Mast Therapeutics, Inc.
Form 10-Q
August 05, 2013
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2013

OR

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

For the transition period from _____ to _____

Commission File Number 001-32157

Mast Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**84-1318182**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

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

(858) 552-0866

(Registrant s telephone number, including area code)

N/A

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

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

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company x

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

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

Table of Contents

TABLE OF CONTENTS

	Page
PART I FINANCIAL INFORMATION	1
Item 1. Financial Statements (Unaudited)	1
a. Condensed Consolidated Balance Sheets as of June 30, 2013 and December 31, 2012	1
b. Condensed Consolidated Statements of Operations and Comprehensive Income/(Loss) for the three and six months ended June 30, 2013 and 2012 and for the period from inception (June 12, 1996) through June 30, 2013	2
c. Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2013 and 2012 and for the period from inception (June 12, 1996) through June 30, 2013	3
d. Notes to Condensed Consolidated Financial Statements (Unaudited)	5
Item 2. Management_s Discussion and Analysis of Financial Condition and Results of Operations	12
Item 3. Quantitative and Qualitative Disclosures About Market Risk	20
Item 4. Controls and Procedures	20
PART II OTHER INFORMATION	21
Item 1. Legal Proceedings	21
Item 1A. Risk Factors	21
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	43
Item 3. Defaults Upon Senior Securities	43
Item 4. Mine Safety Disclosures	43
Item 5. Other Information	43
Item 6. Exhibits	43
SIGNATURES	44

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)

	June 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 44,972,236	$ 22,500,440
Short-term investments	8,450,318	14,010,962
Interest and other receivables	9,659	15,689
Prepaid expenses	684,126	646,571
Total current assets	54,116,339	37,173,662
Property and equipment, net	119,951	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	$ 63,836,085	$ 46,971,815
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 950,805	$ 698,838
Accrued liabilities	1,579,423	1,283,976
Accrued compensation and payroll taxes	799,061	445,352
Contingent liability		142,500
Total current liabilities	3,329,289	2,570,666
Deferred income tax liability	2,608,755	2,608,755
Total liabilities	5,938,044	5,179,421
Stockholders equity:		
Common stock, $0.001 par value; 500,000,000 shares authorized; 102,710,286 and 47,719,365 shares issued at June 30, 2013 and December 31, 2012, respectively; 102,710,286 and 46,265,286 shares outstanding at June 30, 2013 and December 31, 2012, respectively	102,710	47,720
Treasury stock, at cost 0 and 1,454,079 shares at June 30, 2013 and December 31, 2012, respectively		(1,454)
Additional paid-in capital	253,274,749	226,696,863
Accumulated other comprehensive loss	(8,838)	(2,194)
Deficit accumulated during the development stage	(195,470,580)	(184,948,541)
Total stockholders equity	57,898,041	41,792,394

Total liabilities and stockholders equity	$ 63,836,085	$ 46,971,815

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Mast Therapeutics, Inc. and Subsidiaries

(A Development Stage Enterprise)

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

(Unaudited)

	Three months ended June 30,		Six months ended June 30,		Inception (June 12, 1996) through
	2013	2012	2013	2012	June 30, 2013
Revenues:					
Net sales	$	$	$	$	$ 174,830
Licensing revenue					1,300,000
Grant revenue					618,692
Total net revenues					2,093,522
Cost of goods sold					51,094
Gross margin					2,042,428
Operating expenses:					
Research and development	2,836,935	2,107,861	6,279,847	4,318,315	92,337,303
Selling, general and administrative	2,099,925	1,871,059	4,212,631	3,916,297	71,879,343
Transaction-related expenses	7,500	205,899	35,000	91,511	706,652
Depreciation and amortization	8,879	36,739	18,674	66,931	11,043,909
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	4,953,239	4,221,558	10,546,152	8,393,054	192,270,403
Loss from operations	(4,953,239)	(4,221,558)	(10,546,152)	(8,393,054)	(190,227,975)
Reduction of fair value of warrants					(12,239,688)
Interest income	10,895	19,285	25,311	37,953	4,857,519
Interest expense					(191,729)
Other income (expense), net	1,172	(8,890)	(1,198)	(8,579)	128,507
Loss before cumulative effect of change in accounting principle	(4,941,172)	(4,211,163)	(10,522,039)	(8,363,680)	(197,673,366)
Cumulative effect of change in accounting principle					(25,821)
Net loss	(4,941,172)	(4,211,163)	(10,522,039)	(8,363,680)	(197,699,187)
Preferred stock dividends					(621,240)
Deemed dividends on preferred stock					(10,506,683)
Net loss applicable to common stock	$ (4,941,172)	$ (4,211,163)	$ (10,522,039)	$ (8,363,680)	$ (208,827,110)
Net loss per common share basic and diluted	$ (0.09)	$ (0.09)	$ (0.21)	$ (0.18)	

Weighted average shares outstanding	basic and diluted	53,749,791	47,715,709	50,028,214	47,715,709	
Comprehensive Income/(Loss):						
Net loss		$ (4,941,172)	$ (4,211,163)	$ (10,522,039)	$ (8,363,680)	$ (197,699,187)
Other comprehensive gains (losses)		1,804	(136)	(6,644)	3	(8,838)
Comprehensive loss		$ (4,939,368)	$ (4,211,299)	$ (10,528,683)	$ (8,363,677)	$ (197,708,025)

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Mast Therapeutics, Inc. and Subsidiaries

(A Development Stage Enterprise)

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six months ended June 30,		Inception (June 12, 1996) through
	2013	2012	June 30, 2013
Cash flows from operating activities:			
Net loss	$ (10,522,039)	$ (8,363,680)	$ (197,699,187)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	18,674	66,931	10,593,911
Loss on disposals of equipment	99,875	4,503	161,190
Loss on fair value of warrants			12,239,688
Loss/(gain) on change in fair value of contingent consideration	35,000	91,511	(1,493,907)
Amortization of debt discount			450,000
Forgiveness of employee receivable			30,036
Impairment loss write-off of goodwill			5,702,130
Share-based compensation expense related to employee stock options and restricted stock issued	716,693	714,329	12,266,017
Expenses related to options issued to non-employees			204,664
Expenses paid by issuance of common stock			1,341,372
Expenses paid by issuance of warrants			573,357
Expenses paid by issuance of preferred stock			142,501
Expenses related to stock warrants issued			612,000
Equity in loss of investee			178,936
In-process research and development			10,422,130
Write-off of license agreement			152,866
Impairment of equipment		300,114	510,739
Cumulative effect of change in accounting principle			25,821
Amortization of premium / (accretion of discount) on investments in securities		18,883	(1,571,502)
Changes in assets and liabilities, net of effect of acquisitions:			
Increase in prepaid expenses and other assets	(31,526)	(283,368)	(987,385)
Increase in accounts payable and accrued liabilities	523,693	46,610	2,818,871
Net cash used in operating activities	(9,159,630)	(7,404,167)	(143,325,752)
Cash flows from investing activities:			
Purchases of certificates of deposit	(3,984,000)	(8,859,000)	(27,967,179)
Proceeds from maturities of certificates of deposit	9,538,000	2,856,000	18,981,330
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			113,036,378
Purchases of property and equipment	(17,176)	(205,916)	(1,753,980)
Proceeds from sale of property and equipment			66,920
Cash paid for acquisitions, net of cash acquired			32,395
Payment on obligation under license agreement			(106,250)
Issuance of note receivable related party			(35,000)

Payments on note receivable			405,993
Advance to investee			(90,475)
Cash transferred in rescission of acquisition			(19,475)
Cash received in rescission of acquisition			230,000
Net cash provided by/(used in) investing activities	5,536,824	(6,208,916)	(8,155,227)

Table of Contents

Cash flows from financing activities:			
Proceeds from sale of common stock	28,097,500		151,756,371
Proceeds from exercise of stock options			714,561
Proceeds from sale or exercise of warrants			14,714,258
Proceeds from sale of preferred stock			44,474,720
Repurchase of Subject to Vesting Shares			(1,454)
Repurchase of warrants			(55,279)
Payments for financing and offering costs	(2,001,599)		(15,898,966)
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	26,095,901		196,442,874
Effect of exchange rate changes on cash	(1,299)		10,341
Net increase/(decrease) in cash and cash equivalents	22,471,796	(13,613,083)	44,972,236
Cash and cash equivalents at beginning of period	22,500,440	43,569,947	
Cash and cash equivalents at end of period	$ 44,972,236	$ 29,956,864	$ 44,972,236

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

Mast Therapeutics, Inc. and Subsidiaries

(A Development Stage Enterprise)

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Basis of Presentation

Mast Therapeutics, Inc., a Delaware corporation (Mast Therapeutics, we or our company), prepared the unaudited interim condensed consolidated financial statements included in this report in accordance with United States generally accepted accounting principles (U.S. GAAP) for interim financial information and the rules and regulations of the Securities and Exchange Commission (SEC) related to quarterly reports on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for annual audited financial statements and should be read in conjunction with our audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on March 19, 2013 (2012 Annual Report). The condensed consolidated balance sheet as of December 31, 2012 included in this report has been derived from the audited consolidated financial statements included in the 2012 Annual Report. In the opinion of management, these condensed consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any future period, including the full year.

We are a biopharmaceutical company focused on developing therapies for serious or life-threatening diseases. We have devoted substantially all of our resources to research and development (R&D), and acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue. Through our acquisition of SynthRx, Inc. in 2011, we acquired our Membrane Adhesion & Sealant Technology (MAST) platform, which includes proprietary poloxamer-related data and know-how derived from over two decades of clinical, nonclinical and manufacturing experience, and we are leveraging the MAST platform to develop MST-188 for diseases and conditions characterized by microcirculatory insufficiency.

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

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

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 R&D expenses and share-based compensation expenses. We base our estimates on historical experience and various other relevant assumptions we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

3. Acquisition of SynthRx

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

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

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

Table of Contents

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

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

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

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

Acquired In-Process Research and Development

Our acquired IPR&D was the estimated fair value as of the acquisition date of MST-188, which was SynthRx s lead product candidate. We determined that the estimated fair value of the MST-188 program was $6.5 million as of the acquisition date using the Multi-Period Excess Earnings Method, or MPEEM, which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset s incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life.

To calculate fair value of the MST-188 program under the MPEEM, we used probability-weighted cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by development-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to MST-188 in sickle cell disease and then reduced by a contributory charge on requisite assets employed. Contributory assets included debt-free working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through the market exclusivity period estimated to be provided by orphan drug designation. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles substantially similar to that of SynthRx, which we believe represents the rate that market participants would use to value the assets. We compensated for the phase of development of this program by applying a probability factor to our estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, such as the time and resources needed to complete the development and approval of MST-188 in sickle cell disease, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product and associated risks, including the inherent difficulties and uncertainties in drug development, such as obtaining marketing approval from the FDA and other regulatory agencies, and risks related to the viability of and potential alternative treatments in any future target markets.

(6)

Table of Contents

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

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.

Table of Contents

The contingent liability related to the First Milestone Shares was settled in May 2013 with achievement of the First Milestone and our subsequent issuance of 250,000 of the First Milestone Shares. In accordance with ASC 815-40, we remeasured the contingent liability as of its settlement date, which remeasurement resulted in $7,500 of transaction-related expenses for the three-month period ended June 30, 2013.

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 June 30, 2013, the fair value of our short-term investments was $8,450,318. The cost basis of such investments was $8,457,000 and our unrealized losses were $6,682.

5. Fair Value of Financial Instruments

Our short-term investments are and, prior to its settlement, our contingent liability was carried at fair value. The fair value of financial assets and liabilities is measured under a framework that establishes levels which are defined as follows: (i) Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities; (ii) Level 2 fair value is determined from quoted prices for similar items in active markets or quoted prices for identical or similar items in markets that are not active; and (iii) Level 3 fair value is determined using the entity s own assumptions about the inputs that market participants would use in pricing an asset or liability.

The fair value at June 30, 2013 of our short-term investments is summarized in the following table:

	June 30, 2013			
	Total Fair Value	Fair Value Determined Under: (Level 1)	(Level 2)	(Level 3)
Short-term investments	$ 8,450,318	$	$ 8,450,318	$

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

	Six months ended June 30, 2013
Balance at December 31, 2012	$ (142,500)
Settlements	177,500
Total net unrealized losses included in earnings	(35,000)
Balance at June 30, 2013	$ 0

The fair value of the contingent liability was measured and recorded on a recurring basis using significant unobservable inputs (Level 3). At each remeasurement date until the contingent arrangement was settled, we determined the fair value of the contingent liability based on the market price of our common stock on the measurement date and our estimate of the number of First Milestone Shares we would issue, which was based on our estimate of the probability of achievement of the First Milestone and assumptions regarding the circumstances under which it would be achieved. As discussed in Note 3, the contingent liability was settled in May 2013 and we issued 250,000 of the First Milestone Shares. The remeasurement of the fair value of the contingent liability as of its settlement date resulted in the recognition of $7,500 in transaction-related expenses for the three months ended June 30, 2013.

