Mast Therapeutics, Inc.
Form 10-Q
October 31, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2014

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.)
12390 El Camino Real, Suite 150, San Diego, CA (Address of principal executive offices)	92130 (Zip Code)

(858) 552-0866

(Registrant's telephone number, including area code)

N/A

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

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

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

Large accelerated filer ¨ Accelerated filer ¨

Non-accelerated filer ¨ Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The number of shares outstanding of the registrant's common stock, $0.001 par value per share, as of October 29, 2014 was 128,517,274.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$25,981,605	$25,681,092
Investment securities	17,092,504	18,711,448
Prepaid expenses and other current assets	984,841	1,135,490
Total current assets	44,058,950	45,528,030
Property and equipment, net	185,715	105,747
In-process research and development	8,549,000	6,549,000
Goodwill	3,006,883	3,006,883
Other assets	363,497	60,312
Total assets	$56,164,045	$55,249,972
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,154,266	$963,947
Accrued liabilities	4,845,604	2,495,088
Accrued compensation and payroll taxes	1,511,745	1,374,343
Total current liabilities	7,511,615	4,833,378
Deferred income tax liability	3,403,675	2,608,755
Total liabilities	10,915,290	7,442,133
Stockholders' equity:		
Common stock, $0.001 par value; 500,000,000 shares authorized; 127,508,434 and 102,710,286 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	127,509	102,710
Additional paid-in capital	272,961,560	254,154,693
Accumulated other comprehensive loss	(22,521)	(20,738)
Accumulated deficit	(227,817,793)	(206,428,826)
Total stockholders' equity	45,248,755	47,807,839
Total liabilities and stockholders' equity	$56,164,045	$55,249,972

See accompanying notes to unaudited condensed consolidated financial statements.

(1)

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Income/(Loss)

(Unaudited)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Revenues	$—	$—	$—	$—
Operating expenses:				
Research and development	5,401,661	3,102,240	14,502,600	9,382,087
Selling, general and administrative	2,454,830	2,158,417	7,091,023	6,371,048
Transaction-related expenses	1,860	—	271,307	35,000
Depreciation and amortization	25,775	10,064	59,763	28,738
Total operating expenses	7,884,126	5,270,721	21,924,693	15,816,873
Loss from operations	(7,884,126)	(5,270,721)	(21,924,693)	(15,816,873)
Interest income	17,376	17,327	49,594	42,638
Other income/(expense), net	253	(137)	486,132	(1,335)
Net loss	$(7,866,497)	$(5,253,531)	$(21,388,967)	$(15,775,570)
Net loss per share - basic and diluted	$(0.06)	$(0.05)	$(0.19)	$(0.23)
Weighted average shares outstanding - basic and diluted	123,287,118	102,710,286	114,709,434	67,781,879
Comprehensive Income/(Loss):				
Net loss	$(7,866,497)	$(5,253,531)	$(21,388,967)	$(15,775,570)
Other comprehensive gains/(losses)	(6,764)	(19,884)	(3,939)	(26,528)
Comprehensive net loss	$(7,873,261)	$(5,273,415)	$(21,392,906)	$(15,802,098)

See accompanying notes to unaudited condensed consolidated financial statements.

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine months ended September 30,	
	2014	2013
Cash flows from operating activities:		
Net loss	$(21,388,967)	$(15,775,570)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	59,763	28,738
Loss on change in fair value of contingent consideration	—	35,000
Gain on bargain purchase	(485,944)	—
Share-based compensation expense related to employee stock options and restricted stock issued	1,513,068	1,159,021
Changes in assets and liabilities, net of effect of acquisitions:		
Decrease/(increase) in prepaid expenses and other assets	60,606	90,500
Increase in accounts payable and accrued liabilities	1,611,098	1,533,636
Net cash used in operating activities	(18,630,376)	(12,928,675)
Cash flows from investing activities:		
Purchases of certificates of deposit	(12,463,020)	(19,407,030)
Proceeds from maturities of certificates of deposit	14,078,000	14,260,000
Purchases of property and equipment	(136,568)	(45,348)
Security deposit for new sublease	(130,600)	—
Cash obtained through acquisition	3,534,480	—
Net cash provided by (used in) investing activities	4,882,292	(5,192,378)
Cash flows from financing activities:		
Proceeds from sale of common stock	14,765,546	28,097,500
Proceeds from exercise of warrants	65	—
Payments for financing and offering costs	(717,014)	(2,244,211)
Net cash provided by financing activities	14,048,597	25,853,289
Effect of exchange rate changes on cash	—	(1,522)
Net increase in cash and cash equivalents	300,513	7,730,714
Cash and cash equivalents at beginning of period	25,681,092	22,500,440
Cash and cash equivalents at end of period	$25,981,605	$30,231,154

See accompanying notes to unaudited condensed consolidated financial statements.

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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, 2013, filed with the SEC on March 26, 2014 ("2013 Annual Report"). The condensed consolidated balance sheet as of December 31, 2013 included in this report has been derived from the audited consolidated financial statements included in the 2013 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 MST-188, our lead product candidate, 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, sodium nitrite inhalation solution for intermittent inhalation via nebulizer, which we are developing to treat pulmonary hypertension associated with left heart disease.

