



NEWS RELEASE

# Mast Therapeutics Reports Second Quarter 2016 Financial Results

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SAN DIEGO, Aug. 9, 2016 /PRNewswire/ -- **Mast Therapeutics, Inc.** (NYSE MKT: MSTX), a biopharmaceutical company developing novel, clinical-stage therapies for sickle cell disease and heart failure, today reported financial results for the quarter ended June 30, 2016.

"We continued to advance our assets toward valuable inflection points during the second quarter. Announcing top-line data from the EPIC study continues to be our top priority. With 388 subjects randomized at study sites around the globe, EPIC was the largest placebo-controlled study in sickle cell disease ever concluded and we look forward to announcing results next month. To support our NDA for vepoloxamer, we also continue to enroll patients in EPIC-E, our repeat exposure study for EPIC patients, and in a clinical pharmacokinetics study of vepoloxamer in individuals with varying degrees of renal insufficiency," stated Brian M. Culley, Chief Executive Officer.

"In addition, clinical development of AIR001 in heart failure with preserved ejection fraction is progressing through multiple Phase 2 studies. In particular, we are pleased that the first patient was dosed in the 100-patient Phase 2 study being conducted by the Heart Failure Clinical Research Network," continued Mr. Culley.

## Second Quarter 2016 Operating Results

The Company's net loss for the second quarter of 2016 was \$10.7 million, or \$0.05 per share (basic and diluted), compared to a net loss of \$10.2 million, or \$0.06 per share (basic and diluted), for the same period in 2015.

Research and development (R&D) expenses for the second quarter of 2016 were \$7.8 million, compared to \$7.7 million for the same period in 2015. Increases of \$0.5 million in external clinical study fees and expenses and \$0.1 million in share-based compensation expense were offset by a \$0.5 million decrease in external nonclinical study fees and expenses.

The increase in external clinical study fees and expenses was due primarily to increased costs related to the Company's Phase 2 study of vepoloxamer in heart failure (\$0.7 million) and the Phase 2 studies of AIR001 in HFpEF (\$0.4 million), offset by decreases in costs for the EPIC study (\$0.4 million) and the Phase 2 study of vepoloxamer in acute limb ischemia, which the Company began to wind-down in the third quarter of 2015 (\$0.2 million). The decrease in external nonclinical study fees and expenses was due primarily to decreases in research-related manufacturing costs for vepoloxamer (\$1.2 million) and nonclinical studies of vepoloxamer (\$0.4 million), offset by increased costs related to preparing a new drug application for vepoloxamer (\$0.9 million) and research-related manufacturing for AIR001 (\$0.2 million).

Selling, general and administrative (SG&A) expenses were \$2.4 million in each of the second quarter of 2016 and the second quarter of 2015.

Interest expense for the second quarter of 2016 was \$512,000, \$511,000 of which was related to the Company's debt facility. There was interest expense of \$1,000 for the second quarter of 2015.

## Year-to-Date Financial Results

The Company's net loss for the six months ended June 30, 2016 was \$21.9 million, or \$0.12 per share (basic and diluted), compared to a net loss of \$19.8 million, or \$0.12 per share (basic and diluted), for the same period in 2015.

R&D expenses for the six months ended June 30, 2016 were \$15.6 million, an increase of \$1.8 million, or 13%, compared to \$13.8 million for the same period in 2015. The increase was due primarily to increases of \$1.0 million in external clinical study fees and expenses, \$0.4 million in external nonclinical study fees and expenses, \$0.2 million in personnel expenses and \$0.2 million in share-based compensation.

The \$1.0 million increase in external clinical study fees and expenses was due primarily to increases in costs for our Phase 2 study of vepoloxamer in heart failure (\$1.2 million) and the Phase 2 studies of AIR001 in HFpEF (\$0.4 million), offset by a decrease in costs for the Phase 2 study of vepoloxamer in ALI (\$0.5 million). The \$0.4 million increase in external nonclinical study fees and expenses was due primarily to increases in costs related to preparing a new drug application for vepoloxamer (\$1.4 million) and research-related manufacturing for AIR001 (\$0.2 million), offset by decreases in research-related manufacturing costs for vepoloxamer (\$0.8 million) and costs for nonclinical studies of vepoloxamer (\$0.3 million).

SG&A expenses for the six months ended June 30, 2016 were \$5.3 million, a decrease of \$0.7 million, or 12%, compared to \$6.0 million for the same period in 2015. SG&A expenses for the first six months of 2015 included \$0.4 million of severance expenses and \$0.3 million of share-based compensation resulting from the termination of employment of the Company's former president and chief operating officer in February 2015 and the acceleration

of stock option vesting pursuant to the terms of his option agreements.

Interest expense for the six months ended June 30, 2016 was \$1,031,000, \$1,029,000 of which was related to the Company's debt facility. There was interest expense of \$1,000 for the same period of 2015.

