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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported):

April 3, 2013

Mast Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

001-32157

84-1318182

(State or other jurisdiction  
of incorporation)

(Commission  
File Number)

(I.R.S. Employer  
Identification No.)

12390 El Camino Real, Suite 150, San Diego,  
California

92130

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

858-552-0866

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

**Item 7.01 Regulation FD Disclosure.**

Beginning on April 3, 2013, the information attached as Exhibit 99.1 to this report, which primarily relates to research and development of Mast Therapeutics, Inc.'s (the "Company") lead product candidate, MST-188, may be presented from time to time by the Company at various scientific, investor and analyst meetings.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

The list of exhibits called for by this Item is incorporated by reference to the Exhibit Index filed with this report.

The information in this report, including the information contained in Exhibit 99.1 attached hereto, is being furnished pursuant to this Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this report.

By filing this report and furnishing this information, including the information contained in Exhibit 99.1 attached hereto, the Company makes no admission as to the materiality of any information in this report. The information contained in Exhibit 99.1 hereto is summary information that is intended to be considered in the context of the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including its Annual Report on Form 10-K filed on March 19, 2013, and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as it believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases, or through other public disclosure.

**Forward-Looking Statements**

Mast Therapeutics cautions you that statements included in this report, including in Exhibit 99.1 attached hereto, that are not a description of historical facts are forward-looking statements that are based on the Company's current expectations and assumptions. Such forward-looking statements include, but are not limited to, statements regarding the Company's development and commercialization plans for MST-188, including in sickle cell disease, acute limb ischemia, and other indications, and plans for protecting its intellectual property related to MST-188, as well as the timing of activities related to those plans. Among the factors that could cause or contribute to material differences between the Company's actual results and the expectations indicated by the forward-looking statements are risks and uncertainties that include, but are not limited to: the potential for 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 clinical trial material, completing manufacturing process development activities, and being subject to a "clinical hold"; the risk of suspension or termination of a clinical study, including due to lack of adequate funding or patient safety concerns; the potential for institutional review boards or the FDA or other regulatory agencies to require additional nonclinical or clinical studies prior to initiation of planned phase 2 clinical studies of MST-188 in any particular indication in which the Company determines to develop MST-188, including acute limb ischemia, which likely would increase the total time and cost of development in the indication; the risk that clinical studies of MST-188 are not successfully executed and/or do not successfully demonstrate its safety or efficacy; the risk that, even if clinical studies are successful, the FDA determines they are not sufficient to support a new drug application; the risk that even if clinical studies of MST-188 in one indication are successful, clinical studies in another indication may not be successful; the Company's reliance on contract research organizations (CROs), contract manufacturing organizations (CMOs), and other third parties to assist in the conduct of important aspects of development of MST-188, including clinical studies, and regulatory activities for MST-188 and that such third parties may fail to perform as expected; the Company's ability to obtain additional funding on a timely basis or on acceptable terms, or at all; the potential for the Company to delay, reduce or discontinue current and/or planned development activities, including clinical studies, partner MST-188 at inopportune times or pursue less expensive but higher-risk and/or lower return development paths if it is unable to raise sufficient additional capital as needed; the risk that acceptable partnering opportunities for MST-188 may not be available in particular jurisdictions or indications and, consequently, the Company may not be able to pursue development of MST-188 in certain jurisdictions and indications; the risk that the FDA and regulatory agencies outside of the U.S. do not grant marketing approval of MST-188, on a timely basis, or at all; the risk that the Company is not able to adequately protect its intellectual property rights relating to the MAST platform and MST-188 and prevent competitors from duplicating or developing equivalent versions of its product candidates, including MST-188; and other risks and uncertainties more fully described in the Company's periodic filings with the SEC and press releases.

You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. 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. This caution is made under the safe harbor provisions of Section 21E of the Exchange Act.

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SIGNATURES

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

Mast Therapeutics, Inc.

