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, 2014

OR

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

For the transition period from __________ to __________

Commission File Number 001-32157

Mast Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**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 6, 2014 was 121,632,240.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(Unaudited)

	June 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 26,368,452	$ 25,681,092
Investment securities	20,069,278	18,711,448
Prepaid expenses and other current assets	1,126,150	1,135,490
Total current assets	47,563,880	45,528,030
Property and equipment, net	186,345	105,747
In-process research and development	8,549,000	6,549,000
Goodwill	3,006,883	3,006,883
Other assets	63,497	60,312
Total assets	$ 59,369,605	$ 55,249,972
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 1,226,280	$ 963,947
Accrued liabilities	3,478,823	2,495,088
Accrued compensation and payroll taxes	1,039,976	1,374,343
Total current liabilities	5,745,079	4,833,378
Deferred income tax liability	3,403,675	2,608,755
Total liabilities	9,148,754	7,442,133
Stockholders equity:		
Common stock, $0.001 par value; 500,000,000 shares authorized; 119,842,541 and 102,710,286 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	119,843	102,710
Additional paid-in capital	270,070,217	254,154,693
Accumulated other comprehensive loss	(17,913)	(20,738)
Accumulated deficit	(219,951,296)	(206,428,826)
Total stockholders equity	50,220,851	47,807,839

Total liabilities and stockholders equity	$ 59,369,605	$ 55,249,972

See accompanying notes to unaudited condensed consolidated financial statements.

(1)

Table of Contents

Mast Therapeutics, Inc. and Subsidiaries

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

(Unaudited)

	Three months ended June 30, 2014	Three months ended June 30, 2013	Six months ended June 30, 2014	Six months ended June 30, 2013
Revenues	$	$	$	$
Operating expenses:				
Research and development	4,820,122	2,836,935	9,100,939	6,279,847
Selling, general and administrative	2,369,960	2,099,925	4,636,193	4,212,631
Transaction-related expenses	(10,905)	7,500	269,447	35,000
Depreciation and amortization	22,538	8,879	33,988	18,674
Total operating expenses	7,201,715	4,953,239	14,040,567	10,546,152
Loss from operations	(7,201,715)	(4,953,239)	(14,040,567)	(10,546,152)
Interest income	16,872	10,895	32,218	25,311
Other income/(expense), net	32,954	1,172	485,879	(1,198)
Net loss	$ (7,151,889)	$ (4,941,172)	$ (13,522,470)	$ (10,522,039)
Net loss per share basic and diluted	$ (0.06)	$ (0.09)	$ (0.12)	$ (0.21)
Weighted average shares outstanding basic and diluted	115,587,056	53,749,791	110,349,506	50,028,214
Comprehensive Income/(Loss):				
Net loss	$ (7,151,889)	$ (4,941,172)	$ (13,522,470)	$ (10,522,039)
Other comprehensive gains/(losses)	8,272	1,804	2,825	(6,644)
Comprehensive net loss	$ (7,143,617)	$ (4,939,368)	$ (13,519,645)	$ (10,528,683)

See accompanying notes to unaudited condensed consolidated financial statements.

(2)

Table of Contents

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Six months ended June 30, 2014	2013
Cash flows from operating activities:		
Net loss	$ (13,522,470)	$ (10,522,039)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	33,988	18,674
Loss on change in fair value of contingent consideration		35,000
Gain on bargain purchase	(485,944)	
Share-based compensation expense related to employee stock options and restricted stock issued	823,836	716,693
Changes in assets and liabilities, net of effect of acquisitions:		
Decrease/(increase) in prepaid expenses and other assets	88,687	(31,526)
(Decrease)/increase in accounts payable and accrued liabilities	(200,392)	623,568
Net cash used in operating activities	(13,262,295)	(9,159,630)
Cash flows from investing activities:		
Purchases of certificates of deposit	(7,981,020)	(3,984,000)
Proceeds from maturities of certificates of deposit	6,626,000	9,538,000
Purchases of property and equipment	(109,561)	(17,176)
Cash obtained through acquisition	3,534,480	
Net cash provided by investing activities	2,069,899	5,536,824
Cash flows from financing activities:		
Proceeds from sale of common stock	12,474,478	28,097,500
Proceeds from exercise of warrants	65	
Payments for financing and offering costs	(594,787)	(2,001,599)
Net cash provided by financing activities	11,879,756	26,095,901
Effect of exchange rate changes on cash		(1,299)
Net increase in cash and cash equivalents	687,360	22,471,796
Cash and cash equivalents at beginning of period	25,681,092	22,500,440
Cash and cash equivalents at end of period	$ 26,368,452	$ 44,972,236

See accompanying notes to unaudited condensed consolidated financial statements.

