

Mast Therapeutics, Inc.
Form 10-Q
November 04, 2013
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2013

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 No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

The number of shares outstanding of the registrant's common stock, \$0.001 par value per share, as of November 1, 2013 was 102,710,286.

Table of Contents**TABLE OF CONTENTS**

	Page
PART I <u>FINANCIAL INFORMATION</u>	1
Item 1. <u>Financial Statements (Unaudited)</u>	1
a. <u>Condensed Consolidated Balance Sheets as of September 30, 2013 and December 31, 2012</u>	1
b. <u>Condensed Consolidated Statements of Operations and Comprehensive Income/(Loss) for the three and nine months ended September 30, 2013 and 2012 and for the period from inception (June 12, 1996) through September 30, 2013</u>	2
c. <u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2013 and 2012 and for the period from inception (June 12, 1996) through September 30, 2013</u>	3
d. <u>Notes to Condensed Consolidated Financial Statements</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4. <u>Controls and Procedures</u>	22
PART II <u>OTHER INFORMATION</u>	22
Item 1. <u>Legal Proceedings</u>	22
Item 1A. <u>Risk Factors</u>	22
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	22
Item 3. <u>Defaults Upon Senior Securities</u>	22
Item 4. <u>Mine Safety Disclosures</u>	22
Item 5. <u>Other Information</u>	22
Item 6. <u>Exhibits</u>	23
<u>SIGNATURES</u>	24

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements****Mast Therapeutics, Inc. and Subsidiaries**

(A Development Stage Enterprise)

Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,231,154	\$ 22,500,440
Investment securities	19,131,616	14,010,962
Interest and other receivables	29,185	15,689
Prepaid expenses	542,423	646,571
Total current assets	49,934,378	37,173,662
Property and equipment, net	115,092	198,358
In-process research and development	6,549,000	6,549,000
Goodwill	3,006,883	3,006,883
Other assets	43,912	43,912
Total assets	\$ 59,649,265	\$ 46,971,815
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 794,674	\$ 698,838
Accrued liabilities	2,155,179	1,283,976
Accrued compensation and payroll taxes	1,026,888	445,352
Contingent liability		142,500
Total current liabilities	3,976,741	2,570,666
Deferred income tax liability	2,608,755	2,608,755
Total liabilities	6,585,496	5,179,421
Stockholders equity:		
Common stock, \$0.001 par value; 500,000,000 shares authorized; 102,710,286 and 47,719,365 shares issued at September 30, 2013 and December 31, 2012, respectively; 102,710,286 and 46,265,286 shares outstanding at September 30, 2013 and December 31, 2012, respectively	102,710	47,720

Edgar Filing: Mast Therapeutics, Inc. - Form 10-Q

Treasury stock, at cost 0 and 1,454,079 shares at September 30, 2013 and December 31, 2012, respectively		(1,454)
Additional paid-in capital	253,713,892	226,696,863
Accumulated other comprehensive loss	(28,722)	(2,194)
Deficit accumulated during the development stage	(200,724,111)	(184,948,541)
Total stockholders' equity	53,063,769	41,792,394
Total liabilities and stockholders' equity	\$ 59,649,265	\$ 46,971,815

See accompanying notes to unaudited condensed consolidated financial statements.

(1)

Table of Contents**Mast Therapeutics, Inc. and Subsidiaries**

(A Development Stage Enterprise)

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

(Unaudited)

	Three months ended		Nine months ended		Inception
	September 30,		September 30,		(June 12, 1996)
	2013	2012	2013	2012	through
					September 30, 2013
Revenues:					
Net sales	\$	\$	\$	\$	\$ 174,830
Licensing revenue					1,300,000
Grant revenue					618,692
Total net revenues					2,093,522
Cost of goods sold					51,094
Gross margin					2,042,428
Operating expenses:					
Research and development	3,102,240	1,657,902	9,382,087	5,976,217	95,439,543
Selling, general and administrative	2,158,417	1,816,181	6,371,048	5,732,478	74,037,760
Transaction-related expenses		(266,222)	35,000	(174,711)	706,652
Depreciation and amortization	10,064	10,638	28,738	77,569	11,053,973
Write-off of in-process research and development					10,422,130
Goodwill impairment					5,702,130
Equity in loss of investee					178,936
Total operating expenses	5,270,721	3,218,499	15,816,873	11,611,553	197,541,124
Loss from operations	(5,270,721)	(3,218,499)	(15,816,873)	(11,611,553)	(195,498,696)
Reduction of fair value of warrants					(12,239,688)
Interest income	17,327	18,347	42,638	56,300	4,874,846
Interest expense					(191,729)
Other income (expense), net	(137)	1,099	(1,335)	(7,480)	128,370
Loss before cumulative effect of change in accounting principle	(5,253,531)	(3,199,053)	(15,775,570)	(11,562,733)	(202,926,897)
Cumulative effect of change in accounting principle					(25,821)

Edgar Filing: Mast Therapeutics, Inc. - Form 10-Q

Net loss	(5,253,531)	(3,199,053)	(15,775,570)	(11,562,733)	(202,952,718)
Preferred stock dividends					(621,240)
Deemed dividends on preferred stock					(10,506,683)
Net loss applicable to common stock	\$ (5,253,531)	\$ (3,199,053)	\$ (15,775,570)	\$ (11,562,733)	\$ (214,080,641)
Net loss per common share and diluted	\$ (0.05)	\$ (0.07)	\$ (0.23)	\$ (0.24)	
Weighted average shares outstanding	102,710,286	47,715,709	67,781,879	47,715,709	
<u>Comprehensive Income/(Loss):</u>					
Net loss	\$ (5,253,531)	\$ (3,199,053)	\$ (15,775,570)	\$ (11,562,733)	\$ (202,952,718)
Other comprehensive gains (losses)	(19,884)	76	(26,528)	79	(28,722)
Comprehensive loss	\$ (5,273,415)	\$ (3,198,977)	\$ (15,802,098)	\$ (11,562,654)	\$ (202,981,440)

See accompanying notes to unaudited condensed consolidated financial statements.

