

Mast Therapeutics, Inc.
Form 10-Q
May 15, 2013
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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 March 31, 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)

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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 May 13, 2013 was 46,265,286.

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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)

| | March 31, 2013 | December 31, 2012 |
|---|----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 21,409,923 | \$ 22,500,440 |
| Short-term investments | 10,597,514 | 14,010,962 |
| Interest and other receivables | 10,831 | 15,689 |
| Prepaid expenses | 511,216 | 646,571 |
| Total current assets | 32,529,484 | 37,173,662 |
| Property and equipment, net | 198,706 | 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 | \$ 42,327,985 | \$ 46,971,815 |
| Liabilities and Stockholders Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 575,766 | \$ 698,838 |
| Accrued liabilities | 1,863,764 | 1,283,976 |
| Accrued compensation and payroll taxes | 555,065 | 445,352 |
| Contingent liability | 170,000 | 142,500 |
| Total current liabilities | 3,164,595 | 2,570,666 |
| Deferred income tax liability | 2,608,755 | 2,608,755 |
| Total liabilities | 5,773,350 | 5,179,421 |
| Stockholders equity: | | |
| Common stock, \$0.001 par value; 500,000,000 shares authorized; 47,719,365 shares issued and 46,265,286 shares outstanding at both March 31, 2013 and December 31, 2012 | 47,720 | 47,720 |
| Treasury stock, at cost 1,454,079 shares at both March 31, 2013 and December 31, 2012 | (1,454) | (1,454) |
| Additional paid-in capital | 227,048,419 | 226,696,863 |
| Accumulated other comprehensive loss | (10,642) | (2,194) |
| Deficit accumulated during the development stage | (190,529,408) | (184,948,541) |
| Total stockholders equity | 36,554,635 | 41,792,394 |
| Total liabilities and stockholders equity | \$ 42,327,985 | \$ 46,971,815 |

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See accompanying notes to unaudited condensed consolidated financial statements.

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(A Development Stage Enterprise)

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

(Unaudited)

| | Three months ended March 31, | | Inception (June 12, 1996) through March 31, 2013 |
|--|------------------------------|-----------------------|---|
| | 2013 | 2012 | |
| 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 | 3,442,912 | 2,210,454 | 89,500,368 |
| Selling, general and administrative | 2,112,706 | 2,045,238 | 69,779,418 |
| Transaction-related expenses | 27,500 | (114,388) | 699,152 |
| Depreciation and amortization | 9,795 | 30,192 | 11,035,030 |
| 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 | 5,592,913 | 4,171,496 | 187,317,164 |
| Loss from operations | (5,592,913) | (4,171,496) | (185,274,736) |
| Reduction of fair value of warrants | | | (12,239,688) |
| Interest income | 14,416 | 18,668 | 4,846,624 |
| Interest expense | | | (191,729) |
| Other income/(expense), net | (2,370) | 311 | 127,335 |
| Loss before cumulative effect of change in accounting principle | (5,580,867) | (4,152,517) | (192,732,194) |
| Cumulative effect of change in accounting principle | | | (25,821) |
| Net loss | (5,580,867) | (4,152,517) | (192,758,015) |
| Preferred stock dividends | | | (621,240) |
| Deemed dividends on preferred stock | | | (10,506,683) |
| Net loss applicable to common stock | \$ (5,580,867) | \$ (4,152,517) | \$ (203,885,938) |
| Net loss per common share basic and diluted | \$ (0.12) | \$ (0.09) | |
| Weighted average shares outstanding basic and diluted | 46,265,286 | 47,715,709 | |

Comprehensive Income/(Loss):

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| | | | |
|------------------------------------|-----------------------|-----------------------|-------------------------|
| Net loss | \$ (5,580,867) | \$ (4,152,517) | \$ (192,758,015) |
| Other comprehensive gains/(losses) | (8,448) | 139 | (10,642) |
| Comprehensive net loss | \$ (5,589,315) | \$ (4,152,378) | \$ (192,768,657) |

See accompanying notes to unaudited condensed consolidated financial statements.

