Mast Therapeutics, Inc.
Form 10-Q
November 08, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number 001-32157

Mast Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	84-1318182 (I.R.S. Employer Identification No.)
3611 Valley Centre Dr., Suite 500, San Diego, CA (Address of principal executive offices)	92130 (Zip Code)

(858) 552-0866

(Registrant's telephone number, including area code)

N/A

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

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

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

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

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

The number of shares outstanding of the registrant's common stock, $0.001 par value per share, as of November 3, 2016 was 238,230,454.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except for share and par value data)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$20,521	$23,052
Investment securities	6,429	17,929
Prepaid expenses and other current assets	1,333	1,271
Total current assets	28,283	42,252
Property and equipment, net	148	226
In-process research and development	8,549	8,549
Goodwill	3,007	3,007
Other assets	131	183
Total assets	$40,118	$54,217
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,497	$2,600
Accrued liabilities	6,902	8,152
Accrued compensation and payroll taxes	901	1,430
Debt facility	11,593	10,991
Total current liabilities	20,893	23,173
Long-term lease obligation	19	25
Debt facility, net of current portion	2,615	3,726
Deferred income tax liability	3,404	3,404
Total liabilities	26,931	30,328
Stockholders' equity:		
Common stock, $0.001 par value; 500,000,000 shares authorized; 232,892,110 and 163,614,297 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	233	164
Additional paid-in capital	317,988	298,715
Accumulated other comprehensive income/(loss)	4	(17)
Accumulated deficit	(305,038)	(274,973)
Total stockholders' equity	13,187	23,889

Total liabilities and stockholders' equity	$40,118	$54,217

See accompanying notes to unaudited condensed consolidated financial statements.

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except for share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues	$45	$—	$45	$—
Operating expenses:				
Research and development	5,088	7,330	20,715	21,106
Selling, general and administrative	2,134	2,460	7,408	8,448
Depreciation and amortization	24	38	86	105
Total operating expenses	7,246	9,828	28,209	29,659
Loss from operations	(7,201)	(9,828)	(28,164)	(29,659)
Interest income	31	32	107	94
Interest expense	(948)	(101)	(1,979)	(102)
Other income (loss), net	(34)	(15)	(29)	(12)
Net loss	$(8,152)	$(9,912)	$(30,065)	$(29,679)
Net loss per share - basic and diluted	$(0.04)	$(0.06)	$(0.15)	$(0.18)
Weighted average shares outstanding - basic and diluted	214,714,029	163,614,297	196,527,686	161,748,944
Comprehensive Income/(Loss):				
Net loss	$(8,152)	$(9,912)	$(30,065)	$(29,679)
Other comprehensive income/(loss)	(3)	(1)	22	34
Comprehensive net loss	$(8,155)	$(9,913)	$(30,043)	$(29,645)

See accompanying notes to unaudited condensed consolidated financial statements.

Mast Therapeutics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(30,065)	$(29,679)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	86	105
Share-based compensation expense related to employee stock options	1,951	2,122
Amortization of debt issuance costs and debt discount	947	29
Changes in assets and liabilities:		
Decrease/(increase) in prepaid expenses and other assets	38	(251)
(Decrease)/increase in accounts payable and accrued liabilities	(2,895)	3,536
Net cash used in operating activities	(29,938)	(24,138)
Cash flows from investing activities:		
Purchases of certificates of deposit	—	(8,235)
Proceeds from maturities of certificates of deposit	11,521	12,044
Purchases of property and equipment	(8)	(118)
Net cash provided by investing activities	11,513	3,691
Cash flows from financing activities:		
Proceeds from borrowings under debt facility	—	15,000
Payments made on debt facility	(1,294)	—
Costs paid in connection with debt facility	(123)	(160)
Proceeds from sale of common stock	17,942	2,140
Proceeds from exercise of warrants	408	—
Payments for offering costs	(1,033)	(129)
Payments for capital lease	(6)	(5)
Net cash provided by financing activities	15,894	16,846
Net decrease in cash and cash equivalents	(2,531)	(3,601)
Cash and cash equivalents at beginning of period	23,052	35,808
Cash and cash equivalents at end of period	$20,521	$32,207

See accompanying notes to unaudited condensed consolidated financial statements.