(2)

Table of Contents**Mast Therapeutics, Inc. and Subsidiaries**

(A Development Stage Enterprise)

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Nine months ended		Inception
	September 30,		(June 12, 1996)
	2013	2012	through September 30, 2013
Cash flows from operating activities:			
Net loss	\$ (15,775,570)	\$ (11,562,733)	\$ (202,952,718)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	28,738	77,569	10,603,975
Loss on disposals of equipment		4,503	61,315
Loss on fair value of warrants			12,239,688
Loss/(gain) on change in fair value of contingent consideration	35,000	(174,711)	(1,493,907)
Amortization of debt discount			450,000
Forgiveness of employee receivable			30,036
Impairment loss write-off of goodwill			5,702,130
Share-based compensation expense related to employee stock options and restricted stock issued	1,159,021	1,073,872	12,708,345
Expenses related to options issued to non-employees			204,664
Expenses paid by issuance of common stock			1,341,372
Expenses paid by issuance of warrants			573,357
Expenses paid by issuance of preferred stock			142,501
Expenses related to stock warrants issued			612,000
Equity in loss of investee			178,936
In-process research and development			10,422,130
Write-off of license agreement			152,866
Impairment of equipment		300,114	510,739
Cumulative effect of change in accounting principle			25,821
Amortization of premium / (accretion of discount) on investments in securities		21,840	(1,571,502)
Changes in assets and liabilities, net of effect of acquisitions:			
Decrease/(increase) in prepaid expenses and other assets	90,500	(437,266)	(865,359)
Increase in accounts payable and accrued liabilities	1,533,636	127,484	3,828,814
Net cash used in operating activities	(12,928,675)	(10,569,328)	(147,094,797)

Cash flows from investing activities:			
Purchases of certificates of deposit	(19,407,030)	(13,581,000)	(43,390,209)
Proceeds from maturities of certificates of deposit	14,260,000	6,880,000	23,703,330
Proceeds from sale of certificate of deposit			248,000
Purchases of other investment securities			(111,183,884)
Proceeds from maturities and sales of other investment securities			113,036,378
Purchases of property and equipment	(45,348)	(210,909)	(1,782,152)
Proceeds from sale of property and equipment			66,920
Cash paid for acquisitions, net of cash acquired			32,395
Payment on obligation under license agreement			(106,250)
Issuance of note receivable - related party			(35,000)
Payments on note receivable			405,993
Advance to investee			(90,475)
Cash transferred in rescission of acquisition			(19,475)
Cash received in rescission of acquisition			230,000
Net cash used in investing activities	(5,192,378)	(6,911,909)	(18,884,429)

(3)

Table of Contents**Cash flows from financing activities:**

Proceeds from sale of common stock	28,097,500		151,756,371
Proceeds from exercise of stock options			714,561
Proceeds from sale or exercise of warrants			14,714,258
Proceeds from sale of preferred stock			44,474,720
Repurchase of Subject to Vesting Shares			(1,454)
Repurchase of warrants			(55,279)
Payments for financing and offering costs	(2,244,211)		(16,141,578)
Payments on notes payable and long-term debt			(605,909)
Proceeds from issuance of notes payable and detachable warrants			1,344,718
Cash paid in lieu of fractional shares for reverse stock split			(146)
Net cash provided by financing activities	25,853,289		196,200,262
Effect of exchange rate changes on cash	(1,522)		10,118
Net increase/(decrease) in cash and cash equivalents	7,730,714	(17,481,237)	30,231,154
Cash and cash equivalents at beginning of period	22,500,440	43,569,947	
Cash and cash equivalents at end of period	\$ 30,231,154	\$ 26,088,710	\$ 30,231,154

See accompanying notes to unaudited condensed consolidated financial statements.

(4)

Table of Contents

Mast Therapeutics, Inc. and Subsidiaries

(A Development Stage Enterprise)

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, 2012, filed with the SEC on March 19, 2013 (2012 Annual Report). The condensed consolidated balance sheet as of December 31, 2012 included in this report has been derived from the audited consolidated financial statements included in the 2012 Annual Report. In the opinion of management, these condensed consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any future period, including the full year.

We are a biopharmaceutical company focused on developing 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. 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 for diseases and conditions characterized by microcirculatory insufficiency.

In prior years, we were developing Exelbine and ANX-514, both of which are investigational oncology programs, but, beginning in 2012, we have focused our resources almost exclusively on development of MST-188.

In March 2013, we merged our wholly-owned subsidiary, Mast Therapeutics, Inc., with and into us and changed our name from ADVENTRX Pharmaceuticals, Inc. to Mast Therapeutics, Inc. The merger had no effect on our financial statements.

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 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 SynthRx

On February 12, 2011, we entered into an agreement and plan of merger (the Merger Agreement) to acquire SynthRx, Inc. (SynthRx), a privately-held Delaware corporation, in exchange for shares of our common stock as described below. The transaction was completed on April 8, 2011 and SynthRx became a wholly-owned subsidiary of Mast Therapeutics. As consideration for the transaction, all shares of SynthRx common stock outstanding immediately prior to the effective time of the merger were cancelled and automatically converted into the right to receive shares of our common stock, in the aggregate, as follows:

(i) 862,078 shares of our common stock, which were issued on April 8, 2011 (the Fully Vested Shares) and represent 1,000,000 shares less 137,922 shares that were deducted as a result of certain expenses of SynthRx;

(ii) up to 1,938,773 shares of our common stock (the Subject to Vesting Shares, and together with the Fully Vested Shares, the Closing Shares), which were issued on April 8, 2011 subject to various repurchase rights by us that were triggered based on the timing and circumstances of achievement of the First Milestone (defined below);

(iii) up to 1,000,000 shares of our common stock (the First Milestone Shares) issuable upon achievement of the First Milestone;

(5)

Table of Contents

(iv) 3,839,400 shares of our common stock (the **Second Milestone Shares**) issuable upon achievement of the Second Milestone (defined below); and

(v) 8,638,650 shares of our common stock (the **Third Milestone Shares**, and together with the First Milestone Shares and the Second Milestone Shares, the **Milestone Shares**) issuable upon achievement of the Third Milestone (defined below).