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

(A Development Stage Enterprise)

Condensed Consolidated Statements of Cash Flows

(Unaudited)

| | Three months ended March 31, | | Inception (June 12, 1996) through March 31, 2013 |
|--|------------------------------|----------------|---|
| | 2013 | 2012 | |
| Cash flows from operating activities: | | | |
| Net loss | \$ (5,580,867) | \$ (4,152,517) | \$ (192,758,015) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 9,795 | 30,192 | 10,585,032 |
| 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 | 27,500 | (114,388) | (1,501,407) |
| 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 | 351,556 | 377,505 | 11,900,880 |
| 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 | | | 510,739 |
| Cumulative effect of change in accounting principle | | | 25,821 |
| Amortization of premium / (accretion of discount) on investments in securities | | 10,710 | (1,571,502) |
| Changes in assets and liabilities, net of effect of acquisitions: | | | |
| Decrease/(increase) in prepaid expenses and other assets | 140,213 | (81,820) | (815,646) |
| Increase/(decrease) in accounts payable and accrued liabilities | 563,439 | (533,492) | 2,858,617 |
| Net cash used in operating activities | (4,488,364) | (4,459,307) | (138,654,486) |
| Cash flows from investing activities: | | | |
| Purchases of certificates of deposit | (2,988,000) | (5,312,000) | (26,971,179) |
| Proceeds from maturities of certificates of deposit | 6,393,000 | 1,440,000 | 16,084,330 |
| Proceeds from sale of certificate of deposit | | | 248,000 |
| Purchases of other short-term investments | | | (111,183,884) |
| Proceeds from maturities and sales of other short-term investments | | | 112,788,378 |
| Purchases of property and equipment | (4,725) | (187,363) | (1,741,529) |
| 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) |

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| | | | |
|---|---------------|---------------|---------------|
| 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 provided by/(used in) investing activities | 3,400,275 | (4,059,363) | (10,291,776) |
| Cash flows from financing activities: | | | |
| Proceeds from sale of common stock | | | 123,658,871 |
| 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 | | | (13,897,367) |
| 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 | | | 170,346,973 |
| Effect of exchange rate changes on cash | (2,428) | | 9,212 |
| Net (decrease)/increase in cash and cash equivalents | (1,090,517) | (8,518,670) | 21,409,923 |
| Cash and cash equivalents at beginning of period | 22,500,440 | 43,569,947 | |
| Cash and cash equivalents at end of period | \$ 21,409,923 | \$ 35,051,277 | \$ 21,409,923 |

See accompanying notes to unaudited condensed consolidated financial statements.

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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.

Certain prior year amounts have been reclassified in the condensed consolidated financial statements to conform to the current year presentation. These reclassifications were not material and had no effect on previously reported results of operations.

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 contingent consideration, 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:

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(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;

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(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 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 consider the dosing of the first patient in the EPIC (Evaluation of Purified 188 In Children) study, our phase 3 study 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 is 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 exceeds 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.

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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, 2012, no impairment was noted. There were no events or changes in circumstances during the three months ended March 31, 2013 that we considered indications of impairment of our acquired IPR&D.

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. As of September 30, 2012, no impairment was noted. For the quarter ended December 31, 2012, we determined that the persistently low trading price of our common stock, even after announcement during that quarter of our phase 3 clinical development plans for MST-188 in sickle cell disease, may be an indicator of impairment of our goodwill and we performed an impairment test as of December 31, 2012. Through Step 1 of the two-step quantitative impairment test, we concluded that, as of December 31, 2012, our goodwill was not impaired. There were no events or changes in circumstances during the three months ended March 31, 2013 that we considered indications of impairment of our goodwill.

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.

