacy of a single, three-hour infusion of vepoloxamer compared to placebo, including vepoloxamer's effect on markers of cardiac injury (troponin) and wall stress (NT-proBNP), as well as clinical outcomes such as changes in echocardiographic

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measurements, exercise tolerance and quality of life. The study drugs will be administered in an outpatient setting or short-stay inpatient unit depending on local practice and resource availability.

We also are evaluating vepoloxamer's potential in stroke. Based on nonclinical data we announced earlier this year, as well as published data from recent 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. Consequently, during the third quarter, we elected to discontinue our clinical program in ALI and further pursue the opportunity for clinical development of vepoloxamer in stroke. We anticipate the cost savings from discontinuing the ALI study to more than offset 2015 expenses related to the stroke program.

In addition to our clinical studies, we are conducting or plan to conduct a number of other ex vivo, nonclinical in vivo and in vitro studies of vepoloxamer to further characterize its pharmacologic effects and support our intellectual property positions. We also are conducting and plan to conduct additional research-related manufacturing activities, some of which may result in additional intellectual property rights and protection for our product candidates.

AIR001

Based on the positive hemodynamic effects observed in Phase 1 and Phase 2 studies of AIR001 in more than 120 healthy volunteers and patients with various forms of pulmonary hypertension and data showing AIR001 was well tolerated in those studies, we believe AIR001 may be uniquely suitable to address the serious unmet need of patients with HFpEF. To better understand AIR001's potential in that patient population, we are supporting ongoing Phase 2a studies of AIR001 in patients with HFpEF sponsored by Mayo Clinic and the University of Pittsburgh. If results from these Phase 2a studies are positive, we expect to conduct a Phase 2b proof-of-concept study of AIR001 in HFpEF patients.

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.

Although we anticipate that our cash, cash equivalents and investment securities will be sufficient to fund our operations for at least the next 12 months, provided that we are not required to prepay \$10 million of the principal balance under our debt facility with Hercules on April 30, 2016, we do not anticipate that such capital alone will be sufficient to fund our operations through the completion of development and commercialization of our product candidates. As described above under "Liquidity and Capital Resources," if we do not satisfy specific financial and/or clinical development conditions under our loan and security agreement with Hercules, we will be required to prepay \$10 million of the principal balance on April 30, 2016, in which case, based on our cash, cash equivalents and investment securities as of September 30, 2015, we may not have sufficient resources to fund our operations for the next 12 months. In addition, we may utilize our financial resources sooner than we currently expect if we incur unanticipated expenses or we pursue development or commercial-readiness activities for our product candidates at levels or on timelines other than currently planned or we expand our product pipeline through acquisition of new product candidates and/or technologies. For the foreseeable future, we plan to fund our operations through public or private equity and/or debt financings and through collaborations, including licensing arrangements. However, adequate additional capital may not be available to us in the future on acceptable terms, on a timely basis, or at all. Our failure to raise capital as and when needed would have a material and adverse effect on our financial condition and ability to pursue our business strategy.

Recent Accounting Pronouncements

See Note 12, “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,” “indicate” and similar 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, timing of initiation and completion, and costs of clinical studies and nonclinical testing, the indications in which we plan to pursue development of our product candidates, our plans regarding partnering or other collaborative arrangements and for raising additional capital to support our operations, and our belief that we have

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sufficient liquidity to fund our operations for at least the next 12 months. 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:

- our ability, or that of a future partner, to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates;
- 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 maintain our relationships with the single-source third-party manufacturers and suppliers for clinical trial material, including the API and finished drug product, and the ability of such manufacturers and suppliers to successfully and consistently meet our manufacturing and supply requirements;
- 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;
- our ability to obtain additional capital as needed on acceptable terms, or at all;
- an event of default under our loan and security agreement with Hercules requiring us to repay all principal balance and accumulated interest immediately, or our failure to satisfy certain conditions under the agreement, which would trigger prepayment of \$10 million of the principal balance on April 30, 2016;
- 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 in sickle cell disease prior to accepting a new drug application for review or granting regulatory approval, even if the EPIC study is successful;
- 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 establish and protect our intellectual property rights related to our product candidates;
- claims against us for infringing the proprietary rights of third parties;
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healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent commercial success;
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- 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 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 quarterly report on Form 10-Q filed with the SEC on August 12, 2015.

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

Under SEC rules and regulations, as a smaller reporting company we are not required to provide the information required by this item.

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 September 30, 2015. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of September 30, 2015 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.

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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 II of our quarterly report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 12, 2015, 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 quarterly report on Form 10-Q for the quarter ended June 30, 2015, filed with the SEC on August 12, 2015.

The terms of our debt facility place restrictions on our operating and financial flexibility, and failure to comply with covenants or to satisfy certain conditions of the agreement governing the debt facility may result in acceleration of our repayment obligations and foreclosure on our pledged assets, which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our common stock to decline.