The **First Milestone** was defined in the Merger Agreement as the dosing of the first patient in a phase 3 clinical study of purified poloxamer 188 carried out pursuant to a protocol that is mutually agreed to by SynthRx and Mast Therapeutics; provided, however, that the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint shall not exceed 250 unless otherwise mutually agreed (the **First Protocol**). If the U.S. Food and Drug Administration (**FDA**) indicates that a single phase 3 clinical study will not be adequate to support approval of a new drug application covering the use of purified poloxamer 188 for the treatment of sickle cell crisis in children (the **188 NDA**), **First Milestone** shall mean the dosing of the first patient in a phase 3 clinical study carried out pursuant to a protocol that (a) is mutually agreed to by SynthRx and Mast Therapeutics as such and (b) describes a phase 3 clinical study that the FDA has indicated may be sufficient, with the phase 3 clinical study described in the First Protocol, to support approval of the 188 NDA. We considered the dosing of the first patient in the EPIC study, our phase 3 clinical trial of MST-188 in sickle cell disease, to be the First Milestone.

The Subject to Vesting Shares were issued subject to a repurchase option that provided us the right to repurchase up to approximately 75% of the Subject to Vesting Shares, or 1,454,079 shares, for \$0.001 per share based on the timing of achievement of the First Milestone and whether and the extent to which the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint exceeds 250 patients, unless otherwise agreed.

Under the Merger Agreement, the number of shares issuable upon achievement of the First Milestone was subject to reduction by up to 75%, or 750,000 shares, based on the timing of achievement of the First Milestone and whether and the extent to which the number of evaluable patients planned to target statistical significance with a p value of 0.01 in the primary endpoint exceeded 250 patients, unless otherwise agreed.

The **Second Milestone** means the FDA's acceptance of the 188 NDA for review, and the **Third Milestone** means the approval by the FDA of the 188 NDA. Although issuance of the Second Milestone Shares and the Third Milestone Shares is contingent upon achievement of the Second Milestone and Third Milestone, respectively, the number of shares issuable upon achievement of each of those milestones is fixed.

Based on the estimated fair value of the Closing Shares and the Milestone Shares as of April 8, 2011, the acquisition date, the total purchase price was approximately \$6.7 million.

Acquired In-Process Research and Development

Our acquired IPR&D was the estimated fair value as of the acquisition date of MST-188, which was SynthRx's lead product candidate. We determined that the estimated fair value of the MST-188 program was \$6.5 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 MST-188 program under the MPEEM, we used probability-weighted cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by development-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to MST-188 in sickle cell disease 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 the market exclusivity period estimated to be provided by orphan drug designation. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles substantially similar to that of SynthRx, which we believe represents the rate that market participants would use to value the assets. We compensated for the phase of development of this program by applying a probability factor to our estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, such as the time and resources needed to complete the development and approval of MST-188 in sickle cell disease, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in drug development, such as obtaining marketing approval from the FDA and other regulatory agencies, and risks related to the viability of and potential alternative treatments in any future target markets.

(6)

Table of Contents

We test our acquired IPR&D for impairment annually (and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying amount may be impaired) in accordance with Accounting Standards Codification (ASC) Topic 350, *Intangibles – Goodwill and Other* and Accounting Standards Update (ASU) No. 2012-02, *Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment*. We perform our annual indefinite-lived intangible assets impairment testing as of September 30 of each year. As of September 30, 2013, no impairment was noted.

Goodwill

A value of \$3.0 million, representing the difference between the total purchase price and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed, was recorded as goodwill. We acquired SynthRx to expand our product pipeline, enter into new therapeutic areas and address unmet market needs. These are among the factors that contributed to a purchase price for the SynthRx acquisition that resulted in the recognition of goodwill.

We test our goodwill for impairment annually (and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying amount may be impaired) in accordance with ASC Topic 350, *Intangibles – Goodwill and Other*, and ASU No. 2011-08, *Intangibles – Goodwill and Other (Topic 350): Testing Goodwill for Impairment*. We perform our annual goodwill impairment testing as of September 30 of each year and this year we elected to bypass the qualitative assessment and proceed directly to the two-step quantitative impairment test. Step 1 requires a comparison of the carrying value of a reporting unit, including goodwill, to its estimated fair value. We test for goodwill impairment at the entity level because we operate on the basis of a single reporting unit. In Step 1 of the two-step quantitative test, we compared our carrying value, including goodwill and acquired IPR&D, to estimated fair value. Estimated fair value of the entity included market values for our cash, cash equivalents and investment securities, as well as the estimated fair value of acquired IPR&D. We calculated the estimated fair value of acquired IPR&D by using the MPEEM. This method requires us to make long-term projections of revenues and expenses related to development and commercialization of MST-188 in sickle cell disease and assumptions regarding the rate of return on contributory assets, the weighted average cost of capital and the probability adjustment factor for estimated future after-tax cash flows. Through Step 1 of the impairment test, we concluded that, as of September 30, 2013, the fair value of the entity was substantially greater than its carrying value, and, therefore, goodwill was not considered impaired. We estimated fair value based on assumptions that we believe to be reasonable but that are highly judgmental due in part to the inherent unpredictability of drug development, particularly by a development-stage company.

Deferred Income Tax Liability

The \$2.6 million recorded for 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 end of year valuation allowance as the acquired IPR&D is considered to have an indefinite life until we complete or abandon development of MST-188.

Contingent Consideration

The Milestone Shares and 1,454,079 of the Subject to Vesting Shares were considered contingent consideration at the acquisition date because our obligation to issue the Milestone Shares and our repurchase rights with respect to 1,454,079 of the Subject to Vesting Shares were contingent on future events. To determine the classification of the fair value of this contingent consideration as a liability or equity, we reviewed ASC Topic 815-40, *Derivatives and Hedging – Contracts in Entity's Own Equity* (ASC 815-40), which requires that contingent consideration arrangements that include potential net cash settlements or variable provisions be classified as a liability (or an asset,

as applicable). Such classification requires a fair value measurement initially and subsequently at each reporting date. Changes in the fair value of contingent consideration classified as a liability or an asset are recognized in earnings until the contingent consideration arrangement is settled. Classification as equity requires fair value measurement initially and there are no subsequent re-measurements. Settlement of equity-classified contingent consideration is accounted for within equity.