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Mast Therapeutics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Basis of Presentation

Mast Therapeutics, Inc., a Delaware corporation ("Mast Therapeutics," "we," "us," "our" 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, 2015, filed with the SEC on March 14, 2016 ("2015 Annual Report"). The condensed consolidated balance sheet as of December 31, 2015 included in this report has been derived from the audited consolidated financial statements included in the 2015 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 clinical-stage 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 Aires Pharmaceuticals, Inc. ("Aires") in February 2014, we acquired AIR001, a sodium nitrite inhalation solution for intermittent inhalation via nebulization, which we are developing for the treatment of heart failure with preserved ejection fraction (HFpEF). Through our acquisition of SynthRx, Inc. ("SynthRx") in 2011, we acquired vepoloxamer (also known as MST-188).

The accompanying condensed consolidated financial statements have been prepared assuming we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. However, our working capital, anticipated operating expenses and net losses and the uncertainties surrounding our ability to raise additional capital as needed, as discussed below, raise substantial doubt about our ability to continue as a going concern. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to our ability to continue as a going concern.

We have incurred significant operating losses since inception and have relied on our ability to fund our operations primarily though equity financings and a debt financing. For the year ended December 31, 2015 and the nine months ended September 30, 2016, we incurred losses from operations of $39.4 million and $28.2 million, respectively, and our net cash used in operating activities was $32.9 million and $29.9 million, respectively. At September 30, 2016, our cash, cash equivalents and investment securities totaled $27.0 million and our working capital was $7.4 million. Our planned operating activities call for expenditures over the next 12 months to exceed our current cash, cash equivalents and investment securities balances and working capital. We intend to raise additional capital this year

through our “at the market,” or ATM, equity offering program (See Note 13, “Stockholders’ Equity”) and seek other funding opportunities, including equity or debt financings and opportunities to strategically monetize our development program assets. However, there can be no assurance that we will be successful in these efforts or in our ongoing efforts to manage our operating costs. Subject to limited exceptions, our debt facility (See Note 8, “Debt Facility”) prohibits us from incurring indebtedness without the lender’s prior written consent. Our anticipated operating expenses and net losses and the uncertainties surrounding our ability to raise additional capital as needed raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and might realize significantly less than the values at which they are carried on our financial statements. We expect that our cash, cash equivalents and investment securities as of September 30, 2016, will be sufficient to fund our operations into the first quarter of 2017.

In addition to the uncertainties surrounding our ability to raise additional capital as needed, which raise substantial doubt about our ability to continue as a going concern, our business, operating results, financial condition, and growth prospects are subject to significant other risks and uncertainties, including failing to successfully develop and license or commercialize our product candidates even if we are able to raise significant additional capital.

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 and assumptions, 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. Goodwill and IPR&D

At September 30, 2016 and December 31, 2015, our goodwill and IPR&D consisted of the following (in thousands):

Goodwill	$3,007
IPR&D	
Acquired IPR&D related to SynthRx acquisition	6,549
Acquired IPR&D related to Aires acquisition	2,000
Total goodwill and IPR&D	$11,556

Our goodwill represents the difference between the total purchase price for SynthRx and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed.

Our IPR&D consists of the estimated fair values of the vepoloxamer and AIR001 programs as of the dates we acquired SynthRx and Aires, respectively.

We test our goodwill and acquired IPR&D for impairment annually as of September 30, or, in the case of initially acquired IPR&D, on the first anniversary of the date we acquired it and subsequently on September 30, and between annual tests if we become aware of an event or a change in circumstances that would indicate the carrying value may be impaired.

We performed a quantitative assessment of our goodwill as of September 30, 2016. We tested for impairment at the entity level because we operate on the basis of a single reporting unit. A quantitative assessment of goodwill utilizes a two-step approach. We first compared our carrying value, including goodwill, to our estimated fair value. If the carrying value had exceeded the estimated fair value, we would have performed Step 2 to measure the amount of any impairment charge. As the carrying value did not exceed estimated fair value, we did not perform Step 2 and concluded that no impairment charge for goodwill is required.

We performed a qualitative assessment of our acquired IPR&D for AIR001 as of September 30, 2016. We noted no events or circumstances that would lead us to determine that the carrying value of our acquired IPR&D exceeds its fair value. Therefore, we concluded that no impairment charge is required.