Table of Contents

6. Property and Equipment

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

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

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

7. Accrued Liabilities

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

	June 30, 2013	December 31, 2012
Accrued contracts and study expenses	$ 1,026,375	$ 1,203,808
Financing-related expenses	274,101	
Other accrued liabilities	278,947	80,168
Total accrued liabilities	$ 1,579,423	$ 1,283,976

8. Share-Based Compensation Expense

Estimated share-based compensation expense related to equity awards granted to our employees and non-employee directors for the three and six months ended June 30, 2013 and 2012 was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Selling, general and administrative expense	$ 324,177	$ 346,122	$ 638,605	$ 697,926
Research and development expense	40,960	(9,298)	78,088	16,403
Share-based compensation expense	$ 365,137	$ 336,824	$ 716,693	$ 714,329

There were no employee or non-employee director stock options exercised during the three and six months ended June 30, 2013 or 2012. During the three and six months ended June 30, 2013, we granted stock options to acquire an aggregate of 3,236,054 shares and 3,720,354 shares of our common stock, respectively, to our employees and non-employee directors, with an estimated weighted-average grant date fair value of $0.40 and $0.42 per share, respectively. There were no employee or non-employee director stock options granted during the three and six months ended June 30, 2012. At June 30, 2013, total unrecognized estimated compensation cost related to non-vested employee and non-employee director share-based awards granted prior to that date was $3.5 million, which is expected to be recognized over a weighted-average period of

3.0 years.

(9)

Table of Contents

9. Net Loss Per Common Share

Basic and diluted net loss per common share was calculated by dividing the net loss applicable to common stock for the three and six months ended June 30, 2013 and 2012 by the weighted-average number of common shares outstanding during those periods, respectively, without consideration for outstanding common stock equivalents because their effect would have been anti-dilutive. Common stock equivalents are included in the calculation of diluted earnings per common share only if their effect is dilutive. For the periods presented, our outstanding common stock equivalents consisted of options and warrants to purchase shares of our common stock. The weighted-average number of those common stock equivalents outstanding for each of the periods presented is set forth in the table below:

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Options	4,443,575	2,832,503	4,252,226	2,862,318
Warrants	20,193,597	17,419,349	18,351,250	17,621,714

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 June 30, 2013.

In December 2011, FASB issued ASU 2011-11, *Balance Sheet (Topic 210): Disclosures about Offsetting Assets and Liabilities* (ASU 2011-11). ASU 2011-11 requires companies to provide new disclosures about offsetting and related arrangements for financial instruments and derivatives. The provisions of ASU 2011-11 are effective for annual reporting periods beginning on or after January 1, 2013, and must be applied retrospectively. We adopted this guidance effective January 1, 2013. The adoption of this standard did not have a significant impact on our consolidated financial position, results of operations and other comprehensive income/loss or cash flows.

11. Supplemental Cash Flow Information

Non-cash investing and financing transactions presented separately from the condensed consolidated statements of cash flows for the six months ended June 30, 2013 and 2012 and for the period from inception (June 12, 1996) through June 30, 2013 are as follows:

	Six months ended June 30,		Inception (June 12, 1996) through June 30, 2013
	2013	2012	
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	6,644	(3)	6,682
Cashless exercise of warrants			4,312
Dividends accrued			621,040
Trade asset converted to available-for-sale asset			108,000
Dividends extinguished			408,240
Trade payable converted to note payable			83,948
Issuance of warrants for return of common stock			50,852
Detachable warrants issued with notes payable			450,000
Cumulative preferred stock dividends			13,502,403
Purchases of property and equipment in accounts payable	22,966		22,966
Financing costs in accounts payable and accrued liabilities	355,762		355,762

Table of Contents

12. Stockholders Equity

Underwritten Public Offering of Common Stock and Warrants

In June 2013, we completed an underwritten public offering of 56,195,000 shares of our common stock and warrants to purchase up to 28,097,500 additional shares of our common stock. Of the 56,195,000 shares of our common stock issued, 1,454,079 of such shares were issued from our treasury stock. These securities were offered and sold to the underwriters and the public in units with each unit consisting of one share of common stock and one warrant to purchase up to 0.5 of a share of common stock. The gross proceeds from this financing were $28.1 million and, after deducting underwriting discounts and commissions and our other offering expenses, our net proceeds were $25.7 million. We may receive up to $18.3 million of additional proceeds from the exercise of the warrants issued in the financing. The exercise price of the warrants is $0.65 per share. Subject to certain beneficial ownership limitations, the warrants are exercisable at any time on or before June 19, 2018.

Outstanding Warrants

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

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

Table of Contents

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and accompanying notes appearing elsewhere in this report. For additional context with which to understand our financial condition and results of operations, see the discussion and analysis included in Part II, Item 7 of our annual report on Form 10-K for the year ended December 31, 2012, filed with the U.S. Securities and Exchange Commission, or SEC, on March 19, 2013, as well as the consolidated financial statements and accompanying notes contained therein. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results could differ materially from those discussed in these forward-looking statements as a result of various factors, including but not limited to those identified under Forward Looking Statements below and those discussed in Item 1A (Risk Factors) of Part II of this report. 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 $10.5 million for the six months ended June 30, 2013. Our cash, cash equivalents and short-term investments were $53.4 million as of June 30, 2013.

We continue to focus our resources on MST-188. We believe that its pharmacologic effects support its development in a wide range of diseases and conditions and we intend to develop MST-188 in multiple clinical indications, both independently and through collaborations. We are enrolling patients in EPIC (Evaluation of Purified 188 In Children), a pivotal phase 3 study of MST-188 in sickle cell disease, and have announced plans to develop MST-188 for complications of arterial disease, initially as an adjunct to thrombolytics in acute limb ischemia. 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 are conducting *in vitro* studies to evaluate the effect of MST-188 on blood coagulation, which may support further development in pre- and post-surgical resuscitation following major trauma.

In July 2013, we announced results of our thorough QT/QTc clinical study of MST-188, or the TQT study. The study met its primary endpoint and demonstrated that, based on analysis of electrocardiograms, MST-188 did not have an adverse effect on cardiac repolarization, as measured by prolongation of the QT interval. Sixty four subjects received MST-188 and it was generally well-tolerated at both therapeutic and supratherapeutic doses. The TQT study was a single-center, four-period, four-way cross-over, placebo- and positive-controlled, double-blind, randomized clinical trial in healthy volunteers that compared the effects of MST-188 at therapeutic and supratherapeutic doses to placebo and moxifloxacin on cardiac ventricular repolarization, specifically, Fridericia s corrected QT-Interval (QTcF) from the surface electrocardiogram. The primary endpoint was to confirm a lack of effect of MST-188 on QTcF.

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

In June 2013, we completed an underwritten public offering with gross proceeds of $28.1 million from the sale of units consisting of 56,195,000 shares of our common stock and warrants to purchase up to 28,097,500 additional shares of our common stock. Net proceeds were $25.7 million after deducting underwriting discounts and commissions and our other offering expenses. The warrants have an exercise price of $0.65 per share and, subject to certain beneficial ownership limitations, are exercisable at any time on or before June 19, 2018.

Table of Contents

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.

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.

Table of Contents

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.

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

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

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

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

Results of Operations Overview

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

Revenue

We have not generated any revenue from product sales to date, and we do not expect to generate revenue from product sales until such time, if any, that we have obtained approval from a regulatory agency to sell one or more of our product candidates, which we cannot predict with certainty will occur.

Operating Expenses

Research and Development Expenses. We maintain and evaluate our R&D expenses by the type of cost incurred rather than by project. We do this primarily because we outsource a substantial portion of our work and our R&D personnel and consultants work across multiple programs rather than dedicating their time to one particular program. We began maintaining such expenses by type on January 1, 2005. We categorize our R&D expenses as external clinical study fees and expenses, external nonclinical study fees and expenses, personnel costs and share-based compensation expense. The major components of our external clinical study fees and expenses are fees and expenses related to CROs and clinical study investigative sites and investigators. The major components of our external nonclinical study fees and expenses are fees and

expenses related to preclinical studies and other nonclinical testing, research-related manufacturing, quality assurance and regulatory affairs services. Research-related manufacturing expenses include costs associated with purchasing active pharmaceutical ingredient (API), conducting process development activities, producing clinical trial material, producing material for stability testing to support regulatory filings, related labeling, testing and release, packaging and storing services and related consulting fees. Impairment losses on R&D-related manufacturing equipment are also considered research-related manufacturing expenses. Personnel costs relate to employee salaries, benefits and related costs.

Table of Contents

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

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

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

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

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

Selling, General and Administrative Expenses. Selling, general and administrative, or SG&A, expenses consist primarily of salaries, benefits and related costs for personnel in executive, finance and accounting, legal and market research functions, and professional and consulting fees for accounting, legal, investor relations, business development, market research, human resources and information technology services. Other SG&A expenses include facility lease and insurance costs.

Transaction-Related Expenses. Transaction-related expenses consist of legal, accounting, financial and business development advisory fees associated with the evaluation of potential acquisition targets and execution of acquisition transactions, including our acquisition of SynthRx. Transaction-related expenses also include any changes in the fair value of the contingent consideration related to our acquisition of SynthRx, which we remeasured as of the end of each quarter until the contingent arrangements were settled and as of their respective settlement dates.

Table of Contents

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 June 30, 2013 and 2012

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

R&D Expenses. Our R&D expenses for the three months ended June 30, 2013 consisted primarily of external costs associated with EPIC and the TQT study. The following table summarizes our consolidated R&D expenses by type for each of the periods listed and their respective percent of our total R&D expenses for such periods:

	Three months ended June 30,				January 1, 2005 through
	2013	%	2012	%	June 30, 2013
External clinical study fees and expenses	$ 1,823,425	64%	$ 178,420	8%	$ 30,229,026
External nonclinical study fees and expenses	449,439	16%	1,437,715	68%	37,152,827
Personnel costs	523,111	18%	501,024	24%	14,427,888
Share-based compensation expense	40,960	2%	(9,298)	(0%)	3,053,309
Total	$ 2,836,935	100%	$ 2,107,861	100%	$ 84,863,050

R&D expenses increased by $0.7 million, or approximately 34.6%, to $2.8 million for the three months ended June 30, 2013, compared to $2.1 million for the same period in 2012. This increase was due primarily to a $1.7 million increase in external clinical study fees and expenses, 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 EPIC and the TQT study, which were initiated in 2013. 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 $0.2 million, or approximately 12.2%, to $2.1 million for the three months ended June 30, 2013, compared to $1.9 million for the same period in 2012. This increase resulted primarily from an increase in legal expenses and consulting fees.

Transaction-Related Expenses. Transaction-related expenses were $7,500 for the three months ended June 30, 2013, compared to $0.2 million for the same period in 2012. We recognized transaction-related expenses for the three months ended June 30, 2013 as a result of an increase in the fair value of the contingent liability related to the consideration for our acquisition of SynthRx at its settlement date, May 30, 2013, relative to March 31, 2013, which increase was due to the increase in our stock price at the settlement date ($0.71 per share) relative to March 28, 2013 ($0.68 per share), the last trading day of the three months ended March 31, 2013. Transaction-related expenses for the three months ended June 30, 2012 were due to changes in the fair values at June 30, 2012 relative to March 31, 2012 of the contingent asset and contingent liability related to the consideration for our acquisition of SynthRx. Given that both the contingent asset and contingent liability have been settled, we do not anticipate future transaction-related expenses in connection with our acquisition of SynthRx.

Interest Income. Interest income amounted to $11,000 for the three months ended June 30, 2013, compared to $19,000 for the same period in 2012. The decrease in interest income for the three months ended June 30, 2013 was attributable primarily to lower cash balances for most of the period compared to the same period in 2012.

Net Loss. Net loss was $4.9 million, or $0.09 per share, for the three months ended June 30, 2013, compared to net loss of $4.2 million, or $0.09 per share, for the same period in 2012.

Comparison of Six Months Ended June 30, 2013 and 2012

Revenue. We recognized no revenue for the six months ended June 30, 2013 and 2012.

(16)

Table of Contents

R&D Expenses. Our R&D expenses for the six months ended June 30, 2013 consisted primarily of external costs associated with EPIC and the TQT study. The following table summarizes our consolidated R&D expenses by type for each of the periods listed and their respective percent of our total R&D expenses for such periods:

	Six months ended June 30,			
	2013	**%**	**2012**	**%**
External clinical study fees and expenses	$ 4,131,527	66%	$ 429,470	10%
External nonclinical study fees and expenses	996,790	16%	2,985,610	69%
Personnel costs	1,073,442	17%	886,832	21%
Share-based compensation expense	78,088	1%	16,403	0%
Total	$ 6,279,847	100%	$ 4,318,315	100%

R&D expenses increased by $2.0 million, or approximately 45.4%, to $6.3 million for the six months ended June 30, 2013, compared to $4.3 million for the same period in 2012. This increase was due primarily to a $3.7 million increase in external clinical study fees and expenses, a $0.2 million increase in personnel costs and a $0.1 million increase in share-based compensation expense, offset by a $2.0 million decrease in external nonclinical study fees and expenses. The increase in external clinical study fees and expenses was related primarily to EPIC and the TQT study. The increase in personnel costs was related primarily to increased headcount. The $2.0 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 $0.3 million, or approximately 7.6%, to $4.2 million for the six months ended June 30, 2013, compared to $3.9 million for the same period in 2012. This increase resulted primarily from a $0.2 million increase in legal expenses and consulting fees and a $0.1 million increase in personnel costs related to increased headcount.