We have an outstanding principal balance of \$15 million under our debt facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P. (collectively referred to as Hercules) that is secured by a lien covering substantially all of our assets, excluding intellectual property, but including proceeds from the sale, licensing or disposition of our intellectual property. The loan and security agreement governing the debt facility requires us to comply with customary covenants (affirmative and negative), including restrictive covenants that limit our ability to: incur additional indebtedness; encumber the collateral securing the loan; acquire, own or make investments; repurchase or redeem any class of stock or other equity interest; declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest; transfer a material portion of our assets; acquire other businesses; and merge or consolidate with or into any other organization or otherwise suffer a change in control, in each case subject to exceptions. Our intellectual property also is subject to customary negative covenants. In addition, subject to limited exceptions, Hercules could declare an event of default upon the occurrence of any event that it interprets as having a material adverse effect upon our business, operations, properties, assets, or financial condition or upon our ability to perform or pay the secured obligations under the loan and security agreement or upon the collateral or Hercules' liens on the collateral under the agreement, thereby requiring us to repay the loan immediately or renegotiate the terms of the agreement. If we default under the facility, Hercules may accelerate all of our repayment obligations and, if we are unable to access funds to meet those obligations or to renegotiate our agreement, Hercules could take control of our pledged assets and we could immediately cease operations. If we were to renegotiate our agreement under such circumstances, the terms may be significantly less favorable to us. If we were liquidated, Hercules' right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by Hercules of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

In addition, our loan and security agreement with Hercules requires us to prepay \$10 million of the principal balance on April 30, 2016, unless our vepoloxamer and AIR001 programs achieve certain clinical development milestones by December 31, 2015, and, by April 30, 2016, we either (a) receive unrestricted and unencumbered net cash proceeds of at least \$15 million from either, or a combination of, upfront cash payments from one or more strategic corporate partnerships or one or more equity financings, or (b) demonstrate positive results from the EPIC study. If this prepayment obligation is triggered, the payment of \$10 million to Hercules that would be required on April 30, 2016 could not only significantly harm our liquidity, financial condition and operating results and cause the price of our

common stock to decline, but also significantly impair our ability to raise adequate additional capital to fund our operations and pursue our business strategy.

Sales of substantial amounts of our common stock or the perception that such sales may occur could cause the market price of our common stock to decline significantly, even if our business is performing well.

The market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, us or our existing stockholders of shares of our common stock. Sales by our existing stockholders might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate. In August 2015, we entered into a new sales agreement under which we may, from time to time, sell shares of our common stock having an aggregate offering price of up to \$30 million through an “at the market” equity offering program, or ATM program. As of September 30, 2015, we had not yet sold any shares under the ATM program. The shelf registration statement on Form S-3 under which the ATM program is registered may be used to register the sale and issuance of up to approximately \$120 million of additional securities, subject to limitations if our public float is less than \$75 million. In addition, we have outstanding warrants to purchase approximately 77.4 million additional shares of our common stock and warrants to purchase

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more than 13 million of those shares have an exercise price of \$0.01 per share and warrants to purchase another 51.6 million of those shares have an exercise price of less than \$1.00 per share. Collectively, the ATM program, the shelf registration statement and the outstanding, in-the-money warrants, may increase the likelihood of sales of substantial amounts of our shares, or the perception that substantial sales may occur, by us or our existing securityholders from time to time, which could cause the market price of our common stock to decline significantly.

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

In connection with our loan and security agreement with Hercules and the amendment thereto, on August 11, 2015, we entered into a Warrant Agreement with Hercules Technology III, L.P. and, on September 28, 2015, we entered into a First Amendment to Warrant Agreement with Hercules Technology III, L.P., together, referred to as the Amended Warrant Agreement. The Amended Warrant Agreement provides for warrants to purchase an aggregate of 1,524,390 shares of our common stock and at an exercise price of \$0.41 per share, at any time, or from time to time, through August 11, 2020. 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. Under the Amended Warrant Agreement, Hercules received a warrant exercisable for 853,658 shares as of August 11, 2015 and a warrant exercisable for an additional 670,732 shares as of September 28, 2015, which, in the aggregate, represent the right to purchase 1,524,390 shares of our common stock.

We offered and sold the warrants described above to Hercules in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act, provided by Section 4(2) of the Securities Act. We relied on this exemption based in part on representations made to us by Hercules, including Hercules' intention to acquire the securities for investment only and not with a view to, or a present intention of, selling or distributing any part thereof in violation of applicable laws, and Hercules' status as an "accredited investor," as such term is defined in Rule 501 of Regulation D promulgated under the Securities Act.

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.

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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: November 12, 2015 By: /s/ Brian M. Culley
Brian M. Culley

Chief Executive Officer

(Principal Executive Officer)

By: /s/ Brandi L. Roberts
Brandi L. Roberts

Chief Financial Officer and Senior Vice President

(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference		Date Filed
		Filed Herewith	Form File/Film No.	
10.1	Loan and Security Agreement, dated as of August 11, 2015, among the registrant, Hercules Technology III, L.P. and Hercules Technology Growth Capital, Inc.	X		
10.2	First Amendment to Loan and Security Agreement, dated as of September 28, 2015, among the registrant, Hercules Technology III, L.P. and Hercules Technology Growth Capital, Inc.	X		
10.3	Warrant Agreement, dated as of August 11, 2015, between the registrant and Hercules Technology III, L.P.	X		
10.4	First Amendment to Warrant Agreement, dated as of September 28, 2015, between the registrant and Hercules Technology III, L.P.	X		
10.5	Sales Agreement, dated August 21, 2015, between the registrant and Cowen and Company, LLC		Form 8-K 001-32157-151069175	08/21/15
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		

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101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X

±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.

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