The probability-weighted fair values of the Second Milestone Shares and the Third Milestone Shares were recorded as equity as there is no net cash settlement provision and the number of shares that ultimately may be issued upon achievement of each of those milestones is fixed. However, the probability-weighted fair value of the First Milestone Shares was recorded as a contingent liability and the probability-weighted fair value of 1,454,079 of the Subject to Vesting Shares was recorded as a contingent asset because there was variability with respect to the number of shares that we ultimately would be required to issue and repurchase, respectively, based on the circumstances of achievement of the First Milestone, as described above.

The contingent liability related to the First Milestone Shares was eliminated, or settled, in May 2013 with achievement of the First Milestone and our subsequent issuance of 250,000 of the First Milestone Shares. The contingent asset related to the 1,454,079 Subject to Vesting Shares was settled in December 2012 by our exercise in full of our repurchase option and purchase of the 1,454,079 shares from the former SynthRx stockholders for \$0.001 per share. In accordance with ASC 815-40, we remeasured the contingent liability and contingent asset as of their respective settlement dates.

(7)

Table of Contents**4. Investment Securities**

Investment securities are marketable equity or debt securities. All of our investment securities are available-for-sale securities and carried at fair value. Fair value for securities with short maturities and infrequent secondary market trades typically is determined by using a curve-based evaluation model that utilizes quoted prices for similar securities. The evaluation model takes into consideration the days to maturity, coupon rate and settlement date convention. Net unrealized gains or losses on these securities are included in accumulated other comprehensive loss, which is a separate component of stockholders' equity. Realized gains and realized losses are included in other income/(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, 2013, \$2.5 million 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, 2013, the fair value of our investment securities was \$19,131,616. The cost basis of such investments was \$19,158,030 and our net unrealized losses were \$26,414.

5. Fair Value of Financial Instruments

Our investment securities are and, prior to its settlement, our contingent liability was 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 quoted prices for similar items in active markets or quoted prices for identical or similar items in markets that are not active; 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 value at September 30, 2013 of our investment securities is summarized in the following table:

	Total Fair Value	September 30, 2013		
		Fair Value Determined Under:		
		(Level 1)	(Level 2)	(Level 3)
Investment securities	\$ 19,131,616	\$	\$ 19,131,616	\$

The contingent liability was settled in May 2013. A reconciliation of the contingent liability for the nine months ended September 30, 2013 is as follows:

**Nine months ended
September 30, 2013**

Edgar Filing: Mast Therapeutics, Inc. - Form 10-Q

Balance at December 31, 2012	\$	(142,500)
Settlements		177,500
Total net losses included in earnings		(35,000)
Balance at September 30, 2013	\$	0

The fair value of the contingent liability was measured and recorded on a recurring basis using significant unobservable inputs (Level 3). At each remeasurement date until the contingent arrangement was settled, we determined the fair value of the contingent liability based on the market price of our common stock on the measurement date and our estimate of the number of First Milestone Shares we would issue, which was based on our estimate of the probability of achievement of the First Milestone and assumptions regarding the circumstances under which it would be achieved. As discussed in Note 3, the contingent liability was settled in May 2013 and we issued 250,000 of the First Milestone Shares.

(8)

Table of Contents**6. 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.

In connection with our determination in 2012 to discontinue independent development of ANX-514, we assessed the classification and recoverability, at the end of each fiscal quarter, of certain equipment held and used in research and development-related manufacturing of ANX-514 (the ANX-514 equipment) by our contract manufacturer. The original cost of the ANX-514 equipment was \$0.6 million. We determined, based on an independent appraisal, that the carrying amount of the ANX-514 equipment exceeded its estimated fair value and was not recoverable. For the year ended December 31, 2012, we recorded an impairment loss of \$0.4 million, which was the difference between the carrying amount and estimated fair value at December 31, 2012, as a research and development expense in our consolidated statement of operations and comprehensive income/(loss). The ANX-514 equipment was not classified separately as held for sale as of December 31, 2012 because the criteria for that classification, as set forth in ASC Topic 360-10, *Property, Plant and Equipment - Overall*, were not met.

In April 2013, in connection with reaching an agreement with our contract manufacturer regarding final payment for ANX-514 research-related manufacturing activities, we agreed to assign ownership of the ANX-514 equipment with a carrying amount of \$99,875 to the contract manufacturer.

7. Accrued Liabilities

Accrued liabilities at September 30, 2013 and December 31, 2012 were as follows:

	September 30, 2013	December 31, 2012
Accrued contracts and study expenses	\$ 1,829,235	\$ 1,203,808
Other accrued liabilities	325,944	80,168
Total accrued liabilities	\$ 2,155,179	\$ 1,283,976

8. 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, 2013 and 2012 was as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Selling, general and administrative expense	\$ 395,316	\$ 338,447	\$ 1,033,921	\$ 1,036,373
Research and development expense	47,012	21,096	125,100	37,499
Share-based compensation expense	\$ 442,328	\$ 359,543	\$ 1,159,021	\$ 1,073,872

During the nine months ended September 30, 2013, the only equity awards granted to our employees and non-employee directors were stock option awards. The following table summarizes such equity award activity:

	Shares Underlying Option Awards	Weighted- Average Exercise Price
Outstanding at December 31, 2012	3,585,743	\$ 2.31
Granted	3,765,504	\$ 0.51
Exercised		\$
Cancelled/forfeited/expired	(203,144)	\$ 0.74
Outstanding at September 30, 2013	7,148,103	\$ 1.41

(9)

Table of Contents

At September 30, 2013, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was \$3.0 million, which is expected to be recognized over a weighted-average period of 2.9 years.

9. Net Loss Per Common Share

Basic and diluted net loss per common share was calculated by dividing the net loss applicable to common stock for the three and nine months ended September 30, 2013 and 2012 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,	
	2013	2012	2013	2012
Options	7,190,672	3,120,646	5,242,471	2,949,056
Warrants	44,585,932	16,652,811	27,192,242	17,296,389

10. Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board (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, with early adoption permitted. We do not believe that the adoption of this standard will have an impact on our consolidated financial position, results of operations or cash flows.