April 3, 2013

By: */s/ Patrick L. Keran*

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*Name: Patrick L. Keran*

*Title: President and Chief Operating Officer*

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Mast Therapeutics, Inc. corporate presentation slide deck, dated April 3, 2013



## Corporate Overview

April 3, 2013  
Brian M. Culley, CEO

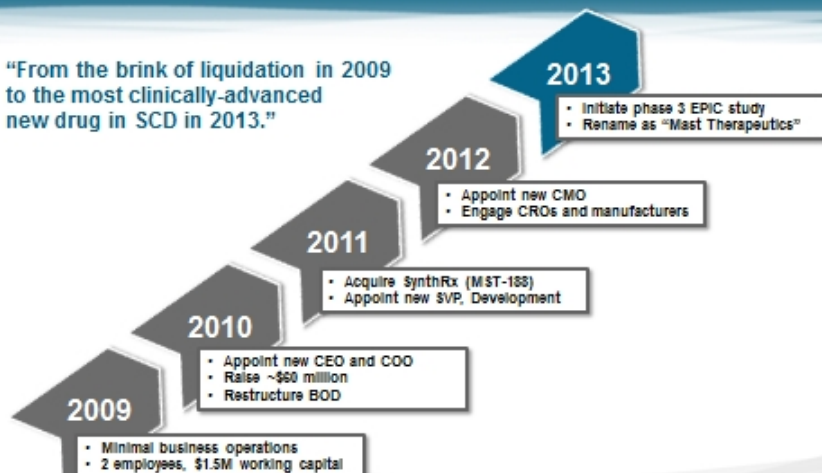
## Forward-Looking Statements

This presentation includes forward-looking statements about our business prospects, financial position, and development of MST-188 for therapeutic use in humans. Any statement that is not a statement of historical fact should be considered a forward-looking statement. Because forward-looking statements relate to the future, they are subject to inherent risks, uncertainties and changes in circumstances that are difficult to predict. Actual events or performance may differ materially from our expectations indicated by these forward-looking statements due to a number of factors, including, but not limited to, results of our pending and future clinical studies, the timeline for clinical and manufacturing activities and regulatory approval; our dependency on third parties to conduct our clinical studies and manufacture our clinical trial material; our ability to raise additional capital, as needed; our ability to establish and protect proprietary rights related to MST-188; and other risks and uncertainties more fully described in our press releases and our filings with the SEC, including our annual report on Form 10-K for the period ended December 31, 2012.

We caution you not to place undue reliance on any of these forward-looking statements, which speak only as of the date of this presentation. We do not intend to update any forward-looking statement included in this presentation to reflect events or circumstances arising after the date of the presentation, except as may be required by law.

## Corporate Restart

“From the brink of liquidation in 2009 to the most clinically-advanced new drug in SCD in 2013.”



# Corporate Overview

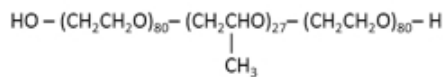
- Developing MST-188 for “microcirculatory insufficiency”
- Initially focused on rare/orphan diseases
  - Sickle Cell Disease
  - Acute Limb Ischemia
- Planned expansion into larger markets
  - Resuscitation Following Major Hemorrhage
  - Acute Decompensated Heart Failure
  - Transfusion (Storage Lesion)
  - Acute Ischemic Cardiovascular Infarction (Stroke)
- Recruiting subjects in pivotal phase 3 study in SCD
  - Most clinically relevant in microcirculatory insufficiency



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## MST-188 Overview



API Structure:

Drug Product: Formulated as a clear, citrate-buffered solution

CMC: Large polymeric molecule (8,500 Daltons) manufactured by chemical synthesis and proprietary purification process

Administration: 24-48h IV in acute-care settings (hospital, ICU, specialized out-patient)



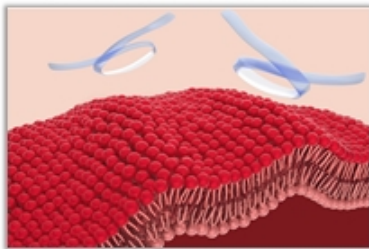
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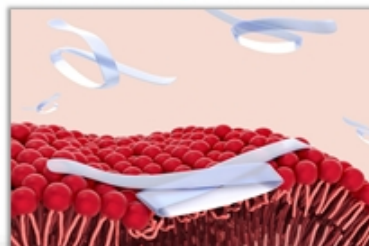
## MST-188 Mechanism of Action