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 commercialize our product candidates before another company develops safe and effective treatments for the indications we are pursuing.

We previously were classified as a "development stage entity" under the Master Glossary of the Accounting Standards Codification and, as such, were required to present inception-to-date information in our statements of operations and income, stockholders' equity, and cash flows. In June 2014, the Financial Accounting Standards Board ("FASB") issued an accounting standards update that eliminates the concept of a development stage entity from U.S. GAAP and removes the related incremental reporting requirements. See Note 11 below for additional information on this new standard. We elected to early adopt the new standard. Accordingly, in contrast to our financial statements in the 2013 Annual Report and our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2014, the financial statements contained in this report do not include inception-to-date information.

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, including estimates related to R&D expenses, in-process research and development ("IPR&D"), goodwill and share-based compensation expenses. We base our estimates on historical experience and various other relevant assumptions we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

3. Acquisition of Aires

In February 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.

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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 is 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 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.

Cash and cash equivalents	$3,534,480
Prepaid expenses and other assets	85,681
In-process research and development	2,000,000
Total assets:	5,620,161
Accounts payable and accrued liabilities	1,069,297
Deferred tax liability	794,920
Total liabilities:	1,864,217
Net assets acquired	$3,755,944

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 income/(expense), net in our condensed consolidated statements of operations and comprehensive income/(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.

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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.

Pro Forma Information

The following unaudited pro forma information presents our condensed consolidated results of operations as if the acquisition of Aires had occurred on January 1, 2013:

	Nine months ended September 30,	
	2014	2013
Revenues	$—	$1,471,351
Loss from operations	(22,431,217)	(22,479,095)
Net loss applicable to common stock	(22,381,109)	(22,434,407)

The $1.5 million of revenues consists of amounts recognized by Aires during the nine months ended September 30, 2013 as a result of a payment by a third-party partner pursuant to a collaboration agreement. The agreement was terminated in the fourth quarter of 2013. Aires recognized no revenues in 2014.

The above unaudited pro forma information includes the following nonrecurring adjustments directly attributable to the acquisition:

	Nine months ended September 30,	
	2014	2013
Transaction-related expenses	$1,306,477	$(1,306,477)

Transaction-related expenses include $0.9 million of severance payments to former executive officers of Aires pursuant to employment agreements between them and Aires.

The above unaudited pro forma condensed consolidated financial information is presented for illustrative purposes only. It is not necessarily indicative of what the results of operations actually would have been had the acquisition been completed on the date indicated. In addition, it does not purport to project the future operating results of the combined entity.

The operations of Aires were consolidated with our operations as of the closing of the acquisition on February 27, 2014. Accordingly, Aires' total operating expenses of $1.7 million for the period from February 27 through September 30, 2014 were included in our condensed consolidated statements of operations and comprehensive income/(loss).

4. Goodwill and IPR&D

At September 30, 2014 and December 31, 2013, our goodwill and IPR&D consisted of the following:

	September 30, 2014	December 31, 2013
Goodwill	$3,006,883	$3,006,883
IPR&D		
Acquired IPR&D related to SynthRx acquisition	6,549,000	6,549,000
Acquired IPR&D related to Aires acquisition	2,000,000	0
Total goodwill and IPR&D	$11,555,883	$9,555,883

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 MST-188 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 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 for our goodwill and our acquired IPR&D related to the SynthRx acquisition as of September 30, 2014 and we concluded that it is not more likely than not that the carrying value of our goodwill or our acquired IPR&D related to the SynthRx acquisition exceeds its fair value. Therefore, we concluded that no impairment charge is required. We did not perform annual impairment testing for our acquired IPR&D related to the Aires acquisition because the acquisition occurred in February 2014 and we are not aware of an event or change in circumstances that would indicate the carrying value may be impaired.

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 income/(expense), 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, 2014, $4.5 million, or approximately 26%, 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, 2014, the fair value of our investment securities was $17,092,504. The cost basis of such investments was $17,115,025 and our net unrealized losses were $22,521.

6. Fair Value of Financial Instruments

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, 2014 and December 31, 2013 of our investment securities are summarized in the following table:

	Total Fair Value	Fair Value Determined Under: (Level 1)	(Level 2)	(Level 3)
Investment securities at September 30, 2014	$17,092,504	$—	$17,092,504	$ —
Investment securities at December 31, 2013	$18,711,448	$—	$18,711,448	$ —

7. Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. 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.

8. Accrued Liabilities

Accrued liabilities at September 30, 2014 and December 31, 2013 were as follows:

	September 30, 2014	December 31, 2013
Accrued R&D agreements and study expenses	$4,588,391	$2,273,860
Other accrued liabilities	257,213	221,228
Total accrued liabilities	$4,845,604	$2,495,088

9. Share-Based Compensation Expense

Estimated 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, 2014 and 2013 was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Selling, general and administrative expense	$464,948	$395,316	$1,152,507	$1,033,921
Research and development expense	224,284	47,012	360,561	125,100
Share-based compensation expense	$689,232	$442,328	$1,513,068	$1,159,021

During the nine months ended September 30, 2014, 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 Exercise

	Option Awards	Price
Outstanding at December 31, 2013	7,304,828	$ 1.38
Granted	6,875,095	$ 0.60
Exercised	—	$ —
Expired/forfeited	(1,117,652)	$ 0.78
Outstanding at September 30, 2014	13,062,271	$ 1.02

At September 30, 2014, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was $4.0 million, which is expected to be recognized over a weighted-average period of 2.9 years.