In February 2013, FASB issued ASU No. 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* (ASU 2013-02). This standard requires companies to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, companies are required to present, either on the face of the statement where net income is presented or in the accompanying notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income, but only if the amount reclassified is required to be reclassified to net income in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, companies are required to cross-reference to other disclosures that provide additional detail on those amounts. ASU 2013-02 is effective prospectively for reporting periods beginning after December 15, 2012. We adopted this guidance effective January 1, 2013. 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. There were no realized gains or losses on marketable securities in the three months ended September 30, 2013.

In December 2011, FASB issued ASU 2011-11, *Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities* (ASU 2011-11). ASU 2011-11 requires companies to provide new disclosures about offsetting and related

arrangements for financial instruments and derivatives. The provisions of ASU 2011-11 are effective for annual reporting periods beginning on or after January 1, 2013, and must be applied retrospectively. We adopted this guidance effective January 1, 2013. The 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.

(10)

Table of Contents**11. 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, 2013 and 2012 and for the period from inception (June 12, 1996) through September 30, 2013 are as follows:

	Nine months ended		Inception (June 12, 1996)
	September 30, 2013	2012	through September 30, 2013
Supplemental disclosures of cash flow information:			
Interest paid	\$	\$	\$ 180,719
Supplemental disclosures of non-cash investing and financing activities:			
Issuance of warrants, common stock and preferred stock for:			
Conversion of notes payable and accrued interest			1,213,988
Prepaid services to consultants			1,482,781
Conversion of preferred stock			13,674
Acquisitions			30,666,878
Issuance of common stock to pay dividends			213,000
Financial advisor services in conjunction with financings			3,477,571
Underwriter commissions in conjunction with financings			766,784
Acquisition of treasury stock in settlement of a claim			34,737
Cancellation of treasury stock			(34,737)
Assumptions of liabilities in acquisitions			1,531,806
Fair value of contingent liabilities, net of contingent assets, recorded at acquisition date			784,419
Issuance of common stock for milestone achievement	250		250
Acquisition of license agreement for long-term debt			161,180
Unrealized loss/(gain) on investment securities	26,528	(79)	26,566
Disposal of equipment in conjunction with settlement of a liability	99,875		99,875
Cashless exercise of warrants			4,312
Dividends accrued			621,040
Trade asset converted to available-for-sale asset			108,000
Dividends extinguished			408,240
Trade payable converted to note payable			83,948
Issuance of warrants for return of common stock			50,852
Detachable warrants issued with notes payable			450,000
Cumulative preferred stock dividends			13,502,403

Purchases of property and equipment in accounts payable		22,966
Financing costs in accounts payable and accrued liabilities	116,336	116,336

12. Stockholders Equity

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. Of the 56,195,000 shares of our common stock issued, 1,454,079 of such shares were issued from our treasury 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.

(11)

Table of Contents***Outstanding Warrants***

At September 30, 2013, outstanding warrants to purchase shares of common stock are as follows:

Shares Underlying

Outstanding Warrants	Exercise Price	Expiration Date
99,696	\$ 11.9125	June 2014
36,071	\$ 3.7500	June 2014
19,007	\$ 4.4750	July 2014
14,183	\$ 4.0625	August 2014
144,000	\$ 5.8750	October 2014
216,000	\$ 3.6700	October 2014
409,228	\$ 3.4400	April 2015
1,062,500	\$ 1.0000	April 2015
1,816,608	\$ 3.6500	May 2015
2,046,139	\$ 2.7500	January 2016
10,625,000	\$ 1.1000	November 2016
28,097,500	\$ 0.6500	June 2018
44,585,932		

(12)

Table of Contents**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, 2012, filed with the U.S. Securities and Exchange Commission, or SEC, on March 19, 2013, 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 could differ materially from those discussed in these forward-looking statements as a result of various factors, including but not limited to those identified under Forward Looking Statements below and those discussed in Item 1A (Risk Factors) of Part II of our quarterly report on Form 10-Q for the period ended June 30, 2013, filed with the SEC on August 5, 2013. Mast Therapeutics, our corporate logo, SynthRx® and Exelbine are trademarks of our company. All trademarks, service marks or trade names appearing in this report are the property of their respective owners. Use or display by us of other parties' trademarks, service marks or trade names is not intended to and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark, service mark or trade name owners.

Overview

We are a biopharmaceutical company developing 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, for diseases and conditions characterized by microcirculatory insufficiency (endothelial dysfunction and/or impaired blood flow).

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 \$15.8 million for the nine months ended September 30, 2013. Our cash, cash equivalents and investment securities were \$49.4 million as of September 30, 2013.

We continue to focus our resources on MST-188. We believe that its pharmacologic effects support its development in a wide range of diseases and conditions and we intend to develop MST-188 in multiple clinical indications, both independently and through collaborations. Earlier this year, we initiated the EPIC study, a pivotal phase 3 study of MST-188 in sickle cell disease, and enrolling subjects in that study is one of our top priorities. In addition to sickle cell disease, our MST-188 pipeline includes development programs in adjunctive thrombolytic therapy (e.g., acute limb ischemia, stroke), heart failure, and resuscitation (i.e., restoration of circulating blood volume and pressure) following major trauma.

In July 2013, we announced that our thorough QT/QTc clinical study of MST-188, or the TQT study, met its primary endpoint and demonstrated that, based on analysis of electrocardiograms, MST-188 did not have an adverse effect on cardiac repolarization, as measured by prolongation of the QT interval. Sixty four subjects received MST-188 and it was generally well-tolerated at both therapeutic and suprathreshold doses.

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 faster than we currently expect. For example, we may pursue development activities for

MST-188 in sickle cell disease and multiple other indications 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 MST-188 through clinical studies and other development activities and seek regulatory approval to commercialize it. 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. We expect that our capital requirements would increase in future periods if we determine to conduct studies of MST-188 in addition to those currently planned or pursue its development in additional indications or if we determine to expand our product pipeline with 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 financing 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.

(13)

Table of Contents

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 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 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;

fees paid to consultants for regulatory-related advisory services;

fees paid to contract research organizations, or CROs, in connection with clinical studies; and

fees paid to investigative sites and investigators in connection with clinical studies.