Transaction-Related Expenses. Transaction-related expenses were $35,000 for the six months ended June 30, 2013, compared to $0.1 million for the same period in 2012. We recognized transaction-related expenses for the six months ended June 30, 2013 as a result of an increase in the fair value of the contingent liability related to the consideration for our acquisition of SynthRx at its settlement date, May 30, 2013, relative to December 31, 2012, which increase was due to the increase in our stock price at the settlement date ($0.71 per share) relative to December 31, 2012 ($0.57 per share). Transaction-related expenses for the six months ended June 30, 2012 were due to changes in the fair values at June 30, 2012 relative to December 31, 2011 of the contingent asset and contingent liability related to the consideration for our acquisition of SynthRx.

Interest Income. Interest income amounted to $25,000 for the six months ended June 30, 2013, compared to $38,000 for the same period in 2012. The decrease in interest income for the six months ended June 30, 2013 was attributable primarily to lower cash balances for most of the period compared to the same period in 2012.

Net Loss. Net loss was $10.5 million, or $0.21 per share, for the six months ended June 30, 2013, compared to net loss of $8.4 million, or $0.18 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 six months ended June 30, 2013, we incurred a loss from operations of $10.5 million. Our cash, cash equivalents and short-term investments were $53.4 million as of June 30, 2013. Our short-term investments at June 30, 2013 consisted entirely of FDIC-insured certificates of deposit.

We historically have funded our operations principally through proceeds from sales of our equity securities. In June 2013, we completed an underwritten public offering involving the issuance of units consisting of shares of our common stock and common stock purchase warrants. This financing resulted in $28.1 million in gross proceeds and $25.7 million in net proceeds, after deducting underwriting discounts and commissions and our other offering expenses.

We may receive up to $0.8 million, $6.6 million, $5.6 million, $11.7 million and $18.3 million of additional net proceeds from the exercise of warrants issued in the registered direct equity financings we completed in October 2009, May 2010 and January 2011 and the underwritten public offerings we completed in November 2011 and June 2013, respectively; however, the exercise of these warrants is subject to certain beneficial ownership limitations. In addition, the exercise prices of these warrants are $3.67, $3.65, $2.75, $1.10 and $0.65 per share,

respectively. In comparison, the closing sale price of our common stock on June 28, 2013, the last trading day of the three months ended June 30, 2013, was $0.43 per share and we do not expect the holders of the warrants to exercise them unless and until our common stock trades at or above the exercise price of their warrants. For additional information regarding outstanding warrants to purchase our common stock, see Note 12, Stockholders Equity, of the Notes to the Condensed Consolidated Financial Statements (Unaudited) in this report.

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

Table of Contents

Operating activities. Net cash used in operating activities was $9.2 million for the six months ended June 30, 2013 compared to $7.4 million for the same period in 2012. The increase in cash used in operating activities was primarily due to a higher net loss for the six months ended June 30, 2013 compared to the same period in 2012 ($2.2 million), offset by an increase in accounts payable and accrued liabilities ($0.5 million) and a decrease in prepaid expenses and other assets ($0.3 million). We also incurred a $0.3 million equipment impairment charge during the six months ended June 30, 2012 related to ANX-514 research-related manufacturing equipment compared to the $0.1 million write-off of this equipment upon disposal for the same period in 2013.

Investing activities. Net cash provided by investing activities was $5.5 million for the six months ended June 30, 2013 compared to net cash used in investing activities of $6.2 million for the same period in 2012. The difference was due primarily to an increase of $6.7 million in proceeds from maturities of certificates of deposits, a decrease of $4.9 million in purchases of certificates of deposit and a decrease of $0.2 million in purchases of property and equipment.

Financing activities. Net cash provided by financing activities was $26.1 million for the six months ended June 30, 2013, representing the gross proceeds from the underwritten public offering of our equity securities completed during that period, less the underwriting discount and offering expenses paid during the period. We expect to pay an additional $0.4 million in offering expenses during the third quarter, resulting in $25.7 of net proceeds from the offering. There was no cash used in or provided by financing activities during the six months ended June 30, 2012.

Management Outlook

We anticipate that our cash, cash equivalents and short-term investments as of June 30, 2013 will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, our estimate of the period of time through which our current financial resources will be adequate to support our operations is a forward-looking statement based on significant assumptions that involve a number of risks and uncertainties and actual results could differ materially. Factors that will affect our future funding requirements include, but are not limited to: the progress and results of our clinical and nonclinical studies of MST-188, particularly the EPIC study; 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. We expect to enroll 388 subjects from approximately 70 medical centers. In addition to approximately 40 U.S. sites, we plan to open approximately 30 sites outside of the U.S. and we expect to begin opening sites outside of the U.S. in the fourth quarter of 2013. 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 will be approximately $20 million.

Earlier this year, 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 to $4 million.

In addition, we are conducting or 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 indications, including an experimental model of heart failure, *in vitro* studies to evaluate the effect of MST-188 on blood coagulation, and six-month toxicology studies. We also are conducting activities to initiate a sub-study within EPIC that will evaluate the effect of MST-188 on microvascular blood flow and/or tissue oxygen levels. The sub study will be conducted at select EPIC sites using non-invasive devices and we plan to enroll approximately 30 patients. Other than as described above, unless we secure U.S. government or other third-party funding for development of MST-188 in a particular indication, we do not plan to initiate additional clinical studies in 2013.

In parallel with our independent development of MST-188, we are evaluating opportunities for strategic alliances for MST-188. 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.

(18)

Table of Contents

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. 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 identif 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 known and unknown risks and uncertainties that could cause our actual results, performance or achievements to be materially different from any result, performance or achievement expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to the following:

- our ability, or that of a future partner, to successfully develop, obtain regulatory approval for, and then successfully commercialize MST-188;
- our ability to obtain additional funding on a timely basis, or on acceptable terms, or at all;
- the potential for us to delay, scale back, or discontinue development of MST-188, partner it at inopportune times, or pursue less expensive but higher-risk and/or lower-return development paths if we are unable to raise sufficient additional capital as needed;
- delays in the commencement or completion of clinical studies or manufacturing and regulatory activities necessary to obtain regulatory approval to commercialize MST-188;

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

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

our ability to maintain our relationships with the single-source third-party manufacturers and suppliers for clinical trial material, including the API and finished drug product, and the ability of such manufacturers and suppliers to successfully and consistently meet our manufacturing and supply requirements;

the satisfactory performance of third parties, including CROs, on whom we rely significantly to conduct or assist in the conduct of our nonclinical testing, clinical studies and other aspects of our development programs;

Table of Contents

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;

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

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

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

competition in the marketplace for our products, if approved;

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

claims against us for infringing the proprietary rights of third parties;

healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent commercial success;

undesirable side effects that our product candidates or products may cause;

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

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

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

the other factors that are described in Item 1A (Risk Factors) of Part II of this report.

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.

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.

Table of Contents

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 June 30, 2013. Based on that evaluation, our principal executive officer and principal financial officer have concluded that as of June 30, 2013 these disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Investment in our securities involves a high degree of risk. Our business, operating results, growth prospects and financial condition are subject to various risks, many of which are not exclusively within our control, that may cause actual performance to differ materially from historical or projected future performance. We urge investors to consider carefully the risks described below, together with all of the information in this report and our other public filings, including our annual report on Form 10-K for the year ended December 31, 2012, before making investment decisions regarding our securities. Each of these risk factors, as well as additional risks not presently known to us or that we currently deem immaterial, could adversely affect our business, operating results, growth prospects or financial condition, as well as the trading price of our common stock, in which case you may lose all or part of your investment.

We have marked with an asterisk (*) the title of those risk factors below that reflect material changes from the risk factors included in our annual report on Form 10-K for the year ended December 31, 2012.

RISKS RELATED TO OUR BUSINESS

Risks Related to Our Capital Requirements, Finances and Operations

We have incurred losses since our inception, we expect our operating expenses to continue to exceed our revenue for the foreseeable future, and we may never generate revenue sufficient to achieve profitability.

We are a development-stage company and have not generated sustainable revenue from operations or been profitable since inception, and we may never achieve profitability. We have devoted our resources to acquiring and developing proprietary product candidates, but such product candidates cannot be marketed until the regulatory process is completed and governmental approvals have been obtained. We have accumulated net losses totaling approximately $197.7 million as of June 30, 2013, and we expect to continue to incur substantial operating losses for the next several years as we advance MST-188, our lead product candidate, through clinical studies and other development activities and seek approval from the FDA to commercialize it. Accordingly, there is no current source of revenue from operations, much less profits, to sustain our present activities. Further, no revenue from operations will likely be available until, and unless, we enter into an arrangement that provides for licensing revenue or other partnering-related funding or MST-188 or another product candidate is approved by the FDA or another regulatory agency, and successfully marketed, outcomes which we may not achieve.

The success of our business currently is dependent on the success of MST-188 and this product candidate may not receive regulatory approval or be successfully commercialized.

We currently have no products for sale and we are focusing our resources almost exclusively on the development of MST-188. Accordingly, the success of our business currently depends on our ability, or that of a future partner, to successfully develop, obtain regulatory approval for and then successfully commercialize this product candidate and our efforts, or those of a future partner, in this regard may prove unsuccessful. MST-188 requires considerable additional clinical development, including successful completion of EPIC, our ongoing phase 3 clinical study in

sickle cell disease, and significant manufacturing activities prior to commencing any commercial manufacturing, all of which require us to expend significant resources and with which we have limited experience. MST-188 may not be successful in EPIC, or in other clinical studies we initiate in sickle cell disease or other indications or, even if successful in clinical studies, may not receive regulatory approval in a timely manner, or at all. If MST-188 is approved by the FDA or any foreign regulatory agency, our ability to generate revenue from it will depend in substantial part on the extent to which it is accepted by the medical community and reimbursed by third-party payors, as well as our ability to market and sell the product and ensure that our third-party manufacturers produce it in quantities sufficient to meet commercial demand, if any.

Table of Contents

The process of developing and seeking regulatory approval of investigational new drug products requires expenditure of substantial resources, and we cannot estimate with reasonable certainty the duration of or costs to complete our development programs.

Our capital requirements for the foreseeable future will depend in large part on, and could increase significantly as a result of, our expenditures on our development programs. Future expenditures on our development programs are subject to many uncertainties, and will depend on, and could increase significantly as a result of, many factors, including:

- the number and scope of development programs we pursue;
- 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 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 for 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 costs, requirements, timing of, and the ability to, secure regulatory approvals;
- the timing and terms of any collaborative or other strategic arrangement that we may establish;
- the extent to which we increase our workforce and the costs involved in recruiting, training and incentivizing new employees;
- the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities, supply chain management capabilities, and regulatory compliance capabilities, if we obtain regulatory approval for a product candidate and commercialize it without a partner; and
- the costs involved in establishing, enforcing or defending patent claims and other proprietary rights.

If our estimated future expenditures on our development programs increased more than our current expectations, we would need to seek additional capital or reduce other expenditures. We may not be able to raise capital as and when needed or reduce other expenditures to offset an

increase in expenditures on our development programs, which could have a material adverse effect on our financial condition and ability to pursue our business.

We will need to obtain additional funding to pursue our current business strategy and we may not be able to obtain such funding on a timely basis, or on commercially reasonable terms, or at all. Any capital-raising transaction we are able to complete may result in dilution to our existing stockholders, require us to relinquish significant rights or restrict our operations.

We anticipate that our cash, cash equivalents and short-term investments, which were approximately $53.4 million as of June 30, 2013, will be sufficient to fund our currently planned level of operations for at least the next 12 months. However, we may determine to grow our organization and/or pursue development activities for MST-188 or other product candidates at levels or on timelines, or we may incur unexpected expenses, that shorten the period through which our current operating funds will sustain us. We may also seek to expand our product pipeline through acquisition of additional product candidates and/or technologies and the cost to acquire and develop such new product candidates and/or technologies may shorten the period through which our current operating funds will sustain us. We do not expect to generate any substantial revenue from operations in the next several years, and we will need to obtain additional capital to support our planned operating activities.

Table of Contents

For the foreseeable future, we likely will seek to fund our operations through public or private equity and debt financings and/or through collaborations, such as licensing arrangements or partnering transactions, and may execute any such transaction at any time, subject to applicable laws and regulations. Although we were able to raise significant funds in the past through equity financings, the conditions of and our access to capital markets are highly variable and adequate additional financing may not be available to us in the future on acceptable terms, or on a timely basis, or at all. Further, each of these financing alternatives carries risks. Raising capital through the issuance of our common stock, or securities convertible into or exercisable for our common stock, may depress the market price of our stock and may substantially dilute our existing stockholders. If instead we seek to raise capital through strategic transactions, such as licensing arrangements or sales of one or more of our technologies or product candidates, we may be required to relinquish valuable rights and dilute the current and future value of our assets. For example, any licensing arrangement likely would require us to share with our licensee a significant portion of any revenues generated by our licensed technologies. Additionally, our control over the development and/or marketing of any products or product candidates licensed or sold to third parties may be reduced and thus we may not realize the full value of any such products or product candidates. Debt financings could involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens or make investments and may, among other things, preclude us from making distributions to stockholders (either by paying dividends or redeeming stock) and taking other actions beneficial to our stockholders. In addition, investors could impose more one-sided investment terms and conditions on companies that have or are perceived to have limited remaining funds or limited ability to raise additional funds. The lower our cash balance, the more difficult it is likely to be for us to raise additional capital on commercially reasonable terms, or at all.