(3)

Table of Contents

Mast Therapeutics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Basis of Presentation

Mast Therapeutics, Inc., a Delaware corporation (Mast Therapeutics, we or our company), prepared the unaudited interim condensed consolidated financial statements included in this report in accordance with United States generally accepted accounting principles (U.S. GAAP) for interim financial information and the rules and regulations of the Securities and Exchange Commission (SEC) related to quarterly reports on Form 10-Q. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for annual audited financial statements and should be read in conjunction with our audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 26, 2014 (2013 Annual Report). The condensed consolidated balance sheet as of December 31, 2013 included in this report has been derived from the audited consolidated financial statements included in the 2013 Annual Report. In the opinion of management, these condensed consolidated financial statements include all adjustments (consisting of normal recurring adjustments) necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. The results of operations for the interim periods shown in this report are not necessarily indicative of the results that may be expected for any future period, including the full year.

We are a biopharmaceutical company focused on developing therapies for serious or life-threatening diseases. We have devoted substantially all of our resources to research and development (R&D) and acquisition of our product candidates. We have not yet marketed or sold any products or generated any significant revenue. Through our acquisition of SynthRx, Inc. (SynthRx) in 2011, we acquired our Membrane Adhesion & Sealant Technology (MAST) platform, which includes proprietary poloxamer-related data and know-how derived from over two decades of clinical, nonclinical and manufacturing experience, and we are leveraging the MAST platform to develop MST-188, our lead product candidate, for serious or life-threatening diseases and conditions typically characterized by impaired microvascular blood flow and damaged cell membranes. In February 2014, we completed the acquisition of Aires Pharmaceuticals, Inc. (Aires), which is developing AIR001, an intermittently nebulized form of sodium nitrite, to treat pulmonary vascular disorders, and we are in the process of determining the optimal development strategy for this new asset.

Our business, operating results, financial condition, and growth prospects are subject to significant risks and uncertainties, including failing to obtain regulatory approval to commercialize our product candidates and failing to secure additional funding to complete development of and to commercialize our product candidates before another company develops safe and effective treatments for the indications we are pursuing.

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

2. Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including estimates related to R&D expenses, in-process research and development (IPR&D), goodwill and share-based compensation expenses. We base our estimates on historical experience and various other relevant assumptions we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

3. Acquisition of Aires

In February 2014, we completed the acquisition of Aires in an all-stock transaction pursuant to the terms of an agreement and plan of merger, dated February 7, 2014, by and among us, AP Acquisition Sub, Inc., a wholly-owned subsidiary of ours, Aires, and a stockholders representative (the Merger Agreement). Aires survived the merger transaction as a wholly-owned subsidiary of ours. Aires lead product candidate is AIR001 (sodium nitrite) inhalation solution and, prior to the acquisition, Aires had been focused on developing AIR001 in pulmonary arterial hypertension.

Upon completion of the merger, we issued an aggregate of 1,049,706 unregistered shares of our common stock to former Aires stockholders and, following a six-month holdback period, we will issue up to 4,198,830 additional unregistered shares of our common stock, in the aggregate, to former Aires stockholders, subject to adjustment to satisfy indemnification obligations of the former Aires stockholders to us, if any, in accordance with the merger agreement. There are no milestone or earn-out payments under the merger agreement; therefore, the total merger consideration will not exceed 5,248,536 shares.

We accounted for the acquisition of Aires in accordance with Accounting Standards Codification (ASC) Topic 805, *Business Combinations* (ASC Topic 805). The total purchase price of the acquisition is approximately $3.3 million. We calculated the purchase price by first multiplying the estimated total number of shares of our common stock to be issued by $0.80, which was the closing price per share of our common stock on February 27, 2014, the acquisition date. Then, we applied a discount factor to account for lack of market liquidity due to the restrictions on transfer of the securities for a period of six months following the acquisition in accordance with stockholder agreements we entered into with the former Aires stockholders and the fact that the shares are unregistered and we have no obligation to register them for resale.