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

Goodwill and Acquired IPR&D. In accordance with ASC Topic 350, *Intangibles – Goodwill and Other*, 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 on 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. 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 MST-188 or our overall business strategy, and regulatory, market and economic environment and trends.

Table of Contents

Property and Equipment, Net. 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 is generally 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.

In accordance with ASC Topic 360-10, *Property, Plant and Equipment* Overall, we test for recoverability of long-lived assets, including property and equipment, if events or changes in circumstances indicate that the carrying amount for the assets may not be recoverable. If our assessment indicates impairment, we measure the impairment loss as the amount by which the carrying amount exceeds fair value of the assets. Fair value determinations are based on an undiscounted cash flow model, or independent appraisals, as appropriate.

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, the risk-free interest rate and estimated forfeiture 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 began maintaining such expenses by type on January 1, 2005. We categorize our R&D expenses as external clinical study fees and expenses, external nonclinical study fees and expenses, personnel costs and share-based compensation expense. The major components of our external clinical study fees and expenses are fees and expenses related to CROs and clinical study investigative sites and investigators. The major components of our external nonclinical study

fees and expenses are fees and expenses related to preclinical studies and other nonclinical testing, research-related manufacturing, quality assurance and regulatory affairs services. Research-related manufacturing expenses include costs associated with 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.

(15)

Table of Contents

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 product candidate in a particular indication and the extent to which we develop the product candidate with a partner or independently. At this time, due to such uncertainties and the risks inherent in product development and the associated regulatory process, we cannot estimate with 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 those associated with clinical studies and research-related manufacturing, can vary significantly among programs as a result of a variety of factors, including:

the number of clinical and nonclinical studies necessary to demonstrate the safety and efficacy of a product candidate in a particular indication;

the number of patients who participate in each clinical study;

the number and location of sites included and the rate of site approval in each clinical study;

the rate of patient enrollment and ratio of randomized to evaluable patients in each clinical study;

the duration of patient treatment and follow-up;

the potential additional safety monitoring or other studies requested by regulatory agencies;

the time and cost to manufacture clinical trial material and commercial product, including process development and scale-up activities, and to conduct stability studies, which can last several years;

the availability and cost of comparative agents used in clinical studies;

the timing and terms of any collaborative or other strategic arrangements that we may establish; and

the cost, requirements, timing of and the ability to secure regulatory approvals.

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

While many of our R&D expenses are transacted in U.S. dollars, certain expenses are required to be paid in foreign currencies and expose us to transaction gains and losses that could result from changes in foreign currency exchange rates. In particular, we may be obligated to pay in foreign currencies for the services of third-party manufacturers of and component suppliers for our product candidates. Our exposure to currency risk may increase in connection with the manufacture of product for commercial sale, if and as we obtain the regulatory approvals necessary to market our product candidates. We include realized gains and losses from foreign currency transactions in operations as incurred.

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 acquisition of SynthRx. Transaction-related expenses also include any changes in the fair value of the contingent consideration related to our acquisition of SynthRx, which we remeasured as of the end of each quarter until the contingent arrangements were settled and as of their respective settlement dates.

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

Table of Contents**Comparison of Three Months Ended September 30, 2013 and 2012**

Revenue. We recognized no revenue for the three months ended September 30, 2013 or 2012.

R&D Expenses. Our R&D expenses for the three months ended September 30, 2013 consisted primarily of external costs associated with the EPIC study and research-related manufacturing activities for MST-188. 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,				January 1, 2005
	2013	%	2012	%	through September 30, 2013
External clinical study fees and expenses	\$ 1,604,131	52%	\$ 277,430	17%	\$ 31,833,157
External nonclinical study fees and expenses	816,759	26%	753,213	45%	37,969,586
Personnel costs	634,338	20%	606,163	37%	15,062,226
Share-based compensation expense	47,012	2%	21,096	1%	3,100,321
Total	\$ 3,102,240	100%	\$ 1,657,902	100%	\$ 87,965,290

R&D expenses increased by \$1.4 million, or approximately 87.1%, to \$3.1 million for the three months ended September 30, 2013, compared to \$1.7 million for the same period in 2012. This increase was due primarily to a \$1.3 million increase in external clinical study fees and expenses and a \$0.1 million increase in external nonclinical study fees and expenses, related primarily to EPIC, which was initiated in 2013.

Selling, General and Administrative Expenses. SG&A expenses increased by \$0.4 million, or approximately 18.8%, to \$2.2 million for the three months ended September 30, 2013, compared to \$1.8 million for the same period in 2012. This increase resulted primarily from an increase in consulting fees and legal expenses.

Transaction-Related Expenses. There were no transaction-related expenses for the three months ended September 30, 2013. Transaction-related expenses were (\$0.3) million for the three months ended September 30, 2012. We recognized transaction-related expenses for the three months ended September 30, 2012 due to changes in the fair values at September 30, 2012 relative to June 30, 2012 of the contingent asset and contingent liability related to the consideration for our acquisition of SynthRx. The net \$0.3 million reduction to transaction-related expenses was primarily due to the increase in our stock price at September 30, 2012 relative to June 30, 2012.

Interest Income. Interest income amounted to \$17,327 for the three months ended September 30, 2013, compared to \$18,347 for the same period in 2012. The slight decrease in interest income for the three months ended September 30, 2013 was attributable primarily to lower interest rates on invested balances.

Net Loss. Net loss was \$5.3 million, or \$0.05 per share, for the three months ended September 30, 2013, compared to net loss of \$3.2 million, or \$0.07 per share, for the same period in 2012.

Comparison of Nine Months Ended September 30, 2013 and 2012

Revenue. We recognized no revenue for the nine months ended September 30, 2013 and 2012.