For particular development programs, such as development of MST-188 for resuscitation of shock following major trauma, we plan to seek funding from the U.S. government. The process of obtaining government contracts is lengthy and uncertain and highly competitive. In addition, changes in government budgets and agendas may result in decreased availability of drug research and development funding. For example, on March 1, 2013, automatic, across-the-board federal budget cuts, known as sequestration, went into effect, which could significantly reduce funding for drug research and development programs and reduce the likelihood of our receipt of government funding in the future. If we do secure government funding, the contracts for such funding may contain termination and audit provisions that are unfavorable to us and cause us to incur significant additional administrative expense. In addition, the U.S. government may require march-in rights that allow it to grant licenses to inventions that arise from development programs it funds if, for example, we do not commercialize the technology within a certain timeframe or the government deems such action necessary to alleviate health or safety needs that are not being reasonably satisfied by us. If the government exercises its march-in rights, we could be obligated to license intellectual property developed by us on terms unfavorable to us and we may not receive compensation from the government for its exercise of such rights, which likely would have a material adverse effect on our financial condition and prospects.

Notwithstanding any effort on our part to raise additional capital, adequate additional funding may not be available on acceptable terms, or on a timely basis, or at all. Even if we incur costs in pursuing, evaluating and negotiating particular capital-raising and/or strategic or partnering transactions, our efforts may not prove successful. We believe global economic conditions, including the continued volatility of U.S. and international equity markets, may adversely impact our ability to raise additional capital. Our failure to raise capital as and when needed would have a material adverse effect on our financial condition and ability to pursue our business strategy.

Our ability to raise capital may be limited by applicable laws and regulations.

Historically, we have raised capital through the sale of our equity securities. Between June 2009 and November 2011, we completed seven equity financings under shelf registration statements on Form S-3. Using a shelf registration statement on Form S-3 to raise additional capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. However, our ability to raise capital using a shelf registration statement may be limited by, among other things, current SEC rules and regulations. Under current SEC rules and regulations, we must meet certain requirements to use a Form S-3 registration statement to raise capital without restriction as to the amount of the market value of securities sold thereunder. One such requirement is that the market value of our outstanding common stock held by non-affiliates, or public float, be at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3. If we do not meet that requirement, then the aggregate market value of securities sold by us or on our behalf under the Form S-3 in any 12-month period is limited to an aggregate of one-third of our public float. Moreover, even if we meet the public float requirement at the time we file a Form S-3, SEC rules and regulations require that we periodically re-evaluate the value of our public float, and if, at a re-evaluation date, our public float is less than $75.0 million, we would become subject to the one-third of public float limitation described above. If our ability to utilize a Form S-3 registration statement for a primary offering of our securities is limited to one-third of our public float, we may conduct such an offering pursuant to an exemption from registration under the Securities Act or under a Form S-1 registration statement, which we have done in the past, including in June 2013, and we would expect either of those alternatives to increase the cost of raising additional capital relative to utilizing a Form S-3 registration statement.

(23)

Table of Contents

In addition, under current SEC rules and regulations, our common stock must be listed and registered on a national securities exchange in order to utilize a Form S-3 registration statement (i) for a primary offering, if our public float is not at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3, or a re-evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (i.e., a resale offering). While currently our common stock is listed on the NYSE MKT equities market, there can be no assurance that we will be able to maintain such listing. The NYSE MKT reviews the appropriateness of continued listing of any issuer that falls below the exchange s continued listing standards. Previously, including during part of 2010, we were not in compliance with certain NYSE MKT continued listing standards and were at risk of having our common stock delisted from the NYSE MKT equities market. For additional information regarding this risk, see the risk factor below titled If we are unable to maintain compliance with NYSE MKT continued listing standards, our common stock may be delisted from the NYSE MKT equities market, which would likely cause the liquidity and market price of our common stock to decline.

Our ability to timely raise sufficient additional capital also may be limited by the NYSE MKT s stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, the NYSE MKT requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our then outstanding common stock, unless the transaction is considered a public offering by the NYSE MKT staff. Based on 102,710,286 shares of our common stock outstanding as of August 1, 2013 and the closing price per share of our common stock on such date, which was $0.45, we could not raise more than approximately $9.2 million without obtaining stockholder approval, unless the transaction is deemed a public offering or does not involve the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering that is not considered a public offering by the NYSE MKT staff and involves the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the greater of book or market value. The NYSE MKT also requires that we obtain stockholder approval if the issuance or potential issuance of additional shares will be considered by the NYSE MKT staff to result in a change of control of our company.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital, which may materially and adversely affect our ability to execute our current business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction. A public offering under the NYSE MKT rules typically involves broadly announcing the proposed transaction, which often times has the effect of depressing the issuer s stock price. Accordingly, the price at which we could sell our securities in a public offering may be less, and the dilution existing stockholders experience may in turn be greater, than if we were able to raise capital through other means.

If we are unable to raise sufficient additional capital as needed, we may be forced to delay, scale back or discontinue our 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 not able to raise sufficient additional capital as needed, we may be required to delay, scale back or discontinue our development of MST-188 or other programs, or to seek collaborators at an earlier stage than otherwise would be desirable or on terms less favorable than might otherwise be available. For example, if we do not have sufficient capital, we may determine not to investigate certain additional indications for MST-188 or to conduct other studies or activities intended to enhance our intellectual property position, improve the probability of regulatory approval, or expand the scope of MST-188 s clinical benefit and market potential. Delays in and/or reduction of development activities could impair our ability to realize the full clinical and market potential of a product candidate and have a material adverse effect on our business and financial condition. In addition, discontinuation of a development program may be viewed negatively, which could adversely affect our stock price.

To the extent we discontinue independent development of a product candidate, we may not realize any value from our investment in the discontinued program. Even if we pursue a strategic option, such as partnering, selling or exclusively licensing the program to a third party, such an option may be not be available on acceptable terms or at all. For example, in prior years, we were focused on developing Exelbine and ANX-514 and expended significant resources on their development; however, in 2011 and 2012, respectively, we elected to discontinue independent development of those programs. Although we are evaluating other opportunities for further development of those agents, such as partnering and licensing arrangements, none may be available and we may not realize any return on our investment in those programs.

Table of Contents

Our business may suffer if we are unable to retain and attract highly qualified personnel and manage internal growth.

Currently, we have a small number of employees and we rely on third parties to perform many essential services for us. Our ability to execute on our business strategy and compete in the highly competitive biopharmaceutical, specialty pharmaceutical, pharmaceutical and biotechnology industries depends, in part, on our ability to attract and retain highly qualified personnel. We are highly dependent on certain personnel, including our chief executive officer, our president and chief operating officer, our chief medical officer, and our senior vice president, development. Our industries in general and our company in particular historically have experienced a high rate of turnover of management personnel. If we lose any of our key employees, our ability to successfully implement our current business strategy could be seriously harmed. Replacing key employees may be a difficult, costly and protracted process, particularly due to the fact that we currently do not have other executive officers or personnel to assume all of the responsibilities of these key employees. In addition, we may seek to increase the size of our organization as development of MST-188 or another product candidate progresses. Competition for qualified personnel, particularly for key positions, is intense among companies in our field, universities and other research organizations, particularly in the San Diego, California area, and many of the organizations against which we compete for qualified personnel have greater financial and other resources and different risk profiles than our company, which may make them more attractive employers. Our ability to compete for qualified personnel may be adversely affected by our highly volatile stock price. The value to employees of stock options we provide to retain and incentivize them is significantly affected by movements in our stock price that we cannot control and may at any time be insufficient to counteract more lucrative offers from other companies. All of our employees, including our executive officers, may terminate their employment with us at any time with or without notice. If we cannot attract and retain skilled personnel, as needed, we may not achieve our development and other goals.

Future internal growth could impose significant added responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees. We may need to devote a significant amount of time to managing these activities and may not be able to do so effectively. If we are unable to effectively manage future internal growth, our expenses may increase more than expected, we may not be able to achieve our development goals, and our ability to generate and/or grow revenue could be diminished. In the meantime, the success of our business also depends, in part, on our ability to develop and maintain relationships with respected service providers and industry-leading consultants and advisers. If we cannot develop and maintain such relationships, as needed, the rate and success at which we can develop and commercialize product candidates may be limited. In addition, our outsourcing strategy, which has included engaging consultants that spend considerable time in our office to manage key functional areas, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition.

If we determine to grow our business through the acquisition of new technologies and/or product candidates, our existing stockholders may experience substantial dilution, we may fail to realize the benefits of any future strategic acquisition or investment and we may incur unexpected costs and disruptions to our business.

Although we are focused on developing MST-188, from time to time, we may evaluate pipeline expansion opportunities that we believe will increase the long-term value of our company. The process of identifying, evaluating, negotiating and implementing the purchase or license of new assets is lengthy and complex and may disrupt other development programs and distract our personnel. We have limited resources with respect to identifying, evaluating, negotiating and implementing the acquisition of new assets or rights thereto and integrating them into our current infrastructure. Supplementing our current resources to complete one or more of these transactions may be costly.

We may use cash, shares of our common stock, securities convertible into our common stock or a combination of cash and our securities to pay the purchase price or license fee for any future strategic transaction. The use of cash could negatively impact our financial position and ability to develop MST-188 or any other product candidate. The use of shares of our common stock or securities convertible into shares of our common stock would dilute the holdings of our existing stockholders and, given our recent market capitalization, such dilution could be substantial. For example, in addition to the 1,596,772 outstanding shares we have issued to SynthRx s former stockholders as consideration for our acquisition of SynthRx that are outstanding, we could issue up to an aggregate of 12,478,050 additional shares of our common stock to such persons upon achievement of milestones related to the development and regulatory approval of MST-188 for the treatment of sickle cell crisis in children. If those milestones are achieved, the number of shares issued and outstanding in connection with the SynthRx acquisition would, in the aggregate, represent an approximately 12.2% ownership stake in our company (based on 102,710,286 shares outstanding as of August 1, 2013 plus shares issued in connection with achievement of the milestones). The issuance of shares in connection with other future strategic transactions, if any, may result in the stockholders who own the majority of our voting securities prior to one or more of such transactions owning less than a majority after such transactions.

Table of Contents

Further, strategic transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention to develop and/or commercialize acquired technologies and/or products candidates;
- incurrence of substantial debt to pay for acquisitions;
- greater than anticipated difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers of any acquired business due to changes in management and ownership; and
- inability to retain key employees of any acquired business.

Our stockholders will be required to rely on the judgment of our management and board of directors as to which new product candidates and/or technologies we pursue and may have limited or no opportunity to evaluate potential new assets prior to completion of a transaction, including the terms of acquisition, the costs of their future development and their commercial potential. We may devote resources to potential acquisition or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. Any technology and/or product candidate that we acquire or to which we acquire rights likely will require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are subject to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities and other risks described under the section titled Risks Related to Drug Development and Commercialization.

We expend substantial resources to comply with laws and regulations relating to public companies, and any failure to maintain compliance could subject us to regulatory scrutiny and cause investors to lose confidence in our company, which could harm our business and have a material adverse effect on our stock price.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the Sarbanes-Oxley Act of 2002, or SOX, and the related rules and regulations adopted by the SEC and by the NYSE MKT have resulted in, and will continue to result in, significant costs to us as we evaluate the implications of these rules and respond to their requirements. For example, compliance with Section 404 of SOX, including performing the system and process documentation and evaluation necessary to issue our annual report on the effectiveness of our internal control over financial reporting and, if applicable, obtain the required attestation report from our independent registered public accounting firm, requires us to incur substantial expense and expend significant management time. Further, we have in the past discovered, and may in the future discover, areas of internal controls that need improvement. If we identify deficiencies in our internal controls that are deemed to be material weaknesses, we could become subject to scrutiny by regulatory authorities and lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on our stock price. Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations, including the possibility of human error and circumvention by collusion or overriding of controls. Accordingly, even an effective internal control system may not prevent or detect material misstatements on a timely basis, or at all. Also, previously effective controls may become inadequate over time as a result of changes in our business or operating structure, and we may fail to take measures to evaluate the adequacy of and update these controls, as necessary, which could lead to a material misstatement.

In addition, new laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees, and as our executive officers. We cannot predict or estimate with

any reasonable accuracy the total amount or timing of the costs we may incur to comply with these laws and regulations.

Table of Contents

Our ability to use net operating loss carry forwards and research and development tax credits to offset future taxable income or future tax will be limited and may be limited further in the future due to changes in ownership (within the meaning of IRC Section 382) that have occurred and may occur in the future.*

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or IRC, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, and certain other tax assets to offset future taxable income, and an ownership change is generally defined as a cumulative change of 50% or more in the ownership positions of certain stockholders during a rolling three year period. In 2012, we identified several ownership changes within the meaning of IRC Section 382 that had occurred during 2010 and 2011, with the most recent as a result of our November 2011 common stock and warrant financing. As a result of those ownership changes, we do not expect to be eligible to utilize the NOL carry forwards and research and development tax credits we had accumulated as of November 11, 2011. In addition, although we have not yet conducted a formal study to identify ownership changes within the meaning of IRC Section 382 for periods after December 31, 2011, we believe that the common stock and warrant financing we completed in June 2013 may be an ownership change for purposes of Sections 382 and 383 of the IRC, which would further limit the availability of our NOL carry forwards.