In accordance with ASC 815-40, we remeasure the contingent liability related to the First Milestone Shares as of the last day of each fiscal quarter until the arrangement is settled. The remeasurement of the contingent liability as of March 31, 2013 resulted in a \$27,500 increase to transaction-related expenses for the three-month period ended March 31, 2013. Upon achievement of the First Milestone, the contingent liability will be remeasured, any change in its fair value as of that settlement date will be recognized in earnings as a transaction-related expense, and the contingent liability will be eliminated. The fair value of First Milestone Shares we ultimately issue will be recorded as equity. As of March 31, 2013, based on the timing of and the planned number of patients in the EPIC study, we will issue 25%, or 250,000, of the First Milestone Shares.

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The contingent asset related to the 1,454,079 Subject to Vesting Shares was eliminated, or 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.

4. Short-Term Investments

We consider income-yielding securities that can be readily converted to cash and have original maturities of more than three months and one year or less at the date of purchase to be short-term investments. All of our short-term investments are marketable securities under the custodianship of a major financial institution and consist primarily of FDIC-insured certificates of deposit.

We account for and report our short-term investments in accordance with ASC Topic 320, *Accounting for Certain Investments in Debt and Equity Securities*. Our short-term investments are classified as available-for-sale securities and carried at fair value. Fair value for securities with short maturities and infrequent secondary market trades is typically 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. Marketable securities are evaluated periodically for impairment. If we determine that a decline in market value of any investment is other than temporary, then the investment basis would be written down to fair value and the decline in value would be charged to earnings.

At March 31, 2013, the fair value of our short-term investments was \$10,597,514. The cost basis of such investments was \$10,606,000 and our unrealized losses were \$8,486.

5. Fair Value of Financial Instruments

Our short-term investments and our contingent liability are carried at fair value. The fair value of financial assets and liabilities is measured under a framework that establishes levels which are defined as follows: (i) Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities; (ii) Level 2 fair value is determined from 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 values at March 31, 2013 of our short-term investments and our contingent liability are summarized in the following table:

| | Total Fair Value | March 31, 2013 | | |
|------------------------|------------------|------------------------------|---------------|--------------|
| | | Fair Value Determined Under: | | |
| | | (Level 1) | (Level 2) | (Level 3) |
| Short-term investments | \$ 10,597,514 | \$ | \$ 10,597,514 | \$ |
| Contingent liability | \$ (170,000) | \$ | \$ | \$ (170,000) |

A reconciliation of the contingent liability for the three months ended March 31, 2013 is as follows:

| | Three months ended March 31, 2013 |
|--|--------------------------------------|
| Balance at December 31, 2012 | \$ (142,500) |
| Settlements | |
| Total net unrealized gains (losses) included in earnings | (27,500) |
| Total net unrealized gains (losses) included in other comprehensive income | |
| Transfers into level 3 (gross) | |
| Transfers out of level 3 (gross) | |

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| | | |
|---|----|-----------|
| Balance at March 31, 2013 | \$ | (170,000) |
| Change in unrealized gains or losses for the period included in earnings for liabilities held at March 31, 2013 | \$ | (27,500) |

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As discussed above, the fair value of the contingent liability is measured and recorded on a recurring basis using significant unobservable inputs (Level 3). At each remeasurement date until the contingent arrangement is settled, we determine 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 will issue, which is based on our estimates of the probability of achievement of the First Milestone and assumptions regarding the circumstances under which it is achieved. The increase in the fair value of the contingent liability at March 31, 2013 compared to December 31, 2012 was due to an increase in the market price of our common stock at March 28, 2013 (\$0.68 per share), which was the last trading day of the quarter, relative to December 31, 2012 (\$0.57 per share).

The following inputs were used in the calculation of the contingent liability at March 31, 2013:

| | Contingent Liability |
|--|-----------------------------|
| Number of shares to be issued | 250,000 |
| Market price of our common stock at March 28, 2013 | \$ 0.68 |
| Probability of achievement of the First Milestone | 100% |

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 is generally 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 to the contract manufacturer. Accordingly, we disposed of the ANX-514 equipment in April 2013.