10. Net Loss Per Common Share

Basic and diluted net loss per common share was calculated by dividing the net loss for the three and nine months ended September 30, 2014 and 2013 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. 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,	
	2014	2013	2014	2013
Options	13,824,355	7,190,672	11,129,739	5,252,471
Warrants	44,424,075	44,585,932	44,518,635	27,192,242

11. Recent Accounting Pronouncements

In August 2014, the FASB issued Accounting Standards Update ("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.

In June 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915), Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation ("ASU 2014-10"). The amendments in ASU 2014-10 remove the definition of a development stage entity from the Master Glossary of the Accounting Standards Codification, thereby removing the financial reporting distinction between development stage entities and other reporting entities from U.S. GAAP. In addition, the amendments eliminate the requirements for development stage entities to: (a) present inception-to-date information in the statements of income, cash flows, and shareholder equity; (b) label the financial statements as those of a development stage entity; (c) disclose a description of the development stage activities in which the entity is engaged; and (d) disclose in the first year in which the entity is no longer a development stage entity that in prior years it had been in the development stage. The amendments also clarify that the guidance in ASC Topic 275, Risks and Uncertainties, is applicable to entities that have not commenced planned principal operations. For public business entities, the removal of the development stage entity reporting requirements in ASC Topic 915, Development Stage Entities, and the clarification to the risks and uncertainties disclosure requirements in ASC Topic 275 are effective for annual and interim reporting periods beginning after December 15, 2014. In addition, ASU 2014-10 changes the current guidance in ASC Topic 810, Consolidation, in that it eliminates the exception provided to development stage entities for determining whether an entity is a variable interest entity on the basis of the amount of investment equity that is at risk. For public business entities, the revised consolidation standards are effective for annual and interim reporting periods beginning after December 15, 2015. Early adoption of ASU 2014-10 is permitted and we have elected to early adopt the provisions of ASU 2014-10 beginning with the interim reporting period ended June 30, 2014.

In June 2014, the FASB issued ASU No. 2014-12, Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period ("ASU 2014-12"). ASU 2014-12 requires that a performance target that affects vesting and could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in ASC Topic 718, Compensation — Stock Compensation, as it relates to such awards. ASU 2014-12 is effective for annual and interim periods beginning after December 15, 2015. Early adoption is permitted. The changes in ASU 2014-12 may be applied either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter, with the cumulative effect of applying ASU 2014-12 as of the beginning of the earliest annual period presented in the financial statements being recognized as an adjustment to the opening retained earnings balance at that date. We anticipate using the prospective method to apply ASU 2014-12. We do not currently have any outstanding share-based payment awards with performance targets and do not expect adoption of this standard will have a significant impact on our consolidated financial position, results of operation or other comprehensive income/loss or cash flows.

In July 2013, the FASB issued ASU No. 2013-11, Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists ("ASU 2013-11"). This standard requires an unrecognized tax benefit related to a net operating loss carryforward, a similar tax loss or a tax credit carryforward to be presented as a reduction to a deferred tax asset, unless the tax benefit is not available at the reporting date to settle any additional income taxes under the tax law of the applicable tax jurisdiction. ASU 2013-11 is effective for fiscal years and interim periods beginning after December 15, 2013. We adopted this guidance effective January 1, 2014. Our adoption of this standard did not have a significant impact on our consolidated financial position, results of operations and other comprehensive income/loss or cash flows.

12. 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, 2014 and 2013 are as follows:

	Nine months ended September 30,	
	2014	2013
Supplemental disclosures of non-cash investing and financing activities:		
Issuance of common stock for acquisitions	3,270,000	250
Assumptions of liabilities in acquisitions	1,069,297	—
Unrealized loss on investment securities	3,939	26,528
Purchases of property and equipment in accounts payable	—	99,875
Financing costs in accounts payable and accrued liabilities	—	116,336

13. Stockholders' Equity

"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" equity offering program (the "ATM program"), under which Cowen acts as sales agent. As of September 30, 2014, we had sold and issued an aggregate of 19,694,346 shares at a weighted-average sales price of $0.75 per share under the ATM program for aggregate gross proceeds of $14.8 million and $14.0 million in net proceeds, after deducting sales agent commission and discounts and our other offering costs.

Underwritten Public Offering of Common Stock and Warrants

In June 2013, we completed an underwritten public offering of 56,195,000 shares of our common stock and warrants to purchase up to 28,097,500 additional shares of our common stock. These securities were offered and sold to the underwriters and the public in units with each unit consisting of one share of common stock and one warrant to purchase up to 0.5 of a share of common stock. The gross proceeds from this financing were $28.1 million and, after deducting underwriting discounts and commissions and our other offering expenses, our net proceeds were $25.7 million. We may receive up to $18.3 million of additional proceeds from the exercise of the warrants issued in the financing. The exercise price of the warrants is $0.65 per share. Subject to certain beneficial ownership limitations, the warrants are exercisable at any time on or before June 19, 2018.