Other ownership changes within the meaning of IRC Section 382 may occur in the future, which could eliminate or restrict our ability to use NOL carry forwards and research and development tax credits generated after June 19, 2013. Limitations on our ability to use NOL carry forwards and research and development tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Similar rules and limitations may apply for state income tax purposes.

Our operations might be interrupted by the occurrence of a natural disaster or other catastrophic event.

Our corporate headquarters are located in a single commercial facility in San Diego, California. Important documents and records, including copies of our regulatory documents and other records for our product candidates, are located at our facilities and we depend on our facilities for the continued operation of our business. Natural disasters and other catastrophic events, such as wildfires and other fires, earthquakes and extended power interruptions, which have impacted San Diego businesses in the past, and terrorist attacks or severe weather conditions, could significantly disrupt our operations and result in additional, unplanned expense. As a small company, we have limited capability to establish and maintain a comprehensive disaster recovery program and, accordingly, we do not have a formal business continuity or disaster recovery plan, and any natural disaster or catastrophic event could disrupt our business operations and result in setbacks to our development programs. Even though we believe we carry commercially reasonable insurance, we might suffer losses that are not covered by or exceed the coverage available under these insurance policies.

Risks Related to Drug Development and Commercialization

Further testing and validation of our product candidates and related manufacturing processes are required and regulatory approval may be delayed or denied, which would delay or prevent us from marketing our product candidates and substantially harm our business.

Human pharmaceutical products generally are subject to rigorous nonclinical testing and clinical studies and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations is time-consuming and requires the expenditure of substantial resources. In addition, these requirements and processes vary widely from country to country. Government regulation and the need for FDA and other regulatory agency approval will delay commercialization of our product candidates, impose costly procedures upon our activities, and may put us at a disadvantage relative to other companies with which we compete. There can be no assurance that FDA or any other regulatory agency will grant marketing approval for MST-188 or any of our product candidates on a timely basis, or at all, including due to factors not within our control. For example, the sequester that took effect on March 1, 2013 may result in significant reductions to the FDA s budget, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of or obtain approval for MST-188.

Clinical studies typically involve a lengthy and expensive process with an uncertain outcome.

Clinical testing typically is expensive and can take years to complete, and its outcome is inherently uncertain. Clinical studies may not commence on time or be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a variety of reasons, including difficulties and delays related to:

obtaining regulatory approval to commence a clinical study;

obtaining institutional review board, or IRB, approval to conduct a clinical study at a prospective site;

identifying appropriate study sites and reaching agreement on acceptable terms with prospective study sites and investigators, the terms of which can be subject to extensive negotiation and may vary significantly among study sites;

Table of Contents

- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, for the conduct of clinical studies and contract manufacturing organizations, or CMOs, for the production of clinical trial material, the terms of which agreements can be subject to extensive negotiation and may vary significantly among different CROs and CMOs;

- failures on the part of our CROs and CMOs in developing procedures and protocols or otherwise conducting activities on timelines requested by us;

- identifying and hiring or engaging, as applicable, additional employees or consultants to assist us in managing CRO and/or CMO activities, managing a clinical study and analyzing the data resulting from a study;

- recruiting and enrolling patients to participate in a clinical study;

- manufacturing sufficient quantities of clinical trial material due, among other things, to lack of availability of capacity at a CMO or of the component materials, including the active pharmaceutical ingredient, or API;

- having patients complete a study and/or return for and complete post-treatment follow-up; and

- unforeseen results from other clinical studies or nonclinical testing that require us to amend a study design or halt or terminate a clinical study.

Patient enrollment, a significant factor in the time required to complete a clinical study, is affected by many factors, including the size and nature of the study subject population, the proximity of patients to clinical sites, the eligibility criteria for the study, the design of the clinical study, competing clinical studies and clinicians and patients perceptions as to the potential advantages of the drug being studied in relation to available alternatives, including therapies being investigated by other companies. Further, completion of a clinical study and/or its results may be adversely affected by failure to retain subjects who enroll in a study but withdraw due to adverse side effects, lack of efficacy, improvement in condition before treatment has been completed or for personal issues or who fail to return for or complete post-treatment follow-up.

In addition, a clinical study may be suspended or terminated by us, an IRB, a data safety monitoring board, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the study in accordance with regulatory requirements or the study s protocol;

- inspection of clinical study operations or sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

- unforeseen safety issues, including adverse side effects;

- changes in governmental regulations or administrative actions; or

- lack of adequate funding to continue the study.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit protocols to IRBs for reexamination or renegotiate terms with CROs and study sites and

investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

Clinical studies may not begin on time or be completed in the timeframes we anticipate and may be more costly than we anticipate for a variety of reasons, including one or more of those described above. For example, although we expect to move MST-188 directly into phase 2 studies for most new indications we plan to pursue, an IRB or the FDA or another regulatory agency may require additional clinical or nonclinical studies prior to initiation of any planned phase 2 study, which likely would increase the total time and cost of development in that indication. The length of time necessary to complete clinical studies varies significantly and is difficult to predict accurately. We may make statements regarding anticipated timing for completion of enrollment in and/or availability of results from our clinical studies, but such predictions are subject to a number of significant assumptions and actual timing may differ materially for a variety of reasons including the factors described above. If we experience delays in the completion of a clinical study or if a clinical study is terminated, the commercial prospects for our product candidate may be harmed and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical studies likely will increase our development costs. Further, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may be introduced to the market in the interim and establish a competitive advantage or diminish the need for our products.

Table of Contents

Positive results in nonclinical testing and prior clinical studies do not ensure that future clinical studies will be successful or that our product candidates will receive the regulatory approvals necessary for their commercialization.

Before obtaining regulatory approval for the commercial sale of any of our product candidates, we must demonstrate through nonclinical testing and clinical studies that each product is safe and effective for use in each target indication. Based on extensive nonclinical testing, we believe we understand MST-188 s mechanism of action; however, previously observed pharmacologic effects and clinical benefits may not be observed in ongoing or future nonclinical or clinical studies. Success in nonclinical testing and prior clinical studies does not ensure that subsequent or larger-scale studies will be successful. For example, non-purified poloxamer 188 was tested in more than 2,000 human subjects in various indications before the program was discontinued, principally due to concerns regarding acute renal dysfunction observed in patients who received the study drug. In contrast, MST-188 was generally well-tolerated in six prior clinical studies and no clinically significant changes in renal function were observed. However, patient safety concerns may be observed in ongoing or future clinical studies, including EPIC and the TQT study. With respect to efficacy, although there is compelling data from nonclinical and clinical studies of poloxamer 188 in multiple indications, ongoing and future studies may fail to demonstrate clinical benefits to human subjects.

Further, clinical study results frequently are susceptible to varying interpretations. Medical professionals, investors and/or regulatory authorities may analyze or weigh study data differently than we do. In addition, determining the value of clinical data typically requires application of assumptions and extrapolations to raw data. Alternative methodologies may lead to differing conclusions, including with respect to the safety or efficacy of our product candidates. For example, alternative methods for applying missing or imputed data may have impacted the treatment effect observed in the prior-sponsor phase 3 study of MST-188 in sickle cell disease. If regulatory authorities disagree with us as to the appropriate methods for analyzing study data, regulatory approval for our product candidates may be delayed, limited or withheld. For instance, despite positive nonclinical testing that indicated bioequivalence between ANX-514 and the reference product, Taxotere, our bioequivalence study of ANX-514 did not demonstrate bioequivalence between ANX-514 and Taxotere based on the FDA s benchmark regulatory standards and the FDA determined ANX-514 could not be approved based on the findings from that study.

In addition, if we license to third parties rights to develop our product candidates in other geographic areas or in other indications, we may have limited control over nonclinical testing or clinical studies that may be conducted by such third-party licensees in those territories or indications. If data from third-party testing identifies a safety or efficacy concern, such data could adversely affect our or another licensee s development of MST-188. For example, we have licensed to a third party certain rights to ANX-514 in South Korea and have limited control over any nonclinical testing or clinical studies that may be conducted by such third party or a future third-party licensee. If data from investigations of ANX-514 sponsored by a third-party licensee identify a safety or efficacy concern with respect to ANX-514, or the lack of comparable pharmacokinetics between ANX-514 and Taxotere, such data could adversely affect the U.S. regulatory process for ANX-514.

There is significant risk that MST-188 could fail to show anticipated results in nonclinical testing and/or clinical studies and, as a result, we may elect to discontinue its development in a particular indication or in whole. A failure to obtain requisite regulatory approvals or to obtain approvals of the scope requested will delay or preclude us from marketing our products or limit the commercial use of the products, and would have a material adverse effect on our business, financial condition and results of operations.

We do not have, and do not have plans to establish, any manufacturing facilities and are dependent on third parties for the manufacture and supply of MST-188, and the loss of any of these manufacturers, or their failure to provide to us with an adequate supply of drug product in a timely manner and on commercially acceptable terms, or at all, could harm our business.

We do not have, and do not have plans to establish, our own manufacturing facilities. For MST-188 clinical trial material, we have entered into supply agreements with Pierre Fabre Médicament (PFM) for API and Patheon Inc. for finished drug product, but our current agreements may not cover all of our clinical trial material needs and we may need to negotiate new or amended agreements with these CMOs or rely on individual proposals or statements of work, which inherently involves uncertainty as to ongoing supply and may result in delays in the completion of ongoing clinical studies or initiation of new studies. In addition, as development of MST-188 progresses, we will need to negotiate agreements for its commercial supply.

Table of Contents

If we fail to maintain relationships with our current CMOs, we may not be able to complete development of MST-188 or market it, if approved, on a timely basis, or at all, which would have a material and adverse effect on our business. Third-party manufacturers and suppliers may not perform as agreed or may terminate their agreements with us. For example, because these third parties provide manufacturing services to a number of other pharmaceutical companies, they may experience capacity constraints or choose to prioritize one or more of their other customers over us. Any significant problem that our manufacturers or suppliers experience could delay or interrupt our supply of clinical trial material or commercial product until the manufacturer or supplier cures the problem or until we locate, negotiate for and validate an alternative source of supply, if one is available.

In addition to our reliance on third parties to manufacture clinical trial material, we rely on them to conduct or assist us in conducting key manufacturing development activities, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials and conducting stability testing, among other things. If these third parties are unable to perform successfully in a timely manner, whether for technical, financial or other reasons, we may be unable to secure clinical trial material, which likely would delay the initiation, conduct or completion of our clinical studies, which, in turn, likely would have a material and adverse effect on our business.

All manufacturers of our clinical trial material and, as applicable, commercial product, including the API manufacturers, must comply with cGMP requirements enforced by the FDA through its facilities inspection program and applicable requirements of foreign regulatory authorities. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our clinical trial material may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we or our representatives generally monitor and audit our manufacturers systems, we have little control over their ongoing compliance with these regulations. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

Currently, we do not anticipate engaging alternative sources to backup our primary sources of clinical trial material and, in the future, we may not engage backup sources for commercial product. Therefore, if our primary sources become unable or unwilling to perform, we could experience protracted delays or interruptions in the supply of clinical trial material and, ultimately, product for commercial sale, which could materially and adversely affect our development programs, commercial activities, operating results and financial condition. For example, if we are unable to maintain our relationship with PFM, we may be unable to identify or establish a relationship with an alternate CMO that has the technical capabilities and desire to perform the development and supply services that we require for MST-188 API on commercially reasonable terms, or at all. Production of purified poloxamer 188, the API in MST-188, requires application of our proprietary supercritical fluid extraction process. This extraction process is complex and requires highly specialized equipment and there are a limited number of CMOs capable of performing and willing to perform the process as we require, which makes identifying and establishing relationships with CMOs more difficult and may provide them with substantial leverage over us in any negotiations. In addition, we use commercially-available poloxamer 188 as API starting material. There are a limited number of sources of poloxamer 188, and we are not aware of any that manufacture it to cGMP requirements applicable to API. The current supplier of our API starting material manufactures it under excipient-grade cGMP conditions. Prior to approval of MST-188, the FDA or other regulatory agencies may require our API starting material to be manufactured consistent with cGMP requirements applicable to API, in which case regulatory approval and commercialization of MST-188 could be delayed significantly and require substantial additional financial resources as we seek to contract with a third party to manufacture poloxamer 188 consistent with cGMP requirements applicable to API or undertake to manufacture it ourselves, and conduct any additional clinical or nonclinical activities with such material as the FDA may require. Even if the FDA accepts our current approach with respect to API starting material, we do not have a direct relationship with the supplier of that starting material and, although that third party has extensive, worldwide operations and poloxamer 188 is part of its standard product portfolio, we do not have any control over its production and the supplier may change its manufacturing process and/or limit the availability of its poloxamer 188 product in the future. If the supplier makes changes to its poloxamer 188 product, the FDA may determine that it is not acceptable API starting material and we may have difficulty obtaining an alternate supply of API starting material that the FDA finds acceptable without our conducting additional clinical or nonclinical activities or taking other remedial measures, which could require substantial time and financial resources. As a result, we could experience significant disruption in our ability to manufacture MST-188, which likely would add significant cost to the overall development and commercialization of MST-188 and adversely affect our ability to develop MST-188 on a timely basis.