7. Accrued Liabilities

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

| | March 31, 2013 | December 31, 2012 |
|--------------------------------------|---------------------------|------------------------------|
| Accrued contracts and study expenses | \$ 1,651,214 | \$ 1,203,808 |
| Other accrued liabilities | 212,550 | 80,168 |
| Total accrued liabilities | \$ 1,863,764 | \$ 1,283,976 |

Our accrued liabilities as of December 31, 2012 included a \$0.4 million accrual that reflected the entire amount of our ANX-514 contract manufacturer's payment demand for ANX-514 manufacturing activities, which amount was in dispute. As discussed above in Note 6, in April 2013, we reached an agreement with the contract manufacturer regarding the amount in dispute. As a result of our agreement, we reduced our accrued liabilities as of March 31, 2013 by \$0.2 million.

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Table of Contents**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 months ended March 31, 2013 and 2012 was as follows:

| | Three months ended March 31, | |
|---|-------------------------------------|-------------------|
| | 2013 | 2012 |
| Selling, general and administrative expense | \$ 314,428 | \$ 351,804 |
| Research and development expense | 37,128 | 25,701 |
| Share-based compensation expense | \$ 351,556 | \$ 377,505 |

There were no employee or non-employee director stock options exercised during the three months ended March 31, 2013 or 2012. During the three months ended March 31, 2013, we granted stock options to acquire an aggregate of 484,300 shares of our common stock to our employees, with an estimated weighted-average grant date fair value of \$0.53 per share. During the three months ended March 31, 2012, we granted no stock options to our employees or non-employee directors. At March 31, 2013, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was \$2.6 million, which is expected to be recognized over a weighted-average period of 2.8 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 months ended March 31, 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 March 31, | |
|----------|-------------------------------------|-------------|
| | 2013 | 2012 |
| Options | 4,058,751 | 2,892,132 |
| Warrants | 16,488,432 | 17,824,080 |

10. Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board (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 March 31, 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.

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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 three months ended March 31, 2013 and 2012 and for the period from inception (June 12, 1996) through March 31, 2013 are as follows:

| | Three months ended March 31, | | Inception (June 12, 1996) |
|--|------------------------------|------|------------------------------|
| | 2013 | 2012 | through March 31, 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 |
| Acquisition of license agreement for long-term debt | | | 161,180 |
| Unrealized (loss)/gain on short-term investments | (8,448) | 139 | (8,486) |
| 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 |

12. Warrants

At March 31, 2013, outstanding warrants to purchase shares of common stock are as follows:

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

16,488,432

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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 may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those identified under "Forward Looking Statements" below and those discussed in Item 1A (Risk Factors) of Part I of our annual report on Form 10-K for the year ended December 31, 2012. 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 \$5.6 million for the three months ended March 31, 2013. Our cash, cash equivalents and short-term investments were \$32.0 million as of March 31, 2013.

We continue to focus our resources on MST-188 and believe that its pharmacologic effects support its development in a wide range of diseases and conditions. Accordingly, we intend to develop MST-188 in multiple clinical indications, both independently and through collaborations. We currently are recruiting patients in EPIC (Evaluation of Purified 188 In Children), a pivotal phase 3 study of MST-188 in sickle cell disease. We also have announced plans to develop MST-188 for complications of arterial disease, initially as an adjunct to thrombolytics in acute limb ischemia, and we intend to initiate a phase 2, clinical proof-of-concept study in acute limb ischemia in late 2013 or early 2014. Additionally, we are conducting or plan to conduct nonclinical studies to investigate the safety and/or efficacy of MST-188 in additional indications, including acute decompensated heart failure and blood transfusion and plan to conduct nonclinical studies that will evaluate the effect of MST-188 on blood coagulation, which may support further development in resuscitation of shock following major trauma.

In March 2013, we changed our name from ADVENTRX Pharmaceuticals, Inc. to Mast Therapeutics, Inc.

We anticipate that our cash, cash equivalents and short-term investments 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 develop MST-188 in indications in addition to those currently planned or 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, and other strategic transactions. We also are seeking funding from U.S. government agencies. 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.

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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.

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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.

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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, including process development activities, 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.

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 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.