Shares Issuable to Former SynthRx Stockholders Upon Achievement of Milestones

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

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

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Outstanding Warrants

At September 30, 2014, outstanding warrants to purchase shares of common stock are as follows:

Shares Underlying Outstanding Warrants	Exercise Price	Expiration Date
144,000	$ 5.875	October 2014
216,000	$ 3.670	October 2014
409,228	$ 3.440	April 2015
1,062,500	$ 1.000	April 2015
1,816,608	$ 3.650	May 2015
2,046,139	$ 2.750	January 2016
10,625,000	$ 1.100	November 2016
28,097,400	$ 0.650	June 2018
44,416,875		

During the nine months ended September 30, 2014, warrants to purchase 168,957 shares of common stock expired.

14. Facilities Lease

In June 2014, we entered into a sublease agreement for approximately 13,700 square feet of office space that we will use as our corporate headquarters in San Diego, California. The subleased premises will replace our current headquarters, the sublease for which will expire in January 2015. The term of the new sublease commences on February 1, 2015 and expires on May 31, 2020. However, we will be given access to the subleased premises on October 1, 2014 to make certain improvements and, if we choose to begin operating our business there before February 1, 2015, the term of the new sublease will commence on such earlier date, with the expiration date remaining the same. In July 2014, we made a payment of $300,000, up to approximately $169,400 of which will be applied to our monthly base rent for months 13, 16, 19 and 24 of the sublease term, subject to certain conditions. The remaining $130,600 will be held by the landlord as a security deposit. We also paid the first month’s rent of $41,121 in July 2014.

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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, 2013, filed with the U.S. Securities and Exchange Commission, or SEC, on March 26, 2014, 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 I of our annual report on Form 10-K for the year ended December 31, 2013. 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 MST-188, our lead product candidate. MST-188 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 damaged cell membranes. Earlier this year, we acquired Aires Pharmaceuticals and we are developing its lead product candidate, AIR001 (sodium nitrite) inhalation solution, in pulmonary hypertension associated with left heart disease.

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 $21.9 million for the nine months ended September 30, 2014. Our cash, cash equivalents, and investment securities were $43.1 million as of September 30, 2014.

We continue to focus our resources primarily on the development of MST-188. We believe that its pharmacologic effects support its development in a wide range of serious or life-threatening diseases and conditions and we intend to develop MST-188 in multiple clinical indications, both independently and through collaborations. Enrolling patients in EPIC, our ongoing pivotal phase 3 study of MST-188 in sickle cell disease, is one of our top priorities. We also are enrolling patients with acute limb ischemia in a phase 2 clinical study of MST-188 in combination with recombinant tissue plasminogen activator (rt-PA) to evaluate whether MST-188 improves effectiveness of thrombolytic therapy. In addition, we are planning to initiate a phase 2 study of MST-188 in patients with acute decompensated heart failure in the first half of 2015. Our MST-188 pipeline also includes preclinical development programs in stroke and resuscitation following major trauma (i.e., restoration of circulating blood volume and pressure).

In addition to MST-188, we are developing AIR001, sodium nitrite inhalation solution for intermittent inhalation via nebulizer, in pulmonary hypertension (PH) associated with left heart disease. We acquired AIR001 in February 2014 through our acquisition of Aires Pharmaceuticals, Inc. In September 2014, we reported top line results from a phase 2 study of AIR001, which we believe support further clinical development in PH, and announced clinical development plans for AIR001 in PH associated with left heart disease, or World Health Organization (WHO) Group 2 PH.

We anticipate that our cash, cash equivalents, and investment securities will be sufficient to fund our operations for at least the next 12 months. However, we have based this estimate on significant assumptions and we could utilize our available financial resources sooner than we currently expect. For example, we may pursue development activities for our product candidates at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our current financial resources will sustain us. We expect to incur significant and increasing losses for the next several years as we advance our product candidates through clinical studies and other development activities and seek regulatory approval for commercialization. We will need additional capital to support our planned operating activities. In addition, we may seek to expand our product pipeline through acquisition of additional product candidates and/or technologies. Our capital requirements likely will increase in future periods if we determine to conduct studies of our product candidates in addition to those currently planned or to expand the scope of a planned study, if we determine to pursue clinical development of our product candidates in additional indications without a partner, or if we determine to 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 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.

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, which represented approximately 5% of our outstanding common stock as of the acquisition date.

Critical Accounting Policies and Significant Judgments and Estimates

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

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

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

- fees paid to contract research organizations, or CROs, in connection with clinical studies;
- fees paid to investigative sites and investigators in connection with clinical studies;
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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 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 in the future may have a material impact on our consolidated results of operations or financial position.

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

Goodwill and Acquired IPR&D. In accordance with ASC Topic 350, Intangibles – Goodwill and Other, or ASC Topic 350, our goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying value may be impaired. We perform our annual impairment testing as of September 30 of each year. 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 is not related to 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.