Any new manufacturer or supplier of finished drug product or its component materials, including API, would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing such product or ingredients. The FDA may require us to conduct additional clinical studies, collect stability data and provide additional information concerning any new supplier, or change in a validated manufacturing process, including scaling-up production, before we could distribute products from that manufacturer or supplier or revised process. For example, if we were to engage a third-party other than PFM to supply API for future MST-188 clinical trial material or commercial product, the FDA may require us to conduct additional clinical and nonclinical studies to ensure comparability of the drug product containing PFM-manufactured API to API manufactured by the new supplier. In addition to the potential for such requirements to result in significant interruption to development and commercialization of MST-188, we likely would incur substantial additional costs to comply with the additional requirements.

(30)

Table of Contents

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling-up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, and shortages of qualified personnel. None of our product candidates, including MST-188, has been manufactured at the scale we believe will be necessary to maximize its commercial value and, accordingly, we may encounter difficulties in attempting to scale-up production and may not succeed in that effort. In addition, the FDA or other regulatory authorities may impose additional requirements as we scale-up initial production capabilities, which may delay our scale-up activities or add expense.

If our manufacturers encounter any of these difficulties or otherwise fail to comply with their contractual obligations, we may have insufficient quantities of clinical trial material for our clinical studies, including our ongoing studies. In addition, any delay or interruption in the supply of materials necessary or useful to manufacture our product candidates could delay the completion of our clinical studies, increase the costs associated with our development programs and, depending upon the period of delay, require us to commence new clinical studies at significant additional expense or terminate the studies completely. We cannot ensure that manufacturing or quality control problems will not arise in connection with the manufacture of our clinical trial material, or that third-party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such clinical trial material. In addition, PFM and Patheon are located in France and Italy, respectively, and, as a result, we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Any of the above factors could cause us to delay or suspend anticipated or on-going trials, regulatory submissions or commercialization of our product candidates, entail higher costs or result in our being unable to effectively commercialize our products. Our dependence upon third parties for the manufacture of our clinical trial material may adversely affect our future costs and our ability to develop and commercialize MST-188 and any other product candidate on a timely and competitive basis.

We rely significantly on third parties to conduct our nonclinical testing and clinical studies and other aspects of our development programs and if those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our product candidates could be adversely affected.

We do not employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs. We engage consultants, advisors, CROs, CMOs and others to assist in the design and conduct of nonclinical and clinical studies of our product candidates and with interpretation of the results of those studies, and we expect to continue to outsource a significant amount of such activities. As a result, many important aspects of our development programs are and will continue to be outside our direct control. Consultants and contractors may not be as committed to the success of our programs as employees and, therefore, may not be willing to devote the same time, thoughtfulness or creativity as would an employee. There can be no assurance that such third parties will perform all of their obligations under arrangements with us or will perform those obligations satisfactorily.

The CROs that we engage to execute our clinical studies play a significant role in the conduct of the studies and subsequent collection and analysis of data, and we likely will depend on CROs and clinical investigators to conduct future clinical studies and to assist in analyzing completed studies and developing regulatory strategies for our product candidates. Individuals working at the CROs with which we contract, as well as investigators at the sites at which our studies are conducted, are not our employees, and we have limited control over the amount or timing of resources that they devote to our programs. If these CROs and/or investigators fail to devote sufficient time and resources to our studies, if they do not comply with all regulatory and contractual requirements or if their performance is substandard, it may delay commencement and/or completion of our studies, submission of our new drug applications to the FDA and other regulatory agencies and approval of our applications by those agencies, and commercialization of our products. Moreover, these CROs may have relationships with other commercial entities, some of which may compete with us. If they assist our competitors at our expense, it could harm our competitive position. Failure of these CROs to meet their obligations could adversely affect development of our product candidates. For example, in 2006, we engaged a CRO to assist with the primary conduct of our bioequivalence study of Exelbine, including monitoring participating clinical sites to ensure compliance with regulatory requirements. FDA guidance recommends that clinical sites randomly select and retain reserve samples of study drugs used in bioequivalence studies. However, the clinical sites that participated in our bioequivalence study of Exelbine failed to do so. In August 2011, we received a complete response letter from the FDA stating that the authenticity of the study drugs used in that bioequivalence study could not be verified and, consequently, the study would need to be repeated to address that deficiency.

If any of our CRO relationships were to terminate, in particular our relationship with Theradex® Systems, Inc., the CRO we engaged to conduct the EPIC study in the U.S., we may not be able to enter into arrangements with alternative CROs on acceptable terms or in a timely manner, or at all. Switching CROs would involve additional cost and divert management time and attention. In addition, there likely would be a transition period when a new CRO commences work. These challenges could result in delays in the commencement or completion of our clinical studies, which could materially impact our ability to meet our desired development timelines and have a material adverse impact on our business and financial condition.

(31)

Table of Contents

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical studies and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all indications, and in turn prevent us from commercializing our product candidates. For example, while we believe our proprietary purification process has addressed the cause of the acute renal dysfunction observed in clinical studies of non-purified poloxamer 188, we cannot provide assurance that the purification process has fully addressed the issue or that renal toxicity will not be observed in ongoing or future studies of MST-188, particularly if we conduct studies in patients with impaired renal function. In addition, transient, generally mild to moderate elevations in liver function tests were associated with treatment with MST-188 in prior clinical studies. If in our clinical studies of MST-188 we observe more pronounced increases in liver function tests, or we observe other previously unidentified adverse events, whether or not statistically significant, we may be required to conduct additional clinical studies of MST-188 or to investigate the clinical significance of the adverse event and MST-188 may not receive regulatory approval.

If any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product or, if applicable, the reference product:

- regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication;
- regulatory authorities may withdraw their approval of the product;
- we may be required to change the way the product is administered, conduct additional clinical studies or change the labeling of the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenue from its sale.

We may not achieve our projected development goals in the time frames we announce.

We set goals for and make public statements regarding our estimates of the timing for accomplishing certain objectives material to successful development of our product candidates. The actual timing of these events can vary, sometimes dramatically, due to many factors, including delays or failures in our nonclinical testing, clinical studies and manufacturing and regulatory activities and the uncertainties inherent in the regulatory approval process. For example, we had expected to initiate the EPIC study in 2012, but unforeseen delays related to the manufacture of clinical trial material delayed initiation of the study to 2013. For additional discussion of these risks, see the risk factors above in this section, Risks Related to Drug Development and Commercialization. Even if we complete a clinical study with successful results, we may not achieve our projected development goals in the time frames we initially anticipate or announce. The FDA may require nonclinical testing and/or clinical studies in addition to EPIC and the TQT study prior to its review or approval of MST-188 in sickle cell disease. If the development plan for MST-188 or any other product candidate becomes more extensive and costly than anticipated, we may determine that the associated time and cost are not financially justifiable and, as a result, discontinue development in a particular indication or of the product candidate as a whole. Any such action may be viewed negatively, which could adversely affect our stock price.

In addition, changes may occur in regulatory requirements or policy during the period of product development and/or regulatory review of a submitted NDA relating to the data required to be included in marketing applications. For example, despite including in our initial Exelbine NDA submission in December 2009 data that we believe met the filing requirements for a new drug promulgated by the International Conference on Harmonization, or ICH, as well as site-specific stability data from lots manufactured at the intended commercial manufacturing site, we received a refusal-to-file letter from the FDA indicating that the data included in that submission was insufficient to support a commercially-viable expiration dating period. Consequently, we had to generate 12 months of stability data from material manufactured at our intended commercial manufacturing site before resubmitting the Exelbine NDA, which we did in November 2010. A change in regulatory policy, which may not have been formalized or publicly disseminated, may have been a factor underlying the FDA s refusal to file our December 2009 submission.

Further, throughout development, we must provide adequate assurance to the FDA and other regulatory authorities that we can consistently produce our product candidates in conformance with current good manufacturing practices, or cGMP, and other regulatory standards. We rely on CMOs for the manufacture of clinical, and future commercial, quantities of our product candidates. If future FDA or other regulatory authority inspections identify cGMP compliance issues at these third-party facilities, production of our clinical trial material or, in the future, commercial product, could be disrupted, causing potentially substantial delay in development or commercialization of our product candidates.

Table of Contents

Even if we receive regulatory approval for MST-188 or another product candidate, we may face development and regulatory difficulties that could materially and adversely affect our business, financial condition and results of operations and cause our stock price to decline.

Even if initial regulatory approval is obtained, or as a condition to the initial approval, the FDA or a foreign regulatory agency may impose significant restrictions on a product s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or marketing surveillance programs, any of which would limit the commercial potential of the product. Our product candidates also will be subject to ongoing FDA requirements related to the manufacturing processes, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information regarding the product. For instance, the FDA may require changes to approved drug labels, require post-approval clinical studies and impose distribution and use restrictions on certain drug products. In addition, approved products, manufacturers and manufacturers facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or a CMO of ours fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend or terminate any ongoing clinical studies;
- refuse to approve pending applications or supplements to approved applications;
- exclude our product from reimbursement under government healthcare programs, including Medicaid or Medicare;
- impose restrictions or affirmative obligations on our or our CMO s operations, including costly new manufacturing requirements;
- close the facilities of a CMO; or
- seize or detain products or require a product recall.

We currently have limited marketing capabilities and no sales capability and our failure to acquire or develop these and related capabilities internally or contract with third parties to perform these activities successfully could delay and/or limit our ability to generate revenue in the event MST-188 or any other product candidate obtains regulatory approval.

We currently have limited marketing capabilities and no sales capability and our company has never marketed or sold products. To commercialize MST-188 or any other product candidate, we will have to acquire or develop marketing, distribution, sales and associated regulatory compliance capabilities, or rely on marketing partners or other third parties for the marketing, distribution and sale of our products. There is no guarantee that we will be able to establish adequate marketing, distribution or sales capabilities or make arrangements with third parties to perform those activities on terms satisfactory to us, or at all, or that any internal capabilities or third-party arrangements will be cost-effective. The acquisition or development of commercialization and associated regulatory compliance capabilities likely will require substantial financial and other resources and divert the attention of our management and key personnel, and, if not completed on time, could delay the launch of an approved product, and otherwise negatively impact our product development and commercialization efforts.

(33)

Table of Contents

To the extent we establish marketing, distribution or sales arrangements with third parties, those third parties may hold significant control over important aspects of the commercialization of our products, including market identification, marketing methods, pricing, composition of sales force and promotional activities. Even if we are successful in establishing and maintaining these arrangements, there can be no assurance that we will be able to control the amount and timing of resources that any third party may devote to our products or prevent any third party from pursuing alternative technologies or products that could result in the development of products that compete with, or the withdrawal of support for, our products. If we retain third-party service providers to perform functions related to the marketing, distribution and sale of our products, key aspects of those functions that may be out of our direct control could include warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management. In this event, we would place substantial reliance on third-party providers to perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, encounter natural or other disasters at their facilities or otherwise fail to perform in a satisfactory manner, or at all, our ability to deliver product to meet commercial demand could be significantly impaired. In addition, we may use third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market our products could be jeopardized or we could be subject to regulatory sanctions.

If any of our product candidates for which we receive regulatory approval fails to achieve significant market acceptance among the medical community, patients or third-party payors, the revenue we generate from its sales will be limited and our business may not be profitable.

Our success will depend in substantial part on the extent to which our products candidates, if approved, are accepted by the medical community and patients and reimbursed by third-party payors, including government payors. The degree of market acceptance with respect to each of our approved products, if any, will depend upon a number of factors, including:

- the safety and efficacy of our product demonstrated in clinical studies;
- acceptance in the medical and patient communities of our product as a safe and effective treatment;
- the perceived advantages of our product over alternative treatments, including with respect to the incidence and severity of any adverse side effects and the cost of treatment;
- the indications for which our product is approved;
- claims or other information (including limitations or warnings) in our product s approved labeling;
- reimbursement and coverage policies of government and other third-party payors;
- pricing and cost-effectiveness of our product relative to alternative treatments;
- availability of alternative treatments;
- the prevalence of off-label substitution of chemically equivalent products or alternative treatments; and

the resources we devote to marketing our product and restrictions on promotional claims we can make with respect to the product.

We cannot predict with reasonable accuracy whether physicians, patients, healthcare insurers or maintenance organizations, or the medical community in general, will accept or utilize any of our products. If our product candidates are approved but do not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenue to become or remain profitable. In addition, our efforts to educate the medical community and third-party payors regarding benefits of our products may require significant resources and may never be successful.

If we determine that a product candidate may not achieve adequate market acceptance or that the potential market size does not justify additional expenditure on the program, we may reduce our expenditures on the development and/or the process of seeking regulatory approval of the product candidate while we evaluate whether and on what timeline to move the program forward.

Even if we receive regulatory approval to market one or more of our product candidates in the U.S., we may never receive approval or commercialize our products outside of the U.S., which would limit our ability to realize the full commercial potential of our product candidates.

In order to market any products outside of the U.S., we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S., as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

Table of Contents

Risks Related to Our Intellectual Property

Our success will depend on patents and other intellectual property protection we obtain that cover our product candidates and proprietary technology.*

Our success will depend in part on our ability to:

- obtain and maintain patent and other exclusivity with respect to our products;
- prevent third parties from infringing upon our proprietary rights;
- maintain proprietary know-how and trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and
- obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur, both in the U.S. and in foreign countries.