Under the acquisition method of accounting, the total purchase price is allocated to Aires net tangible and intangible assets and liabilities based on their estimated fair values as of the acquisition date. The table below summarizes the preliminary estimated fair values of Aires net tangible and intangible assets and liabilities on the acquisition date. The purchase price allocations are preliminary and subject to change as more detailed analyses are completed and additional information with respect to the fair values of the assets and liabilities acquired becomes available.

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

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

Acquired In-Process Research and Development

Acquired IPR&D is the estimated fair value of the AIR001 program as of the acquisition date. We determined that the estimated fair value of the AIR001 program was $2.0 million as of the acquisition date using the Multi-Period Excess Earnings Method, or MPEEM, which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset s incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life.

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

(5)

Table of Contents

Deferred Income Tax Liability

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

Pro Forma Information

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

	Six months ended June 30,	
	2014	**2013**
Revenues	$	$ 906,826
Loss from operations	(14,548,951)	(15,541,664)
Net loss applicable to common stock	(14,516,472)	(15,515,442)

The $0.9 million of revenues consists of amounts recognized by Aires during the six months ended June 30, 2013 as a result of a payment by a third-party partner pursuant to a collaboration agreement. The agreement was terminated in the fourth quarter of 2013. Aires recognized no revenues in 2014.

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

	Six months ended June 30,	
	2014	**2013**
Transaction-related expenses	$ 1,304,617	$ (1,304,617)

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

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

The operations of Aires were consolidated with our operations as of the closing of the acquisition on February 27, 2014. Accordingly, Aires total operating expenses of $1.2 million for the period from February 27 through June 30, 2014 were included in our condensed consolidated statements of operations and comprehensive income/(loss).

4. Goodwill and IPR&D

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

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

Our goodwill represents the difference between the total purchase price for SynthRx and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed. We test our goodwill for impairment annually as of September 30 and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying amount may be impaired.

(6)

Table of Contents

Our IPR&D consists of the estimated fair values of the MST-188 and AIR001 programs as of their respective acquisition dates. As discussed in Note 3 above, the estimated fair value of our IPR&D related to the AIR001 program is a preliminary estimate and subject to change as more detailed analyses are completed. We test our acquired IPR&D for impairment annually as of September 30 and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying amount may be impaired.

5. Investment Securities

Investment securities are marketable equity or debt securities. All of our investment securities are available-for-sale securities and carried at fair value. Fair value for securities with short maturities and infrequent secondary market trades typically is determined by using a curve-based evaluation model that utilizes quoted prices for similar securities. The evaluation model takes into consideration the days to maturity, coupon rate and settlement date convention. Net unrealized gains or losses on these securities are included in accumulated other comprehensive loss, which is a separate component of stockholders equity. Realized gains and realized losses are included in other income/(expense), while amortization of premiums and accretion of discounts are included in interest income. Interest and dividends on available-for-sale securities are included in interest income. We periodically evaluate our investment securities for impairment. If we determine that a decline in fair value of any investment security is other than temporary, then the cost basis would be written down to fair value and the decline in value would be charged to earnings.

Our investment securities are under the custodianship of a major financial institution and consist of FDIC-insured certificates of deposit. We have classified all of our available-for-sale investment securities, including those with maturities beyond one year from the date of purchase, as current assets on our consolidated balance sheets because we consider them to be highly liquid and available for use, if needed, in current operations. As of June 30, 2014, $3.7 million of our investment securities had contractual maturity dates of more than one year and less than or equal to 18 months and none were greater than 18 months.

At June 30, 2014, the fair value of our investment securities was $20,069,278. The cost basis of such investments was $20,085,035 and our net unrealized losses were $15,757.

6. Fair Value of Financial Instruments

Our investment securities are carried at fair value. The fair value of financial assets and liabilities is measured under a framework that establishes levels which are defined as follows: (i) Level 1 fair value is determined from observable, quoted prices in active markets for identical assets or liabilities; (ii) Level 2 fair value is determined from inputs, other than Level 1 inputs, that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities, and (iii) Level 3 fair value is determined using the entity s own assumptions about the inputs that market participants would use in pricing an asset or liability.

The fair values at June 30, 2014 and December 31, 2013 of our investment securities are summarized in the following table:

	Total Fair	Fair Value Determined Under:		
	Value	(Level 1)	(Level 2)	(Level 3)

Investment securities at June 30, 2014	$ 20,069,278	$	$ 20,069,278	$
Investment securities at December 31, 2013	$ 18,711,448	$	$ 18,711,448	$

7. Property and Equipment

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

Table of Contents

8. Accrued Liabilities

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

	June 30,	December 31,