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, including process development activities, 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 U.S. 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:

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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;

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·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.

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. Transaction-related expenses also include the changes in the fair value of the contingent asset and contingent liability related to our acquisition of SynthRx, which we remeasured as of the end of each quarter until the contingent arrangement was settled.

Other Income/(Expense), Net. Other income/(expense), net includes the bargain purchase gain related to the acquisition of Aires, 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, 2014 and 2013

Revenue. We recognized no revenue for the three months ended September 30, 2014 and 2013.

R&D Expenses. Our R&D expenses for the three months ended September 30, 2014 consisted primarily of external costs associated with the EPIC study and our phase 2 study of MST-188 in acute limb ischemia, or ALI. 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:

	Three months ended September 30,			
	2014	%	2013	%
External clinical study fees and expenses	$3,167,943	59 %	$1,604,131	52 %
External nonclinical study fees and expenses	961,716	18 %	816,759	26 %
Personnel costs	1,047,718	19 %	634,338	20 %
Share-based compensation expense	224,284	4 %	47,012	2 %
Total	$5,401,661	100%	$3,102,240	100%

R&D expenses increased by $2.3 million, or approximately 74.1%, to $5.4 million for the three months ended September 30, 2014, compared to $3.1 million for the same period in 2013. This increase was due primarily to a $1.6 million increase in external clinical study fees and expenses, a $0.4 million increase in personnel costs, a $0.2 million increase in share-based compensation expense and a $0.1 million increase in external nonclinical study fees and expenses.

The $1.6 million increase in external clinical study fees and expenses was due primarily to an increase of $1.1 million related to the EPIC study, an increase of $0.3 million related to our phase 2 study of MST-188 in ALI, and an increase of $0.1 million related to the wind-down of the phase 2 studies of AIR001 in pulmonary arterial hypertension (PAH). The increase in personnel costs resulted primarily from severance expenses related to the departure of Dr. Vetticaden, the Company's former Chief Medical Officer.

SG&A Expenses. SG&A expenses increased by $0.3 million, or approximately 13.7%, to $2.5 million for the three months ended September 30, 2014, compared to $2.2 million for the same period in 2013. This increase resulted primarily from an increase in personnel costs.

Transaction-Related Expenses. Transaction-related expenses for the three months ended September 30, 2014 and 2013, respectively, were negligible.

Other Income/(Expense), Net. Other income/(expense), net for the three months ended September 30, 2014 and 2013, respectively, were negligible.

Net Loss. Net loss was $7.9 million, or $0.06 per share, for the three months ended September 30, 2014, compared to net loss of $5.3 million, or $0.05 per share, for the same period in 2013.

Comparison of Nine Months Ended September 30, 2014 and 2013

Revenue. We recognized no revenue for the nine months ended September 30, 2014 and 2013.

R&D Expenses. Our R&D expenses for the nine months ended September 30, 2014 consisted primarily of external costs associated with the EPIC study, our phase 2 study of MST-188 in ALI, research-related manufacturing for MST-188 and the wind-down of the AIR001 studies in PAH. 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:

	Nine months ended September 30,			
	2014	%	2013	%
External clinical study fees and expenses	$8,397,086	58 %	$5,735,658	61 %
External nonclinical study fees and expenses	3,057,790	21 %	1,813,549	20 %
Personnel costs	2,687,163	19 %	1,707,780	18 %
Share-based compensation expense	360,561	2 %	125,100	1 %
Total	$14,502,600	100%	$9,382,087	100%

R&D expenses increased by $5.1 million, or approximately 54.6%, to $14.5 million for the nine months ended September 30, 2014, compared to $9.4 million for the same period in 2013. This increase was due primarily to a $2.7 million increase in external clinical study fees and expenses, a $1.2 million increase in external nonclinical study fees and expenses, a $1.0 million increase in personnel costs and a $0.2 million increase in share-based compensation expense.

The $2.7 million increase in external clinical study fees and expenses was due primarily to an increase of $2.7 million related to the EPIC study, an increase of $1.0 million related to our phase 2 study of MST-188 in ALI, and an increase of $0.8 million related to the wind-down of the AIR001 studies in PAH, offset by a decrease of $1.8 million related to the thorough QT/QTc clinical study of MST-188 that we completed in 2013. The $1.2 million increase in external nonclinical study fees and expenses is primarily due to an increase of $0.9 million in research-related manufacturing costs for MST-188 and an increase of $0.3 million for research-related manufacturing costs for the wind-down of the AIR001 studies in PAH. The increase in personnel costs resulted primarily from additional clinical and research-related manufacturing staff hired after the first half of 2013 and severance expenses related to the departure of Dr. Vetticaden.

SG&A Expenses. SG&A expenses increased by $0.7 million, or approximately 11.3%, to $7.1 million for the nine months ended September 30, 2014, compared to $6.4 million for the same period in 2013. This increase resulted primarily from an increase in personnel costs and consulting expenses.