R&D Expenses. Our R&D expenses for the nine months ended September 30, 2013 consisted primarily of external costs associated with EPIC and the TQT study. 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,			
	2013	%	2012	%
External clinical study fees and expenses	\$ 5,735,658	61%	\$ 706,900	12%
External nonclinical study fees and expenses	1,813,549	20%	3,738,823	63%
Personnel costs	1,707,780	18%	1,492,995	25%
Share-based compensation expense	125,100	1%	37,499	0%
Total	\$ 9,382,087	100%	\$ 5,976,217	100%

R&D expenses increased by \$3.4 million, or approximately 57.0%, to \$9.4 million for the nine months ended September 30, 2013, compared to \$6.0 million for the same period in 2012. This increase was due primarily to a \$5.0 million increase in external clinical study fees and expenses, a \$0.2 million increase in personnel costs and a \$0.1 million increase in share-based compensation expense, offset by a \$1.9 million decrease in external nonclinical study fees and expenses. The increase in external clinical study fees and expenses was related primarily to EPIC and the TQT study. The increase in personnel costs was related primarily to increased headcount. The \$1.9 million decrease in external nonclinical study fees and expenses resulted primarily from a decrease in research-related manufacturing activities for ANX-514, which we discontinued during 2012.

Table of Contents

SG&A Expenses. SG&A expenses increased by \$0.7 million, or approximately 11.1%, to \$6.4 million for the nine months ended September 30, 2013, compared to \$5.7 million for the same period in 2012. This increase resulted primarily from an increase in consulting fees and legal expenses.

Transaction-Related Expenses. Transaction-related expenses were \$35,000 for the nine months ended September 30, 2013, compared to \$(0.2) million for the same period in 2012. 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). Transaction-related expenses for the nine months ended September 30, 2012 were due to changes in the fair values at September 30, 2012 relative to December 31, 2011 of the contingent asset and contingent liability related to the consideration for our acquisition of SynthRx.

Interest Income. Interest income amounted to \$42,638 for the nine months ended September 30, 2013, compared to \$56,300 for the same period in 2012. The decrease in interest income for the nine months ended September 30, 2013 was attributable primarily to lower cash balances for most of the period compared to the same period in 2012 and lower interest rates on invested balances.

Net Loss. Net loss was \$15.8 million, or \$0.23 per share, for the nine months ended September 30, 2013, compared to net loss of \$11.6 million, or \$0.24 per share, for the same period in 2012.

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, 2013, we incurred a loss from operations of \$15.8 million. Our cash, cash equivalents and investment securities were \$49.4 million as of September 30, 2013. Our investment securities at September 30, 2013 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 exercise of these warrants is subject to certain beneficial ownership limitations. In addition, 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, 2013 was \$0.44 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. For additional information regarding outstanding warrants to purchase our common stock, see Note 12, Stockholders' Equity, of the Notes to the Condensed Consolidated Financial Statements (Unaudited) in this report.

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

Operating activities. Net cash used in operating activities was \$12.9 million for the nine months ended September 30, 2013 compared to \$10.6 million for the same period in 2012. The increase in cash used in operating activities was primarily due to a higher net loss for the nine months ended September 30, 2013 compared to the same period in 2012 (\$4.2 million), offset by an increase in accounts payable and accrued liabilities (\$1.4 million), an increase in the fair value of contingent consideration (\$0.2 million), an increase in share-based compensation (\$0.1 million) and a decrease in prepaid expenses and other assets (\$0.5 million). We also incurred a \$0.3 million equipment impairment charge during the nine months ended September 30, 2012 related to ANX-514 research-related manufacturing equipment.

Investing activities. Net cash used in investing activities was \$5.2 million for the nine months ended September 30, 2013 compared to net cash used in investing activities of \$6.9 million for the same period in 2012. The difference was due primarily to an increase of \$7.4 million in proceeds from maturities of certificates of deposits and a decrease of \$0.1 million in purchases of property and equipment, offset by a decrease of \$5.8 million in purchases of certificates of deposit.

Table of Contents

Financing activities. 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 in June 2013, less the underwriting discount and offering expenses paid through September 30, 2013. We paid an additional \$116,366 in offering expenses during the fourth quarter, resulting in \$25.7 million of net proceeds from the offering. There was no cash used in or provided by financing activities during the nine months ended September 30, 2012.

Management Outlook

We anticipate that our cash, cash equivalents and investment securities as of September 30, 2013 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 funding requirements include, but are not limited to: the progress and results of our clinical and nonclinical studies of MST-188, particularly the EPIC study and the planned phase 2 study in acute limb ischemia; the number and nature of indications and jurisdictions in which we pursue development and regulatory approval of MST-188, 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 MST-188, including expenses related to initiating and conducting clinical studies and research-related manufacturing expenses; the extent to which we increase our workforce; the extent to which we seek to commercialize and sell MST-188, if approved, independently or through collaborations; the extent of commercial success of any of our product candidates for which we receive regulatory approval; 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; and the extent to which we seek to expand our product pipeline and execute on transactions intended to do so.

We are focusing our resources on development of MST-188. Earlier this year, we initiated the EPIC study. We expect to enroll 388 subjects in the study from approximately 70 medical centers – 40 in the U.S. and 30 outside the U.S. – and expect to begin opening sites outside the U.S. in early 2014. 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 in late 2015. We estimate that external clinical study fees and expenses for EPIC will total approximately \$20 million.

In addition to enrolling subjects in EPIC, we are conducting activities to evaluate the potential of MST-188 to reduce organ damage and improve survival in patients with sickle cell disease. First, we plan to conduct a sub-study at select EPIC sites to evaluate the effect of MST-188 on microvascular blood flow and/or tissue oxygen levels. While pain is the immediate clinical manifestation of vaso-occlusion, obstructed blood vessels also reduce the flow of oxygen-carrying blood to tissues and organs, often resulting in hypoxia and tissue death. In fact, organ failure is the leading cause of death in adults with sickle cell disease, who have an average life expectancy of around 45 years. It is impractical to conduct multi-decade, interventional studies to evaluate the ability of an agent to improve long-term outcomes in sickle cell patients. However, it is possible to measure drug-related changes in underlying disease pathophysiology. We believe that improving physiologic parameters, such as microvascular blood flow or tissue oxygenation, that are widely accepted as the biological mechanism through which the disease process induces both immediate and long-term clinical events will enhance the value of MST-188 as a treatment for sickle cell disease. We've submitted the sub-study protocol to the FDA. The estimated cost to conduct the sub-study is included in the estimated cost of EPIC.