Hydrophobic core binds to hydrophobic domains in circulation (e.g., damaged cell membranes, acute phase reactant proteins)

No Affinity for Healthy Cell Membranes



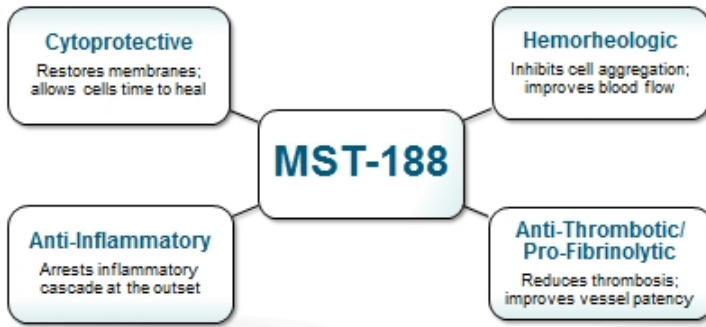
Adheres to Damaged Cell Membranes



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# MST-188 Pharmacodynamics

Single mechanism with four pharmacodynamic effects addresses multiple pathophysiologic processes



## The MST-188 Pipeline

	Preclinical	Phase 1	Phase 2	Phase 3
2013				
Sickle Cell Disease (orphan)	[Progress bar spanning all phases]			
Acute Limb Ischemia (orphan)	[Progress bar spanning Preclinical, Phase 1, and Phase 2]			
Resuscitation following Major Trauma*	[Progress bar spanning Preclinical, Phase 1, and Phase 2]			
Acute Decompensated Heart Failure	[Progress bar spanning Preclinical]			
Transfusion (storage lesion)	[Progress bar spanning Preclinical]			
2014				
Stroke	[Progress bar spanning Preclinical]			

## Sickle Cell Disease (vaso-occlusive crisis)

# Overview

- An inherited genetic disorder and orphan disease
  - Characterized by “sickling” of erythrocytes (red blood cells, RBCs)
- Hallmark is recurring episodes of extreme pain (“crisis”)
  - Typically last 4 to 5 days, but may last a week or longer
  - Patients “suffer at home” until pain requires IV analgesia (hospital visit)
- Significant unmet need
  - Average age of death ~40 years
  - No approved agents to shorten duration or severity of crisis
- Substantial interest from Big Pharma
  - Pfizer: \$395 million\* for phase 2 investigational drug (Oct 2011)
  - Novartis: \$650 million\* for phase 2 investigational drug (Sep 2012)



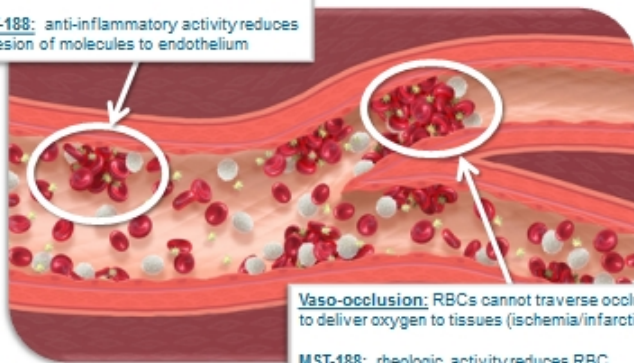
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\* Reported deal value  
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## Pathophysiology: impaired blood flow

**Early stages:** adhesion of circulating blood products to endothelial cells

**MST-188:** anti-inflammatory activity reduces adhesion of molecules to endothelium



**Vaso-occlusion:** RBCs cannot traverse occlusion to deliver oxygen to tissues (ischemia/infarction)

**MST-188:** rheologic activity reduces RBC aggregation, lowers viscosity, improves RBC deformability

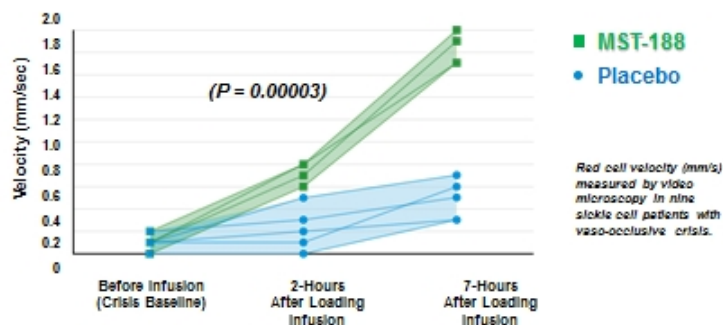


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## MST-188: improves blood flow