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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 and whether we will develop a product candidate with a partner or independently. At this time, due to such uncertainties and the risks inherent in 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.

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Transaction-Related Expenses. Transaction-related expenses consist of legal, accounting, financial and business development advisory fees associated with the evaluation of potential acquisition targets and execution of acquisition transactions, including our 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 remeasure as of the end of each quarter until the contingent arrangement is settled.

Interest and Other Income/(Expense). Interest and other income/(expense) includes interest income, interest expense, unrealized gains and losses due to changes in the exchange rates on assets and liabilities denominated in foreign currencies, realized gains and losses from foreign currency transactions and other non-operating gains and losses.

Comparison of Three Months Ended March 31, 2013 and 2012

Revenue. We recognized no revenue for the three months ended March 31, 2013 and 2012.

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R&D Expenses. Our R&D expenses for the three months ended March 31, 2013 consisted primarily of external costs associated with the EPIC study and the thorough QT/QTc, or TQT, clinical study of MST-188 and research-related manufacturing expenses related to 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 March 31, | | | | January 1, 2005 through |
|--|------------------------------|-------------|---------------------|-------------|-------------------------|
| | 2013 | % | 2012 | % | March 31, 2013 |
| External clinical study fees and expenses | \$ 2,308,102 | 67% | \$ 251,050 | 11% | \$ 28,405,601 |
| External nonclinical study fees and expenses | 547,351 | 16% | 1,547,895 | 70% | 36,703,388 |
| Personnel costs | 550,331 | 16% | 385,808 | 18% | 13,904,777 |
| Share-based compensation expense | 37,128 | 1% | 25,701 | 1% | 3,012,349 |
| Total | \$ 3,442,912 | 100% | \$ 2,210,454 | 100% | \$ 82,026,115 |

R&D expenses increased by \$1.2 million, or approximately 55.8%, to \$3.4 million for the three months ended March 31, 2013, compared to \$2.2 million for the same period in 2012. This increase was due primarily to a \$2.0 million increase in external clinical study fees and expenses and a \$0.2 million in personnel costs, offset by a \$1.0 million decrease in external nonclinical study fees and expenses. The increase in external clinical study fees and expenses was related primarily to the EPIC and TQT clinical studies, which were initiated during the three months ended March 31, 2013. The increase in personnel costs was related primarily to increased headcount. The \$1.0 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.

Selling, General and Administrative Expenses. SG&A expenses increased by \$0.1 million, or approximately 3.3%, to \$2.1 million for the three months ended March 31, 2013, compared to \$2.0 million for the same period in 2012. This increase resulted primarily from an increase in personnel costs related to increased headcount.

Transaction-Related Expenses. Transaction-related expenses were \$27,500 for the three months ended March 31, 2013, compared to (\$114,388) for the same period in 2012. We recognized transaction-related expenses for the three months ended March 31, 2013 due to changes in the fair value at March 31, 2013 relative to December 31, 2012, of the contingent liability related to the consideration for our acquisition of SynthRx. The increase in the fair value of the contingent liability was due to the increase in our stock price at March 28, 2013 (\$0.68 per share), the last trading day of the three months ended March 31, 2013, relative to December 31, 2012 (\$0.57 per share). We recognized transaction-related expenses for the three months ended March 31, 2012 due to changes in the fair values at March 31, 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 \$14,416 for the three months ended March 31, 2013, compared to \$18,668 for the same period in 2012. The decrease in interest income for the three months ended March 31, 2013 was attributable primarily to lower cash balances.

Net Loss. Net loss was \$5.6 million, or \$0.12 per share, for the three months ended March 31, 2013, compared to net loss of \$4.2 million, or \$0.09 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 three months ended March 31, 2013, we incurred a loss from operations of \$5.6 million. Our cash, cash equivalents and short-term investments were \$32.0 million as of March 31, 2013. Our short-term investments at March 31, 2013 consisted entirely of FDIC-insured certificates of deposit.

We historically have funded our operations principally through proceeds from sales of our equity securities. We did not conduct any capital-raising transaction during the three months ended March 31, 2013 or in fiscal year 2012.