We also have initiated the pilot phase of a nonclinical study in a transgenic mouse model of sickle cell disease. The objective of this study is to demonstrate that chronic intermittent administration of MST-188 reduces the accumulating

burden of organ damage and prolongs survival. The transgenic mice express human sickle hemoglobin and have been shown to mirror the pathophysiology and disease progression of sickle cell disease typically seen in humans, including development of neuropathy, organ damage and premature death. The results of this study, coupled with the clinical pharmacodynamic data from the EPIC sub-study described above, may provide the best evidence of MST-188's ability to improve long-term outcomes, where direct evaluation of those outcomes is impractical. We expect to complete this study in early 2015.

Earlier this year, we announced our plans to evaluate whether MST-188 improves the effectiveness of existing thrombolytic agents by conducting a phase 2, clinical proof-of-concept study in acute limb ischemia, or ALI. Thrombolytic agents, such as tissue plasminogen activator, or tPA, are used to break up or dissolve blood clots, which often are the cause of heart attacks, strokes, and ALI. If this phase 2 study in ALI demonstrates that MST-188 improves the clot busting activity of tPA, we believe it not only would progress development in that indication, but also generate interest in developing MST-188 as an adjunctive therapy in larger market opportunities, such as stroke. We submitted a protocol for the ALI study to the FDA in the third quarter of 2013 and expect to initiate the study in early 2014. We anticipate that the study will enroll approximately 60 patients and estimate that external clinical study fees and expenses for the study will be approximately \$3.5 million.

Table of Contents

We also are evaluating MST-188's potential in heart failure, another area of significant unmet medical need that accounts for over 1,000,000 hospitalizations each year in the U.S. Although there have been modest improvements in treatment, acute decompensated heart failure remains associated with high mortality and high hospital admission and readmission rates in patients older than 65 years. MST-188 may offer a new therapeutic approach. Most existing treatments in heart failure target indirect methods that reduce the workload on the heart, but may not directly improve heart function. For example, ACE (angiotensin-converting enzyme) inhibitors, a type of vasodilator, widen blood vessels to lower blood pressure, improve blood flow and decrease workload. Beta blockers slow heart rate and reduce blood pressure. In contrast, MST-188 may directly improve heart function. Its membrane sealant activity may help restore weakened cardiac cell membranes, thus minimizing calcium overload injury. Its hemorheologic activity may improve coronary microvascular blood flow and oxygen delivery. Together, these activities may directly improve heart contractility and function. We currently are conducting a nonclinical study of MST-188 in an experimental model of heart failure and expect to announce results in early 2014. If these data are positive, we plan to pursue a phase 2, clinical proof-of-concept study of MST-188 in heart failure during 2014.

In addition, we are evaluating MST-188's potential in resuscitation (i.e., restoration of circulating blood volume and pressure) following major trauma. Based on feedback from U.S. Department of Defense personnel following a meeting earlier this year, we plan to conduct a nonclinical study of MST-188 in an experimental model of trauma. The results of this study may generate interest from the Department of Defense in further evaluating the utility of MST-188 in the post-trauma / pre-surgical setting.

Finally, we are conducting or plan to conduct a number of smaller, nonclinical studies involving MST-188 to further assess its efficacy, safety and tolerability in sickle cell disease and other indications and to support manufacturing development and enhance our intellectual property position.

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 MST-188. In addition, our capital requirements likely will increase in future periods as we progress development of MST-188 in currently planned indications and potentially pursue its development in additional indications, or 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 recent 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 10, 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, 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 MST-188, including the nature, timing of initiation and completion, and costs of clinical studies and nonclinical testing, the indications outside of sickle cell disease in which we plan to pursue development of MST-188, our plans regarding partnering or other collaborative arrangements for MST-188 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:

(20)

Table of Contents

our ability, or that of a future partner, to successfully develop, obtain regulatory approval for, and then successfully commercialize MST-188;

our ability to obtain additional funding on a timely basis, or on acceptable terms, or at all;

the potential for us to delay, scale back, or discontinue development of MST-188, 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;

delays in the commencement or completion of clinical studies or manufacturing and regulatory activities necessary to obtain regulatory approval to commercialize MST-188;

our ability to successfully execute clinical studies, including timely enrollment, and the ability of MST-188 to demonstrate acceptable safety and efficacy in clinical studies;

suspension or termination of a clinical study, including due to patient safety concerns;

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;

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 ongoing or planned studies are successful;

the potential for the FDA, or another regulatory agency, to require additional nonclinical or clinical studies of MST-188 in any indication outside of sickle cell disease prior to our initiation of a phase 2 clinical study in that indication;

the potential that, even if clinical studies of MST-188 in one indication are successful, clinical studies in another indication may not be successful;

Edgar Filing: Mast Therapeutics, Inc. - Form 10-Q

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 MST-188 in other indications or jurisdictions;

the potential that we may enter into one or more collaborative arrangements, including partnering or licensing arrangements, for MST-188 or another product candidate, and the terms of any such transactions;

the extent of market acceptance of MST-188 in any indication or jurisdiction in which it receives regulatory approval;

the extent to which we increase our workforce and our ability to attract and retain qualified personnel and manage growth;

competition in the marketplace for our products, if approved;

our ability to protect our intellectual property rights with respect to MST-188 and the MAST platform;

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 II of our quarterly report on Form 10-Q for the period ended June 30, 2013, filed with the SEC on August 5, 2013.

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, the forward-looking events and circumstances discussed in this report and in any documents incorporated in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in such forward-looking statements. Accordingly, you are cautioned not to place undue reliance on such forward-looking statements.

(21)

Table of Contents

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, 2013. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of September 30, 2013 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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

(22)

Table of Contents

Item 6. Exhibits

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

(23)

Table of Contents

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Mast Therapeutics, Inc.

Date: November 4, 2013

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)

(24)

Table of Contents**EXHIBIT INDEX**

Exhibit	Description
31.1	Certification of principal executive officer pursuant to Rules 13a-14(a)/15d-14(a)
31.2	Certification of principal financial officer pursuant to Rules 13a-14(a)/15d-14(a)
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
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and is not being filed for purposes of Section 18 of the Exchange Act and is 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 language in such filing.

** Pursuant to Rule 406T of Regulation S-T, the Interactive Data Files on Exhibit 101 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise are not subject to liability under those sections.