Transaction-Related Expenses. Transaction-related expenses were $0.3 million for the nine months ended September 30, 2014 compared to $35,000 for the nine months ended September 30, 2013. Transaction-related expenses for the nine months ended September 30, 2014 consisted primarily of legal fees associated with the acquisition of Aires. We recognized transaction-related expenses for the nine months ended September 30, 2013 as a

result of an increase in the fair value of the contingent liability related to the consideration for our acquisition of SynthRx at its settlement date, May 30, 2013, relative to December 31, 2012, which increase was due to the increase in our stock price at the settlement date ($0.71 per share) relative to December 31, 2012 ($0.57 per share).

Other Income/(Expense), Net. Other income/(expense), 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. Other income/(expense), net for the nine months ended September 30, 2013 was negligible.

Net Loss. Net loss was $21.4 million, or $0.19 per share, for the nine months ended September 30, 2014, compared to net loss of $15.8 million, or $0.23 per share, for the same period in 2013.

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, 2014, we incurred a loss from operations of $21.9 million. Our cash, cash equivalents and investment securities were $43.1 million as of September 30, 2014. Our investment securities at September 30, 2014 consisted entirely of FDIC-insured certificates of deposit.

We historically have funded our operations principally through proceeds from sales of our equity securities. In June 2013, we completed an underwritten public offering involving the issuance of units consisting of 56,195,000 shares of our common stock and warrants to purchase 28,097,500 shares of our common stock. The warrants have an exercise price of $0.65 per share and, subject to certain beneficial ownership limitations, are exercisable at any time on or before June 19, 2018. This financing resulted in $28.1 million in gross proceeds and $25.7 million in net proceeds, after deducting underwriting discounts and commissions and our other offering expenses.

We may receive up to $0.8 million, $6.6 million, $5.6 million, $11.7 million and $18.3 million of additional net proceeds from the exercise of warrants issued in the registered direct equity financings we completed in October 2009, May 2010 and January 2011 and the underwritten public offerings we completed in November 2011 and June 2013, 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 $3.67, $3.65, $2.75, $1.10 and $0.65 per share, respectively. In comparison, the closing sale price of our common stock on September 30, 2014 was $0.56 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” equity offering program, or ATM program, under which Cowen acts as sales agent. During the three months ended September 30, 2014, we received gross proceeds of $2.3 million through the ATM program. As of September 30, 2014, in the aggregate since we commenced the ATM program, we had sold and issued 19,694,346 shares at a weighted-average sales price of $0.75 per share under the ATM program for aggregate gross proceeds of $14.8 million and $14.0 million in net proceeds, after deducting sales agent commission and discounts and our other offering costs.

In June 2014, we entered into a sublease agreement for approximately 13,700 square feet of office space that we will use as our corporate headquarters in San Diego, California. The term of the sublease of our current headquarters expires in January 2015. The term of the new sublease will commence on February 1, 2015 and expire on May 31, 2020. However, we have the option to begin operating our business at the new premises as early as October 2014 and, if we choose to do so, the term of the new sublease will commence on such earlier date, with the expiration date remaining the same. We made a payment of $300,000, up to approximately $169,400 of which will be applied to our monthly base rent for months 13, 16, 19 and 24 of the sublease term, provided that we are not in default of the sublease. The remaining $130,600 will be held by the landlord as a security deposit. We have also paid the first month’s rent of $41,121 and monthly base rent following sublease commencement will be $41,121, subject to annual increases of 3.0% during the sublease term. However, monthly base rent for months 2 and 3 and one-third of month 3, or a total of approximately $95,900, will be abated. In addition to base rent, annually we will pay an amount equal to our proportional share of real estate taxes and certain standard operating expenses that are in excess of the amount of such taxes and expenses associated with the subleased premises for 2015.

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

Operating activities. 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, a net increase of $1.7 million due to changes in assets and liabilities, and depreciation and amortization of $0.1 million, offset by a gain on bargain purchase of $0.5 million. Net cash used in operating activities was $12.9 million for the nine months ended September 30, 2013 and consisted primarily of a net loss of $15.8 million adjusted for non-cash items, including share-based compensation expenses of $1.2 million and a net increase of $1.6 million due to changes in assets and liabilities.

Investing activities. Net cash provided by investing activities was $4.9 million for the nine months ended September 30, 2014 compared to net cash used in investing activities of $5.2 million for the same period in 2013. The difference of $10.1 million was due primarily to a decrease of $6.9 million in purchases of certificates of deposit and $3.5 million in cash obtained in our acquisition of Aires.

Financing activities. 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. Net cash provided by financing activities was $25.9 million for the nine months ended September 30, 2013, representing the gross proceeds from the underwritten public offering of our equity securities completed during that period, less the underwriting discount and offering expenses paid during the period. We paid an additional $0.2 million in offering expenses during the fourth quarter of 2013, resulting in $25.7 million of net proceeds from the offering.