We performed a quantitative assessment of our acquired IPR&D for vepoloxamer as of September 30, 2016. Our prior assessments of vepoloxamer contemplated development of vepoloxamer in sickle cell disease. Due to negative efficacy results in our Phase 3 study of vepoloxamer in sickle cell disease in September 2016, we determined a quantitative assessment was appropriate. First, we considered whether vepoloxamer still has technological feasibility. Based on data from numerous nonclinical studies as well as earlier clinical studies of vepoloxamer, we continue to believe vepoloxamer has potential utility in a wide range of serious or life-threatening diseases and conditions typically characterized by impaired microvascular blood flow and damaged cell membranes, including heart failure and ischemic stroke. Our decision to terminate the Phase 2 study of vepoloxamer in heart failure was due to financial

constraints and not a change in our assessment of its potential utility for heart failure patients. However, because we are winding down our vepoloxamer heart failure program, but are exploring development opportunities for vepoloxamer in ischemic stroke (specifically, through a grant-funded nonclinical study and partnering opportunities), our impairment testing as of September 30, 2016 was based on assumptions for development of vepoloxamer in ischemic stroke.

We calculated the estimated fair value of acquired IPR&D by using the Multi-Period Excess Earnings Method, or MPEEM, which is a form of the income approach. While the inputs under the MPEEM consist primarily of Level 3 inputs, some Level 2 inputs were incorporated to derive the discount rate, as well as certain tax and asset balance assumptions and the probability factor for achieving regulatory approval. Under the MPEEM, we used probability-weighted, projected after-tax cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by companies in a similar lifecycle stage. Cash flows were calculated based on estimated projections of revenues and expenses related to vepoloxamer in ischemic stroke (U.S. and European Union) 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 2039, but to decrease substantially after 2034 based on an assumption of the expiration of the U.S. composition of matter patent covering vepoloxamer in mid-2035. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles comparable to Mast's based on industry-specific information obtained from published sources we believe to be reliable. We compensated for the phase of development of the program by applying a probability factor to our estimation of expected future cash flows. We analyzed a range of probability

factors ranging from the high single digits to the low teens and under all of these scenarios, the fair value of the vepoloxamer-related IPR&D exceeded its carrying value. The projected cash flows were based on significant assumptions, including the time and resources needed to complete the development and regulatory approval of vepoloxamer in ischemic stroke, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product, the term of market exclusivity, 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. Based on the fair value assessment described above, the carrying value of the vepoloxamer-related IPR&D did not exceed its fair value as of September 30, 2016. Therefore, we concluded that no impairment charge is required.

4. Investment Securities

Investment securities are marketable equity or debt securities. All of our investment securities are “available-for-sale” securities and carried at fair value. Fair value for securities with short maturities and infrequent secondary market trades typically is determined by using a curve-based evaluation model that utilizes quoted prices for similar securities. The evaluation model takes into consideration the days to maturity, coupon rate and settlement date convention. Net unrealized gains or losses on these securities are included in accumulated other comprehensive loss, which is a separate component of stockholders’ equity. Realized gains and realized losses are included in other income, net 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, as current assets on our consolidated balance sheets because we consider them to be highly liquid and available for use, if needed, in current operations. As of September 30, 2016, none of our investment securities had contractual maturity dates of more than one year.

At September 30, 2016 and December 31, 2015, our investment securities were as follows (in thousands):

	September 30, 2016	December 31, 2015
Fair value of investment securities	$ 6,429	$ 17,929
Cost basis of investment securities	6,425	17,946

	September 30, 2016	December 31, 2015
Net unrealized (gains)/losses on investment securities	$ (4)	$ 17

5. Fair Value of Financial Instruments

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

The fair values at September 30, 2016 and December 31, 2015 of our cash equivalents and investment securities are summarized in the following table (in thousands):

		Fair Value Determined Under:		
	Total Fair Value	(Level 1)	(Level 2)	(Level 3)
At September 30, 2016:				
Cash equivalents	$6,410	$6,410	$—	$ —
Investment securities	$6,429	$—	$6,429	$ —
At December 31, 2015:				
Cash equivalents	$15,799	$15,799	$—	$ —
Investment securities	$17,929	$—	$17,929	$ —

We believe that our debt facility (see Note 8 “Debt Facility”) bears interest at a rate that approximates prevailing market rates for instruments with similar characteristics and, accordingly, the carrying value of the debt facility approximates fair value. The fair value of our debt facility is determined under Level 2 in the fair value hierarchy.