We may receive up to \$0.8 million, \$6.6 million, \$5.6 million and \$11.7 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 offering we completed in November 2011, 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 and \$1.10 per share, respectively, and, in comparison, the closing sale

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price of our common stock on March 28, 2013, the last trading day of the three months ended March 31, 2013, was \$0.68 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, Warrants, of the Notes to the Condensed Consolidated Financial Statements (Unaudited) in this report.

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For a discussion of our liquidity and capital resources outlook, see [Management Outlook](#) below.

Operating activities. Net cash used in operating activities was \$4.5 million for the three months ended March 31, 2013 and for the same period in 2012. While net cash used in operating activities for the three months ended March 31, 2013 was consistent with the amount used in the same period in 2012, the net loss for the three months ended March 31, 2013 was \$1.4 million greater than the net loss for the same period in 2012. The higher net loss for the three months ended March 31, 2013 was offset by a \$1.1 million increase in accounts payable and accrued liabilities, a \$0.2 million decrease in prepaid expenses and other assets and a \$0.1 million loss on the change in fair value of contingent consideration related to our acquisition of SynthRx. The \$1.1 million increase in accounts payable and accrued liabilities was related primarily to fees and expenses of the TQT and EPIC clinical studies.

Investing activities. Net cash provided by investing activities was \$3.4 million for the three months ended March 31, 2013 compared to net cash used in investing activities of \$4.1 million for the same period in 2012. The difference was due primarily to an increase of \$5.0 million in proceeds from maturities of certificates of deposits, a decrease of \$2.3 million in purchases of certificates of deposit and a decrease of \$0.2 million in purchases of property and equipment.

Financing activities. There was no cash used in or provided by financing activities during the three months ended March 31, 2013 or 2012.

Management Outlook

We anticipate that our cash, cash equivalents and short-term investments as of March 31, 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 of our clinical and nonclinical studies of MST-188, particularly the EPIC study; 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 or other strategic transactions; 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 or other strategic transactions; 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 almost exclusively on the development of MST-188. Earlier this year, we initiated the EPIC study and one of our top priorities is to enroll subjects in that study. In addition to the approximately 40 sites that we plan to open in the U.S., we are engaging another CRO to expand EPIC by opening approximately 30 sites outside of the U.S., beginning early 2014. Accordingly, we expect to enroll 388 subjects from a total of approximately 70 medical centers. Although predicting the rate of enrollment for EPIC is subject to a number of assumptions and the actual rate may differ materially, we expect to complete enrollment in 2015. We currently estimate that external clinical study fees and expenses for EPIC, including preliminary estimates for the cost of opening sites and enrolling subjects outside of the U.S., will be approximately \$20 million.

In January 2013, we initiated a TQT study of MST-188 in healthy volunteers to evaluate its effect on cardiac ventricular repolarization, specifically the QT-interval, and we expect to announce results later this year. We estimate that external clinical study fees and expenses for the TQT study will be approximately \$2 million. In addition, in 2013, we plan to initiate a sub-study within EPIC to evaluate the effect of MST-188 on microvascular blood flow (mBF) and tissue oxygen saturation (StO₂). This sub-study will be conducted at select EPIC sites using non-invasive devices to measure mBF and StO₂ and we plan to enroll approximately 30 patients in the sub-study.

In February 2013, we announced our plans to develop MST-188 for complications of arterial disease, initially as an adjunct to thrombolytics in acute limb ischemia. We plan to submit a protocol for our planned phase 2, clinical proof-of-concept study in acute limb ischemia to the FDA in the third quarter of 2013, and, depending in part upon FDA input, we expect to initiate the study in late 2013 or early 2014. We anticipate that the study will enroll approximately 60 patients and we estimate that external clinical study fees and expenses for the study will be approximately \$2 million.