Management Outlook

We anticipate that our cash, cash equivalents and investment securities as of September 30, 2014 will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, our estimate of the period of time through which our current financial resources will be adequate to support our operations is a forward-looking statement based on significant assumptions that involve a number of risks and uncertainties and actual results could differ materially. Factors that will affect our future capital requirements include, but are not limited to: the progress and results of our clinical and nonclinical studies of our product candidates, particularly the EPIC study, the phase 2 study of MST-188 in acute limb ischemia, and our planned phase 2 study of MST-188 in heart failure; the design and timing of initiation of the planned phase 2 study of MST-188 in heart failure; the number and nature of indications and jurisdictions in which we pursue development and regulatory approval of our product candidates, and the extent to which we do so independently or through collaborations; the rate of progress and costs of development and regulatory approval activities associated with our product candidates, including expenses related to initiating and conducting clinical studies and research-related manufacturing; the extent to which we increase or decrease our workforce; the extent to which we seek to commercialize and sell one or more of our product candidates, if approved, independently or through collaborations; the costs and timing of establishing commercial manufacturing supply arrangements for our product candidates and establishing or acquiring sales and distribution capabilities for any approved products; 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.

MST-188

We are focusing our resources primarily on development of MST-188. In 2013, we initiated the EPIC study and enrolling subjects in that study is one of our top priorities. We expect to enroll 388 subjects in the study from approximately 70 medical centers within and outside the U.S. We have opened 50 U.S. study sites and more than ten study sites outside of the U.S. More than half of the EPIC study sites have enrolled at least one patient. Although predicting the rate of enrollment for EPIC is subject to a number of significant assumptions and the actual rate may differ materially, we expect to complete enrollment by the end of 2015. We estimate that external clinical study fees and expenses from October 2014 through completion of the EPIC study will be approximately $17 million.

In addition to enrolling subjects in EPIC, we are conducting other activities to evaluate MST-188's potential in sickle cell disease. During the second quarter of 2014, we began enrolling EPIC patients at select U.S. study sites in a sub-study that will investigate and quantify the effect of MST-188 on tissue oxygenation using non-invasive methods, and evaluate the relationship between tissue oxygenation and clinical outcomes, such as the duration of vaso-occlusive crisis. We believe that data from the EPIC sub-study, together with data from an earlier clinical study in which MST-188 significantly improved microvascular blood flow in patients with sickle cell disease and from nonclinical studies we are conducting or planning to conduct in parallel with the EPIC study, will provide insight into the potential for MST-188 to reduce end-organ damage and improve long-term outcomes for individuals with sickle cell disease. Further, while we are still in the planning process, we plan to initiate an open-label study in 2015 to expand our existing safety database regarding repeat exposure to MST-188. The study will enroll patients who have

completed the EPIC study. The estimated external clinical study fees and expenses to conduct the sub-study and the open-label extension study are included in the estimated cost of EPIC stated above.

We also are advancing our other MST-188 programs. Earlier this year, we initiated a phase 2 clinical study of MST-188 in combination with rt-PA. The study will enroll approximately 60 patients with acute lower limb ischemia from approximately 25 sites within and outside the U.S. and compare a high dose and low dose of MST-188 in combination with rt-PA against rt-PA alone. Based on increased investment of our human and financial resources in completing EPIC enrollment by the end of 2015, we now expect to complete enrollment of this phase 2 study in the second half of 2016. As noted above, predicting the rate of enrollment of a clinical study is necessarily subject to a number of significant assumptions and the actual rate may differ materially. We estimate that external clinical study fees and expenses from October 2014 through completion of this study will be approximately $4 million. If this phase 2 study in ALI demonstrates that MST-188 improves the “clot busting” activity of rt-PA, we believe it not only would progress development in that indication, but also generate interest in developing MST-188 in other manifestations of occlusive arterial disease, such as stroke. Therefore, in parallel to the phase 2 study in ALI, we are conducting nonclinical studies to evaluate MST-188’s potential in acute ischemic stroke, including its ability to expand the window in which rt-PA is effective and improve the therapeutic effect of rt-PA.

We also are evaluating MST-188's potential in heart failure, another area of significant unmet medical need. Acute decompensated heart failure is associated with high mortality and high hospital admission and readmission rates in patients older than 65 years. In contrast with current treatments, such as vasodilators and beta blockers, which are effective at reducing the symptoms of heart failure but may not directly improve heart function, MST-188 may preserve cardiac tissue and thereby directly improve heart contractility and function. Earlier this year, we announced positive results from a randomized, placebo-controlled, nonclinical study of MST-188 in a model of chronic heart failure. Encouraged by those results, we are planning to initiate a phase 2 study of MST-188 in patients with acute decompensated heart failure in the first half of 2015. While we are still in the planning process, we expect to conduct the study in two parts – a safety run-in (Part A) that evaluates multiple dosages of MST-188, followed by a larger phase (Part B) that evaluates the safety and efficacy of MST-188, including its effect on markers of cardiac injury (troponin) and wall stress (NT-proBNP), as well as clinical outcomes. We estimate that Part A will take approximately 12 months to enroll and that external clinical study fees and expenses for Part A will be approximately $3 million. We expect to incur research-related manufacturing expenses related to the planned study in the fourth quarter of 2014, but we do not expect the study otherwise will materially impact our 2014 R&D expenses.