The patent and intellectual property positions of biopharmaceutical companies, including ours, are uncertain and involve complex legal and factual questions. There is no guarantee that we have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims allowed will be sufficient to protect the technology we develop or have developed or that is used by us, our CMOs or our other service providers. In addition, any patents that are issued to us may be challenged, invalidated, infringed or circumvented, including by our competitors, and rights we have under issued patents may not provide competitive advantages to us.

Patent applications in the U.S. are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors listed in any patent or patent application owned by us were the first to conceive of the inventions covered by such patents and patent applications (for U.S. patent applications filed before March 16, 2013), or that such inventors were the first to file patent applications for such inventions outside the United States and, after March 15, 2013, in the United States.

We also rely on unpatented know-how and trade secrets and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with employees, consultants, collaborators and others. We also have invention or patent assignment agreements with our employees and certain consultants. There can be no assurance, however, that binding agreements will not be breached, that we will have adequate remedies for any breach, or that trade secrets or other proprietary information will not otherwise become known or be independently discovered by competitors. In addition, it is possible that inventions relevant to our business could be developed by a person not bound by an invention assignment agreement with us.

With respect to MST-188, we acquired exclusive rights to a variety of issued patents related to poloxamers and their uses. However, all of these patents have expired or will expire in 2013. For exclusivity in sickle cell disease, we expect to rely primarily on the orphan drug designation that the FDA has granted for poloxamer 188 (purified) for the treatment of sickle cell disease, which includes the treatment and prevention of the complications of sickle cell disease. However, the orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process. MST-188 may not receive the seven-year orphan drug marketing exclusivity if it is not the first poloxamer 188 drug product to obtain FDA marketing approval for the treatment of sickle cell disease. In addition, orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantity of the drug. Furthermore, if the FDA later determines another drug or biologic for the treatment of sickle cell disease to be clinically superior to or different from MST-188, the FDA may approve such other product candidate for marketing during MST-188 s seven-year exclusivity period.

(35)

Table of Contents

Our success depends in large part on our ability to prevent competitors from duplicating or developing equivalent versions of our product candidates, but patent protection for MST-188 may be difficult to obtain and any issued claims may be limited due to the extent of published literature regarding the use of poloxamer 188.

We have filed for patent protection covering our proprietary supercritical fluid extraction process, methods of using poloxamers in various clinical settings, and the use of poloxamers in combination therapy. However, these patent applications cover only methods of manufacturing, methods of using MST-188, and combination therapeutic methods; they do not cover the underlying API. Claims covering the API are widely viewed as the strongest form of intellectual property protection for pharmaceutical products, as they apply without regard to how the API is manufactured, used or formulated.

The potential therapeutic benefits of poloxamer 188 have been known for decades and there is substantial prior art describing the use of poloxamer 188 in a wide range of diseases and conditions. As a result, our ability to find novel and non-obvious uses of poloxamer 188 is limited. Further, a patent examiner may combine numerous, disparate references in order to reject a claimed use for obviousness. If the prior art suggests, even implicitly, the desirability of combining previously known elements, such as the use of poloxamer 188 in a particular indication, the subsequent use of MST-188 in that indication may be obvious.

We cannot provide assurance that our pending patent applications will issue as patents, that any issued patents will provide us with significant competitive advantages, or that the validity or enforceability of any of our patents will not be challenged or, if instituted, that these challenges will not be successful. The cost of litigation to uphold the validity and prevent infringement of our patents could be substantial. Furthermore, we cannot provide assurance that others will not independently develop similar technologies or duplicate our technologies or design around the patented aspects of our technologies. We can provide no assurance that our proposed technologies will not infringe patents or rights owned by others, licenses to which might not be available to us in a timely manner or on acceptable terms, or at all.

If we are sued for infringing the proprietary rights of third parties, it will be costly and time consuming, and an unfavorable outcome would have an adverse effect on our business.

Our commercial success depends on our ability and the ability of our CMOs and component suppliers to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may be developing products. As the industries in which we operate (biopharmaceutical, specialty pharmaceutical, biotechnology and pharmaceutical) expand and more patents are issued, the risk increases that we will be subject to claims that our products or product candidates, or their use or manufacture, infringe the rights of others. Because patent applications can take many years to publish and issue, there currently may be pending applications, unknown to us, that may later result in issued patents that our products, product candidates or technologies infringe, or that the process of manufacturing our products or any of their respective component materials, or the component materials themselves, infringe, or that the use of our products, product candidates or technologies infringe.

We or our CMOs or component material suppliers may be exposed to, or threatened with, litigation by third parties alleging that our products, product candidates and/or technologies infringe their patents and/or other intellectual property rights, or that one or more of the processes for manufacturing our products or any of their respective component materials, or the component materials themselves, or the use of our products, product candidates or technologies, infringe their patents and/or other intellectual property rights. If a third-party patent or other intellectual property right is found to cover our products, product candidates, technologies or their uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our products or use our technologies or methods unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us in a timely manner or on acceptable terms, or at all. In addition, during litigation, the third-party alleging infringement could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using or selling our products, technologies or methods.

There generally is a substantial amount of litigation involving patent and other intellectual property rights in the industries in which we operate. If a third party claims that we or our CMOs or component material suppliers infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert our management s time and attention from our core business;

substantial damages for infringement, including the potential for treble damages and attorneys fees, which we may have to pay if it is determined that the product at issue infringes or violates the third party s rights;

Table of Contents

a court prohibiting us from selling or licensing the product unless the third-party licenses its intellectual property rights to us, which it may not be required to do;

if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to the third party; and

redesigning our products or processes so they do not infringe, which may not be possible or may require substantial expense and time.

No assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering our products, product candidates or technology or those of our CMOs or component material suppliers or the use of our products, product candidates or technologies. Because of the large number of patents issued and patent applications filed in the industries in which we operate, there is a risk that third parties may allege they have patent rights encompassing our products, product candidates or technologies, or those of our CMOs or component material suppliers, or uses of our products, product candidates or technologies.

In addition, it may be necessary for us to enforce our proprietary rights, or to determine the scope, validity and unenforceability of other parties proprietary rights, through litigation or other dispute proceedings, which may be costly, and to the extent we are unsuccessful, adversely affect our rights. In these proceedings, a court or administrative body could determine that our claims, including those related to enforcing patent rights, are not valid or that an alleged infringer has not infringed our rights. The uncertainty resulting from the mere institution and continuation of any patent- or other proprietary rights-related litigation or interference proceeding could have a material and adverse effect on us.

RISKS RELATED TO OUR INDUSTRY

We expect intense competition in the marketplace for our product candidates, should any of them receive regulatory approval.

The industries in which we operate (biopharmaceutical, specialty pharmaceutical, biotechnology and pharmaceutical) are highly competitive and subject to rapid and significant change. We are aware of many other organizations developing drug products and other therapies intended to treat or cure the diseases or conditions in which we are developing or plan to develop MST-188. Developments by others may render potential application of MST-188 in a particular indication obsolete or noncompetitive, even prior to completion of its development and approval for that indication. If successfully developed and approved, we expect MST-188 will face intense competition with respect to each indication in which it is approved. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have significantly greater financial, technical and human resources than we do, and may be better equipped to develop, manufacture, market and distribute products. Many of these companies operate large, well-funded research, development and commercialization programs, have extensive experience in nonclinical and clinical studies, obtaining FDA and other regulatory approvals and manufacturing and marketing products, and have multiple products that have been approved or are in late-stage development. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, heightened awareness on the part of academic institutions, government agencies and other public and private research organizations of the potential commercial value of their inventions have led them to actively seek to commercialize the technologies they develop, which increases competition for investment in our programs. In addition, there is increasing interest in developing drugs for rare diseases, which may have the effect of increasing the development of agents to treat sickle cell disease, ALI and other indications we may pursue. Legislative action may generate further interest. For instance, in July 2012, the Food and Drug Administration Safety and Innovation Act was signed into law. This Act amended the Federal Food, Drug, and Cosmetic Act in a variety of ways that encourage or facilitate the development of drugs for patients with rare diseases, including by expanding the priority review voucher system to rare pediatric diseases and encouraging the FDA to implement more effective processes for expedited development and review of new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions using a broad range of surrogate endpoints. Competitive products may be more effective, or more effectively marketed and sold, than ours, which would have a material adverse effect on our ability to generate revenue.

With respect to competition for MST-188 in sickle cell disease, we are aware of numerous companies with product candidates in varying stages of development. Some of our potential competitors in sickle cell disease are large, well-financed and experienced pharmaceutical and biotechnology companies or have partnered with such companies, which may give them development, regulatory and/or marketing advantages over us. For example, Pfizer and Novartis have each invested in privately-held companies, GlycoMimetics, Inc. and Selexys Pharmaceuticals Corporation, respectively, which have clinical-stage agents for the treatment of vaso-occlusive crisis. In addition, numerous non-profit or non-commercial foundations and interest groups also are committed to improving outcomes for patients with sickle cell disease. Advances in the understanding of the signaling pathways associated with sickle cell disease may lead to further interest and development of treatment options. If

an effective treatment or cure for vaso-occlusive crisis or sickle cell disease receives regulatory approval, the potential commercial success of MST-188 could be severely jeopardized.

Table of Contents

With respect to competition for MST-188 for complications of arterial disease, although we intend first to develop MST-188 as an adjunct to thrombolytics, it could compete with current revascularization methods, including thrombolytics. In addition, we are aware of a number of potentially competitive investigational therapies for severe forms of thrombotic arterial disease, including angiogenic growth factors, vasoactive drugs, anticoagulants, thrombolytics, anti-platelet agents, cytoprotectives, and blood substitutes, certain of which are in late-stage clinical development. Should any of these other investigational therapies receive regulatory approval prior to MST-188, they may become entrenched in the standard of care, diminish the need for MST-188, or be difficult to displace.

With respect to resuscitation of shock following major trauma, MST-188 could compete with various investigational therapies for hemorrhagic shock, including agents to improve blood flow in the microvasculature, improve oxygenation of ischemic tissues, and/or prevent reperfusion injury. Some organizations with potentially competitive therapies have received funding from the federal government to progress their research and development. To the extent other therapies demonstrate acceptable safety and efficacy and receive regulatory approval prior to MST-188, the need for MST-188 may be diminished. In addition to investigational pharmacologic approaches, new resuscitation protocols are being explored to reduce morbidity and mortality following major hemorrhage and, to the extent they are successful, they may diminish the need for MST-188.

We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products commercial success, if any of our product candidates are approved.

Our ability to commercialize our products successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. Significant uncertainty exists as to the reimbursement status of newly approved medical products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- our ability to set an appropriate price for our products;
- the rate and scope of adoption of our products by healthcare providers;
- our ability to generate revenue or achieve or maintain profitability;
- the future revenue and profitability of our potential customers, suppliers and collaborators; and
- our access to additional capital.

Our ability to successfully commercialize our products will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish what we believe are appropriate coverage and reimbursement for our products. These payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement, particularly for new therapeutic products or if there is a perception that the target indication of the new product is well-served by existing drugs or other treatments. Accordingly, even if coverage and reimbursement are provided, market acceptance of our products would be adversely affected if the level of coverage and/or reimbursement for our products proved to be unprofitable for healthcare providers or less profitable than alternative treatments.

There have been federal and state proposals to subject the pricing of healthcare goods and services to government control and to make other changes to the U.S. healthcare system. While we cannot predict the outcome of current or future legislation, we anticipate that the U.S. Congress and state legislatures will continue to introduce initiatives directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain if future legislative proposals, whether domestic or abroad, will be adopted that might affect our products or product candidates or what actions federal, state, or private payors for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Any such healthcare reforms could have a material and adverse effect on the marketability of any products for which we ultimately receive FDA or other regulatory agency approval.

(38)

Table of Contents

We face potential product liability exposure and, if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage and it is uncertain whether such increased or additional insurance coverage can be obtained on commercially reasonable terms, if at all.

Our business (in particular, the use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval) will expose us to product liability risks. Product liability claims might be brought against us by patients, healthcare providers, pharmaceutical companies or others selling our products. If we cannot successfully defend ourselves against any such claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for our products and loss of revenue;

impairment of our business reputation;

withdrawal of clinical study participants;

significant costs of related litigation;

substantial monetary awards to patients or other claimants; and

the inability to commercialize our products and product candidates.

We maintain limited product liability insurance for our clinical studies, but our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

We expect that we would expand our insurance coverage to include the sale of commercial products if we obtain marketing approval of any of our product candidates, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

RISKS RELATED TO OUR COMMON STOCK

If we are unable to maintain compliance with NYSE MKT continued listing standards, our common stock may be delisted from the NYSE MKT equities market, which would likely cause the liquidity and market price of our common stock to decline.

Our common stock currently is listed on the NYSE MKT equities market. The NYSE MKT will consider suspending dealings in, or delisting, securities of an issuer that does not meet its continued listing standards, including specified stockholders equity levels. In addition, the NYSE MKT will consider suspending dealings in, or delisting, securities selling for a substantial period of time at a low price per share if the issuer fails to effect a reverse split of such stock within a reasonable time after being notified that the NYSE MKT deems such action to be appropriate under the circumstances.