6. Property and Equipment

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

We lease certain office equipment under leases classified as capital leases. As of September 30, 2016, the total amount of leased equipment was $40,000 with interest rates ranging from 8% to 14% per annum. The equipment is being amortized over the life of the leases, which range from three to five years.

7. Accrued Liabilities

Accrued liabilities at September 30, 2016 and December 31, 2015 were as follows (in thousands):

	September 30, 2016	December 31, 2015
Accrued R&D agreements and study expenses	$ 6,600	$ 7,898
Other accrued liabilities	302	254
Total accrued liabilities	$ 6,902	$ 8,152

8. Debt Facility

Hercules Loan and Security Agreement

In 2015, we borrowed an aggregate of $15.0 million pursuant to a Loan and Security Agreement with Hercules Technology III, L.P. and Hercules Capital, Inc. (formerly known as, Hercules Technology Growth Capital, Inc.) (together, “Hercules”), as amended (the “Loan Agreement”). Pursuant to the terms and conditions of the Loan Agreement, we received the first advance of $5.0 million on August 11, 2015 and the second advance of $10.0 million on September 28, 2015 (the “Second Advance”).

The Loan Agreement required prepayment of $10.0 million of the principal balance of the loan and any accrued but unpaid fees and expenses (the “Second Advance Prepayment”) on or before October 14, 2016 unless the Phase 3 clinical

study of vepoloxamer in sickle cell disease, known as the EPIC study, demonstrated positive results. Our announcement in September 2016 that EPIC did not achieve its primary or secondary efficacy endpoints triggered the Second Advance Prepayment, which was made in October 2016. See Note 14, “Subsequent Events.” The Second Advance was classified as a current liability on our balance sheet as of September 30, 2016.

The interest rate for the principal balance under the Loan Agreement is the greater of (i) 8.95% plus the prime rate as reported in The Wall Street Journal minus 3.25%, and (ii) 8.95%, determined on a daily basis. Monthly payments under the Loan Agreement were interest only until July 1, 2016. On July 1, August 1, and September 1, 2016 we made equal monthly payments against the principal balance in addition to the interest amounts. We are required to repay the loan in equal monthly installments of principal and interest on the first business day of each month through the scheduled maturity date of January 1, 2019. An end of term charge of $712,500 will be due on the scheduled maturity date and is being accrued through interest expense using the effective interest method.

If we elect to prepay the principal balance under the Loan Agreement prior to maturity, a prepayment charge of 1% or 2% of the then outstanding principal balance also will be due, depending upon when the prepayment occurs. No prepayment penalty applied to the Second Advance Prepayment.

Our obligations under the Loan Agreement are secured by a first priority security interest in substantially all of our assets, excluding our intellectual property but including the proceeds from the sale, licensing or disposition of our intellectual property. Our intellectual property is subject to customary negative covenants.

In connection with the Loan Agreement, we have paid facility charges of $225,000 and a commitment charge of $25,000. Such charges were accounted for as debt issuance costs and are being amortized to interest expense using the effective interest method through the scheduled maturity date.

In connection with the Loan Agreement, we entered into a Warrant Agreement with Hercules, dated August 11, 2015, as amended by the First Amendment thereto dated September 28, 2015 and the Second Amendment thereto dated February 25, 2016, pursuant to which Hercules has a right to purchase up to 2,272,727 shares of our common stock at an exercise price of $0.275 per share. Prior to the Second Amendment to Warrant Agreement, the Warrant Agreement, as amended by the First Amendment, provided Hercules a right to purchase up to 1,524,390 shares of our common stock at an exercise price of $0.41 per share.

The warrants issued to Hercules were valued using the Black-Scholes option pricing model with the following assumptions: volatility of 83%, expected term of five years, risk-free interest rate of 1.2% and a zero dividend yield. The warrant fair value of $0.4 million has been recorded as a debt discount and is being amortized through interest expense using the effective interest method through the scheduled maturity date. See Note 13 “Stockholders’ Equity” for further description of the terms of the warrants.

Summary of Carrying Value

The following table summarizes the components of the debt facility carrying value (in thousands):

	As of September 30, 2016	
	Short-term	Long-term
Prepayment to lender	$ 10,000	$ -
Principal payments to lender and end of term charge	1,488	