## About Mast Therapeutics

Mast Therapeutics, Inc. is a publicly traded biopharmaceutical company headquartered in San Diego, California. The Company is developing two clinical-stage investigational new drugs for serious or life-threatening diseases and conditions. Vepoloxamer, the Company's lead product candidate, is in Phase 3 clinical development for the treatment of vaso-occlusive crisis in patients with sickle cell disease and in Phase 2 clinical development for the treatment of patients with heart failure. Enrollment in the Company's 388-patient Phase 3 study of vepoloxamer in patients with sickle cell disease, known as the EPIC study, was completed earlier this year. Enrollment in the Company's Phase 2 study of vepoloxamer in patients with chronic heart failure is ongoing. AIR001, the Company's second product candidate, is in Phase 2 clinical development for the treatment of patients with heart failure with preserved ejection fraction (HFpEF). Enrollment in Phase 2 studies of AIR001 in patients with HFpEF are ongoing, including a 100-patient, multicenter, randomized, double-blind, placebo-controlled, Phase 2 study in patients with HFpEF being conducted by the Heart Failure Clinical Research Network. More information can be found on the Company's web site at [www.masttherapeutics.com](http://www.masttherapeutics.com). (Twitter: [@MastThera](https://twitter.com/MastThera))

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## Forward Looking Statements

Mast Therapeutics cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the Company's current expectations and assumptions. Such forward-looking statements may be identified by the use of forward-looking words such as "expect," "intend," "plan," "anticipate," "believe," among others, and include, but are not limited to, statements relating to prospects for successful development and commercialization of the Company's product candidates, including vepoloxamer for the treatment of vaso-occlusive crisis of sickle cell disease, and anticipated timing of achievement of development milestones, such as completion of clinical studies and announcement of study data. There are a number of factors that could cause or contribute to material differences between actual events or results and the expectations indicated by the forward-looking statements. These factors include, but are not limited to: the inherent uncertainty of outcomes in ongoing and future studies of the Company's product candidates and the risk that vepoloxamer may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including the Phase 3 "EPIC" study; the potential for additional delays in EPIC study closeout procedures, including blinded data validation and quality control and assurance procedures; risks associated with the Company's ability to manage operating expenses and obtain

additional capital as needed; the Company's potential inability to continue as a going concern if it does not raise sufficient additional capital as needed; the risk that the Company may be required to repay its outstanding debt obligations on an accelerated basis and/or at a time that could be detrimental to its financial condition, operations and/or business strategy, including the prepayment of \$10 million of the principal balance of its debt facility if results from the EPIC study are not positive and/or not available on or before October 14, 2016; the potential for the Company to significantly delay, reduce or discontinue current and/or planned development and commercial-readiness activities or sell or license its assets at inopportune times if it is unable to raise sufficient additional capital as needed; the risk that, even if EPIC study results are positive, the FDA may require a second Phase 3 study or other clinical or nonclinical studies to demonstrate substantial evidence of vepoloxamer's effectiveness for sickle cell patients or to provide additional safety and tolerability data or that the FDA may require changes to manufacturing controls or processes that could delay filing of a new drug application; delays in the commencement or completion of clinical studies, including as a result of difficulties in obtaining regulatory agency agreement on clinical development plans or clinical study design, opening trial sites, enrolling study subjects, manufacturing sufficient quantities of clinical trial material, being subject to a "clinical hold," and/or suspension or termination of a clinical study, including due to patient safety concerns or lack of funding; the potential that, even if clinical studies of a product candidate in one indication are successful, clinical studies in another indication may not be successful; the Company's dependence on third parties to assist with important aspects of development of its product candidates, including conduct of its clinical studies and supply and manufacture of clinical trial material, and, if approved, commercial product, and the risk that such third parties may fail to perform as expected, leading to delays in product candidate development or approval or inability to meet market demand for approved products, if any; the risk that, even if the Company successfully develops a product candidate in one or more indications, it may not realize commercial success and may never achieve profitability; the risk that the Company is not able to obtain and maintain effective patent coverage or other market exclusivity protections for its products, if approved, without infringing the proprietary rights of others; and other risks and uncertainties more fully described in the Company's press releases and periodic filings with the Securities and Exchange Commission. The Company's public filings with the Securities and Exchange Commission are available at [www.sec.gov](http://www.sec.gov).

You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date when made. Mast Therapeutics does not intend to revise or update any forward-looking statement set forth in this press release to reflect events or circumstances arising after the date hereof, except as may be required by law.

[Tables to Follow]

Mast Therapeutics, Inc.  
Condensed Consolidated Statements of Operations  
(In thousands, except per share data)

	Three months ended June 30, (Unaudited)		Six months ended June 30, (Unaudited)	
	2016	2015	2016	2015
Total net revenue	\$ —	\$ —		
Operating expenses:				
Research and development	7,752	7,734	15,627	13,776
Selling, general and administrative	2,439	2,410	5,274	5,988
Depreciation and amortization	30	37	61	67
Total operating expenses	<u>10,221</u>	<u>10,181</u>	<u>20,962</u>	<u>19,831</u>
Loss from operations	(10,221)	(10,181)	(20,962)	(19,831)
Interest and other (expense)/income, net	(485)	30	(951)	64
Net loss	<u>\$ (10,706)</u>	<u>\$ (10,151)</u>	<u>\$ (21,913)</u>	<u>\$ (19,767)</u>
Net loss per share – basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.06)</u>	<u>\$ (0.12)</u>	<u>\$ (0.12)</u>
Weighted average shares – basic and diluted	<u>196,554</u>	<u>162,128</u>	<u>187,335</u>	<u>160,801</u>

Mast Therapeutics, Inc.  
Balance Sheet Data  
(In thousands)

	June 30, 2016	December 31, 2015
Cash, cash equivalents and investment securities	\$ 35,072	\$ 40,981
Working capital	10,455	19,079
Total assets	47,676	54,217
Total liabilities	31,250	30,328
Stockholders' equity	16,426	23,889

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/mast-therapeutics-reports-second-quarter-2016-financial-results-300310883.html>

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