Previously, prior to 2011, we were not in compliance with certain NYSE MKT stockholders equity continued listing standards. Specifically, we were not in compliance with (1) Section 1003(a)(ii) of the NYSE MKT Company Guide, or the Company Guide, because we reported stockholders equity of less than $4,000,000 and losses from continuing operations and net losses in three of our four most recent fiscal years, or (2) Section 1003(a)(iii) of the Company Guide, because we reported stockholders equity of less than $6,000,000 and losses from continuing

operations and net losses in our five most recent fiscal years. In addition, we were notified, in accordance with Section 1003(f)(v) of the Company Guide, that the NYSE MKT determined it was appropriate for us to effect a reverse stock split of our common stock to address our low selling price per share.

In April 2010, we announced that we had resolved the stockholders equity continued listing deficiencies and we implemented a 1-for-25 reverse split of our common stock, in part to address the NYSE MKT s requirement that we address our low stock price. However, there is no assurance that we will continue to maintain compliance with such standards. For example, we may determine to pursue development or other activities or grow our organization or product pipeline or at levels or on timelines that reduces our stockholders equity below the level required to maintain compliance with NYSE MKT continued listing standards. In addition, the market price for our common stock historically has been highly volatile, as more fully described below under the risk titled The market price of our common stock historically has been and likely will continue to be highly volatile, and has traded at under $1.00 per share for more than twelve consecutive months. The NYSE MKT may again determine that the selling price per share of our common stock is low and require that we effect a reverse stock split of our common stock, which would require stockholder approval that we may be unable to obtain. Our failure to maintain compliance with NYSE MKT continued listing standards could result in the delisting of our common stock from the NYSE MKT.

Table of Contents

The delisting of our common stock from the NYSE MKT likely would reduce the trading volume and liquidity in our common stock and may lead to decreases in the trading price of our common stock. The delisting of our common stock may also materially impair our stockholders ability to buy and sell shares of our common stock. In addition, the delisting of our common stock could significantly impair our ability to raise capital, which is critical to the execution of our current business strategy.

If our common stock were delisted and determined to be a penny stock, a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock in the secondary market.

If our common stock were removed from listing with the NYSE MKT, it may be subject to the so-called penny stock rules. The SEC has adopted regulations that define a penny stock to be any equity security that has a market price per share of less than $5.00, subject to certain exceptions, such as any securities listed on a national securities exchange. For any transaction involving a penny stock, unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. If our common stock were delisted and determined to be a penny stock, a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

The market price of our common stock historically has been and likely will continue to be highly volatile.

The market price for our common stock historically has been highly volatile, and the market for our common stock has from time to time experienced significant price and volume fluctuations, based both on our operating performance and for reasons that appear to us unrelated to our operating performance. For instance, on August 10, 2011, the market price for our common stock dropped almost 60% following our announcement of our receipt of the complete response letter for our Exelbine NDA, which stated that the FDA could not approve it in its present form. Conversely, the market price for our common stock increased over 66% in a 30-day period in June and July 2011 and more than doubled over two trading days in late December 2009. The market price of our common stock may fluctuate significantly in response to a number of factors, including:

- the level of our financial resources;
- announcements of entry into or consummation of a financing or strategic transaction;
- changes in the regulatory status of our product candidates, including results of any clinical studies and other research and development programs;
- FDA or international regulatory actions and regulatory developments in the U.S. and foreign countries;
- announcements of new products or technologies, commercial relationships or other events (including clinical study results and regulatory events and actions) by us or our competitors;
- market conditions in the pharmaceutical, biopharmaceutical, specialty pharmaceutical and biotechnology sectors;
- developments concerning intellectual property rights generally or those of us or our competitors;
- changes in securities analysts estimates of our financial performance or deviations in our business and the trading price of our common stock from the estimates of securities analysts;

events affecting any future collaborations, commercial agreements and grants;

fluctuations in stock market prices and trading volumes of similar companies;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders or pursuant to shelf or resale registration statements that register shares of our common stock that may be sold by us or certain of our current or future stockholders;

discussion of us or our stock price by the financial and scientific press and in online investor communities;

Table of Contents

commencement of delisting proceedings by the NYSE MKT;

additions or departures of key personnel; and

changes in third-party payor reimbursement policies.

As evidenced by the August 10, 2011 decline, the realization of any of the foregoing could have a dramatic and adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced a substantial decline in market price. Moreover, regulatory entities often undertake investigations of investor transactions in securities that experience volatility following an announcement of a significant event or condition. Any such litigation brought against us or any such investigation involving our investors could result in substantial costs and a diversion of management s attention and resources, which could hurt our business, operating results and financial condition.

Our stock price could decline significantly based on progress with and results of clinical and nonclinical studies of MST-188 and regulatory agency decisions affecting that development program.*

We expect announcements of progress with and results of clinical and certain nonclinical studies of MST-188 and regulatory decisions (by us, the FDA, or another regulatory agency) to affect our stock price. Stock prices of companies in our industry have declined significantly when such results and decisions were unfavorable or perceived to be negative or discouraging or when a product candidate did not otherwise meet expectations. If progress in clinical studies of MST-188 or MST-188 study results are not viewed favorably by us or third parties, including investors, analysts, potential collaborators, the academic and medical communities and regulators, our stock price could decline significantly and you could lose your investment in our common stock.

We may report top-line study data from time to time, which is based on preliminary analysis of then-available data. Such preliminary findings and conclusions are subject to change following a more comprehensive review of the study data. In addition, results of clinical and nonclinical studies often are subject to different interpretations. We may interpret or weigh the importance of study data differently than third parties, including those noted above. Others may not accept or agree with our analysis of study data, which could impact the approvability of MST-188 and/or the value of the MST-188 program and our company in general.

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

The market price of our common stock could decline as a result of sales by, or the perceived possibility of sales by, us or our existing stockholders of shares of our common stock. These sales by our existing stockholders might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate. Currently, we have effective primary registration statements on Form S-3 under which we may sell and issue more than $150 million of securities, subject to certain limitations if our public float is less than $75 million. We also have effective resale registration statements on Form S-3 that register a significant number of shares of our common stock and securities convertible into our common stock that may be sold by us or certain of our stockholders, including an effective resale registration statement for the shares of our common stock that have been and may be issued to the former SynthRx stockholders. Collectively, these registration statements may increase the likelihood of sales by, or the perception of an increased likelihood of sales by, us or our existing stockholders of shares of our common stock.

We currently have voting control with respect to approximately 1.3% of our outstanding common stock and we may obtain voting control over a significant additional amount of our outstanding common stock if we issue the milestone-related shares to the former SynthRx stockholders, and we may determine to cause those shares to be voted in such a manner that does not necessarily coincide with the interests of individual stockholders or particular groups of stockholders.*

Pursuant to the voting and transfer restriction agreement between us and each of the former principal stockholders of SynthRx, each stockholder party has agreed to vote all shares of our common stock beneficially owned by that party with respect to every action or approval by written consent of our stockholders in such manner as directed by us, except in limited circumstances, and has executed an irrevocable proxy appointing and authorizing us to vote such shares in such manner. If the development of MST-188 achieves each of the milestones set forth in our merger agreement with SynthRx, we will issue an additional 12,478,050 shares of our common stock, which, together with previously issued and outstanding shares held by these former SynthRx stockholders, represent an aggregate approximately 11.5% ownership stake in our company (based on 102,710,286 shares outstanding as of August 1, 2013 plus shares issued in connection with achievement of the milestones). As a result of such potential issuances and the voting and transfer restriction agreement, in the future we may have significant control over substantially all

matters requiring approval by our stockholders, including the election of directors and the approval of certain mergers and other business combination transactions. Even if less than all potential milestone-related shares are issued, our ability to control a potentially significant block of stockholder votes pursuant to the voting and transfer restriction agreement may enable us to substantially affect the outcome of proposals brought before our stockholders. Although our board of directors acts in a manner it believes is in the best interest of our stockholders as a whole, the interests of our stockholders as a whole may not always coincide with the interests of individual stockholders or particular groups of stockholders.

Table of Contents

Anti-takeover provisions in our charter documents and under Delaware law may make an acquisition of us, which may be beneficial to our stockholders, more difficult, which could depress our stock price.

We are incorporated in Delaware. Certain anti-takeover provisions of Delaware law and our charter documents as currently in effect may make a change in control of our company more difficult, even if a change in control would be beneficial to our stockholders. Our bylaws limit who may call a special meeting of stockholders and establish advance notice requirements for nomination of individuals for election to our board of directors or for proposing matters that can be acted upon at stockholders meetings. Delaware law also prohibits corporations from engaging in a business combination with any holders of 15% or more of their capital stock until the holder has held the stock for three years unless, among other possibilities, the board of directors approves the transaction. Our board of directors may use these provisions to prevent changes in the management and control of our company. Also, under applicable Delaware law, our board of directors may adopt additional anti-takeover measures in the future. In addition, provisions of certain compensatory contracts with our management, such as equity award agreements, may have an anti-takeover effect by resulting in accelerated vesting of outstanding equity securities held by our executive officers. In particular, in the event of a change in control, the vesting of options we granted since July 2009 to certain key executives will accelerate with respect to fifty percent of the then unvested shares on the day prior to the date of the change in control and, subject to the respective executive s continuous service, with respect to the remaining fifty percent of the then unvested shares on the one year anniversary of the date of the change in control, and could accelerate in full at the time of the change in control if the acquirer does not assume or substitute for the options. As a result, if an acquirer desired to retain the services of those executives following an acquisition, it may be required to provide additional incentive to them, which could increase the cost of the acquisition to the acquirer and may deter or adversely affect the terms of the potential acquisition.

Because we do not expect to pay dividends with respect to our common stock in the foreseeable future, you must rely on stock appreciation for any return on your investment.

We have paid no cash dividends on any of our common stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, with respect to our common stock, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we are subject to various laws and regulations that may restrict our ability to pay dividends and we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Due to our intent to retain any future earnings rather than pay cash dividends on our common stock and applicable laws, regulations and contractual obligations that may restrict our ability to pay dividends on our common stock, the success of your investment in our common stock will likely depend entirely upon any future appreciation and our common stock may not appreciate.

If shares of our common or preferred stock available for issuance or shares eligible for future sale were introduced into the market, it could hurt our stock price.*

As of June 30, 2013, there were an aggregate of 102,710,286 shares of our common stock issued and outstanding. That total excludes, as of that date, 7,252,897 shares of our common stock that may be issued upon the exercise of outstanding stock options, 44,585,932 shares of common stock that may be issued upon the exercise of outstanding warrants and 12,478,050 shares of common stock issuable to the former stockholders of SynthRx upon the achievement of performance milestones related to MST-188 pursuant to the terms of our merger agreement with SynthRx dated February 12, 2011. The exercise of outstanding options and/or warrants or issuance of shares may cause substantial dilution to those who hold shares of common stock prior to such exercises or issuances. In addition, sales of substantial amounts of the common stock in the public market by these holders or perceptions that such sales may take place may lower the common stock s market price.

We have 500,000,000 shares of authorized common stock and we may sell our authorized, but unissued, common stock to satisfy our funding requirements. We are also authorized to issue 1,000,000 shares of preferred stock, without stockholder approval. The preferred stock may have rights that are superior to the rights of the holders of our common stock, at a purchase price then approved by our board of directors. The sale or the proposed sale of substantial amounts of our common or preferred stock in the public markets may adversely affect the market price of our common stock and our stock price. Our stockholders may also experience substantial dilution.

Table of Contents

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

On June 4, 2013, pursuant to the terms of our merger agreement with SynthRx, Inc. and as a result of the achievement of a milestone set forth in the merger agreement, we issued an aggregate of 250,000 shares of our common stock to the former stockholders of SynthRx on a pro rata basis based on each such stockholder s ownership percentage of SynthRx immediately prior to the effective time of the merger.

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

Table of Contents

Signatures

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

Mast Therapeutics, Inc.

Date: August 5, 2013

By: /s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer
(Principal Executive Officer)

By: /s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer and Senior Vice President
(Principal Financial and Accounting Officer)

Table of Contents

EXHIBIT INDEX

Exhibit	Description
10.1#(1)	Mast Therapeutics, Inc. 2013 Omnibus Incentive Plan
10.2#(1)	Form of Non-Statutory Stock Option Grant Agreement Director (for grants to non-employee directors) under the 2013 Omnibus Incentive Plan
10.3#(1)	Form of Incentive Stock Option Grant Agreement (for grants to employees) under the 2013 Omnibus Incentive Plan
10.4#(1)	Form of Senior Executive Incentive Stock Option Grant Agreement (for grants to the registrant s chief executive officer and president and chief operating officer) under the 2013 Omnibus Incentive Plan
10.5#(1)	Form of CMO Incentive Stock Option Grant Agreement (for grants to the registrant s chief medical officer) under the 2013 Omnibus Incentive Plan
10.6(2)	Warrant Agent Agreement by and between Mast Therapeutics, Inc. and American Stock Transfer & Trust Company, dated June 14, 2013, including the form of Common Stock Purchase Warrant as Exhibit A
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 Current Report on Form 8-K on June 21, 2013 (SEC file number 001-32157-13927320)

(2) Filed with the registrant s Current Report on Form 8-K on June 17, 2013 (SEC file number 001-32157-13917371)