We intend to evaluate MST-188 in other conditions in which we believe its pharmacologic effects may translate into improved clinical outcomes, including resuscitation of shock following major trauma, acute decompensated heart failure and blood transfusion. We plan to conduct a number of nonclinical studies of MST-188 to further assess its efficacy, safety and tolerability in sickle cell disease and other

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indications, including six-month toxicology studies that we expect to begin in 2013. However, unless we secure U.S. government or other third-party funding for development of MST-188 in a particular indication, other than as described above, we do not plan to initiate additional clinical studies in 2013.

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In March 2013, we announced that we intend to evaluate opportunities for strategic alliances for MST-188 and had engaged a financial advisor to identify potential partners and advise us in potential transaction discussions. We believe that the European Commission's recent designation of MST-188 as an orphan medicinal product for the treatment of sickle cell disease will enhance its appeal in Europe.

Although we anticipate that our cash, cash equivalents and short-term investments 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. We will need additional capital to support our planned operating activities. In addition, our capital requirements likely will increase in future periods as we pursue development of MST-188 in additional indications, both those identified above and potentially other indications that we have not yet identified, 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, and other strategic transactions. We also are seeking funding from U.S. government agencies. 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. It is difficult to secure funding from the U.S. government without an existing relationship with a federal agency, which we do not have, which difficulty is increased based on current and anticipated constraints on federal spending. 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, indicate and similar expressions are intended to identify forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements we make regarding activities, timing and costs related to developing and seeking regulatory approval for MST-188, including the nature, timing 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 risks and uncertainties that could cause our actual results to differ materially from those reflected in such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to the following:

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

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

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our ability to successfully execute clinical studies 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 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;

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;

our ability to maintain our relationships with the single-source third-party manufacturers and suppliers for our product candidates and certain of their component materials 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 our nonclinical testing, clinical studies and other aspects of our development programs;

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 any of our product candidates for which we receive 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 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 may cause;

potential product liability exposure and, if successful claims are brought against us, liability for a product or product candidate;

the extent to which we acquire new technologies and/or product candidates and our ability to integrate them successfully into our operations;

our ability to maintain compliance with NYSE MKT continued listing standards and maintain the listing of our common stock on the NYSE MKT equities market or another national securities exchange; and

the other factors that are described in Item 1A (Risk Factors) of Part I of our annual report on Form 10-K for the year ended December 31, 2012.

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.

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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 March 31, 2013. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of March 31, 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.

Item 6. Exhibits

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

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Signatures

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

Mast Therapeutics, Inc.

Date: May 15, 2013

By: /s/ Brian M. Culley
Brian M. Culley

Chief Executive Officer and Director

(Principal Executive Officer)

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

Chief Financial Officer and Senior Vice President

(Principal Financial and Accounting Officer)

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| Exhibit | Description |
|----------------|---|
| 3.1(1) | Amended and Restated Certificate of Incorporation of the registrant |
| 3.2(2) | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the registrant dated October 5, 2009 |
| 3.3(3) | Certificate of Amendment to the Amended and Restated Certificate of Incorporation of the registrant, dated April 23, 2010 |
| 3.4(4) | Certificate of Ownership and Merger, effective as of March 11, 2013 |
| 3.5(4) | Amended and Restated Bylaws of the registrant, effective as of March 11, 2013 |
| 10.1# | Director Compensation Policy, adopted March 21, 2013 |
| 10.2#(5) | 2013 Executive Incentive Plan |
| 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 |

Indicates management contract or compensatory plan or arrangement

* 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.

- (1) Filed with the registrant's Annual Report on Form 10-K on March 16, 2006 (SEC file number 001-32157-06693266)
- (2) Filed with the registrant's Current Report on Form 8-K on October 13, 2009 (SEC file number 001-32157-091115090)
- (3) Filed with the registrant's Current Report on Form 8-K on April 26, 2010 (SEC file number 001-32157-10769058)
- (4) Filed with the registrant's Current Report on Form 8-K on March 1, 2013 (SEC file number 001-32157-13657723)
- (5) Filed with the registrant's Current Report on Form 8-K on February 8, 2013 (SEC file number 001-32157-13587943)