In addition, we are evaluating MST-188's potential in resuscitation following major trauma (i.e., restoration of circulating blood volume and pressure). Earlier this year, we signed a Cooperative Research and Development Agreement with a branch of the U.S. military to evaluate the utility of MST-188 in nonclinical models of trauma of interest to the U.S. government. We expect preliminary studies to begin in the fourth quarter of 2014. If results are positive, we believe the U.S. government will be interested in further exploring the potential of MST-188 as a treatment following major trauma.

Finally, we are conducting or plan to conduct a number of other ex vivo, nonclinical in vivo and in vitro studies of MST-188 to further understand its pharmacologic effects and support our intellectual property positions. We are also conducting and plan to conduct additional research-related manufacturing activities.

In July 2014, we filed for patent protection covering various methods of using poloxamers, as well as what we believe is a novel composition of poloxamer material. We continue to evaluate new patent concepts and plan to file additional patent applications. For instance, we expect to develop a patent position around the safe use and/or optimal dosing of MST-188 and to use data from the EPIC study to support these patent claims.

AIR001

In September 2014, we reported positive preliminary data from a phase 2 study of AIR001 for the treatment of pulmonary arterial hypertension. Data are available from 29 patients who enrolled in the study before it was prematurely terminated by Aires due to Aires' capital constraints prior to our acquisition of the company. The data demonstrate improvements in hemodynamic parameters and exercise capacity and that AIR001 was well-tolerated. Consistent with findings from earlier studies of AIR001, the data support AIR001's potential as an agent that can have a positive effect on hemodynamic parameters in patients with pulmonary hypertension and we believe AIR001 may be uniquely suited to address the serious unmet need of patients with PH associated with left heart disease, or WHO Group 2 PH. Accordingly, we are supporting three institution-sponsored phase 2a studies of AIR001 in that patient population to evaluate: (1) acute hemodynamic effects of AIR001, (2) acute effects versus placebo on maximum oxygen consumption and exercise hemodynamics, and (3) inhaled versus intravenous administration of nitrite, as well as the safety of multiple doses of AIR001. We estimate that, from October 2014 through their respective completion, the combined external clinical study fees and expenses and external nonclinical study fees and expenses for these studies will be approximately $1 million.

In parallel with our independent development of MST-188 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, we do not anticipate that such capital alone will be sufficient to fund our operations through the successful development and commercialization of our product candidates. In addition, our capital requirements likely will increase in future periods as we progress development of our product candidates in currently planned indications and potentially pursue their development in additional indications. Further, our capital requirements would likely increase if we were to 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. Even though we were able to raise significant funds in the past through equity financings, adequate additional financing 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 11, “Recent Accounting Pronouncements,” of the Notes to the Condensed Consolidated Financial Statements (Unaudited) in this report for a discussion of recent accounting pronouncements and their effect, if any, on us.

Forward Looking Statements

This report, particularly in Part I, Item 2, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including, but not limited to, statements we make regarding our business strategy, expectations and plans, our objectives for future operations and our future financial position. When used in this report, the words “believe,” “may,” “could,” “would,” “will,” “estimate,” “continue,” “anticipate,” “plan,” “intend,” “expect,” “indicat expressions are intended to identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements we make regarding activities, timing and costs related to developing and seeking regulatory approval for our product candidates, including the nature, 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 sufficient liquidity to fund our currently planned level of 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 MST-188;
- 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;
- 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 MST-188 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 MST-188 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;

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- 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;
- healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent commercial success;
- undesirable side effects that our product candidates or products may cause;
- potential product liability exposure and, if successful claims are brought against us, liability for a product or product candidate;
- the extent to which we acquire new technologies and/or product candidates and our ability to integrate them successfully into our operations;
- our ability to maintain compliance with NYSE MKT continued listing standards and 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 I of our annual report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 26, 2014.

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, 2014. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of September 30, 2014 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

In the normal course of business, we may become subject to lawsuits and other claims and proceedings. Such matters are subject to uncertainty and outcomes are often not predictable with assurance.

Item 1A. Risk Factors

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

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

In February 2014, we acquired Aires Pharmaceuticals, Inc. through a merger transaction in exchange for shares of our common stock. Following a six-month "holdback" period and pursuant to the terms of the merger agreement, we issued an aggregate of 4,053,996 additional shares of our common stock to former stockholders of Aires, 4,000,340 of which we issued on September 4, 2014 and 53,656 of which we issued on September 15, 2014.

The securities described above were offered and sold by us in reliance upon exemptions from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act. Such securities were issued pursuant to Section 4(2) of the Securities Act, and/or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of the securities represented their intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to share certificates issued in these transactions. All recipients had adequate access to information about our company.

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: October 31, 2014 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	Filed Herewith	Incorporated by Reference Form	File/Film No.	Date Filed
10.1 #	Offer letter, dated September 29, 2014, to Edwin L. Parsley	X			
31.1	Certification of principal executive officer pursuant to Rule 13a-14(a)/15d-14(a)	X			
31.2	Certification of principal financial officer pursuant to Rule 13a-14(a)/15d-14(a)	X			
32.1±	Certification of principal executive officer and principal financial officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Taxonomy Extension Schema Document	X			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X			

#Indicates management contract or compensatory plan

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

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