Improvement in microvascular blood flow in SCD patients in crisis following treatment with MST-188



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Source: J. Investig. Med. 2004;62(8):4026

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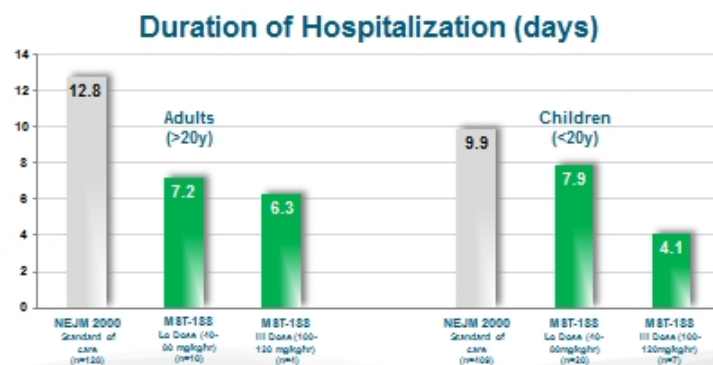
## Completed Phase 2 Study in SCD

Improvement in various endpoints in SCD patients in crisis following treatment with MST-188\*

	Subjects who received $\geq 24$ h infusion (n=45)		
	MST-188*	Placebo	Improvement
Duration of Crisis	60h	88h	32% shorter
Duration of Hospitalization	5 days	7 days	2 days shorter
Total Analgesic Use	49mg	169mg	71% less
Parenteral Analgesic Use	40mg	150mg	73% less

## Completed Phase 2 Study in SCD

Reduction in duration of hospitalization in SCD patients (n=41) with acute chest syndrome following treatment with MST-188



## Completed Phase 3 Study in SCD (Primary and Post-Hoc Analyses)

Improvement in duration of crisis in SCD patients in crisis following treatment with MST-188

Group	MST-188	Placebo	P Value
All treated patients (n=249)	132 hours	140 hours	0.07
Patients <16 years old (n=73)	127 hours	149 hours	0.01

## Completed Phase 3 Study in SCD (Primary and Post-Hoc Analyses)

Improvement in duration of crisis in SCD patients in crisis following treatment with MST-188

Group	MST-188	Placebo	P Value
All treated patients (n=249)	132 hours	140 hours	0.07
Patients <16 years old (n=73)	127 hours	149 hours	0.01

Original trial statistical plan required 350 patients. Reduced by almost 30% by prior sponsor (capital constraints).



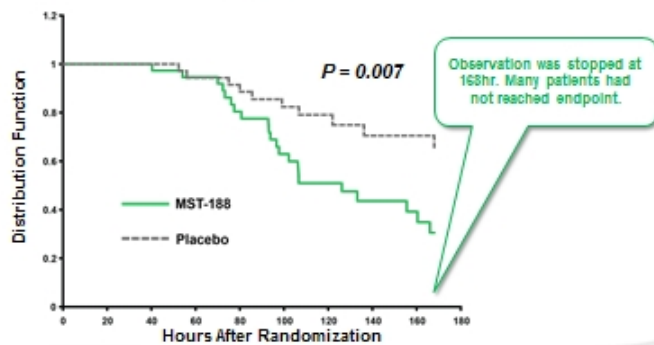
Source: JAMA, November 17, 2001 – Vol 286, No. 17

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## Completed Phase 3 Study in SCD (Post-Hoc Analysis)

Proportion of Patients <16 Years Remaining in Crisis Over Time (n=73)



Source: JAMA, November 17, 2001 – Vol 286, No. 17

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## Completed Phase 3 Study in SCD (Post-Hoc Analysis)

Proportion of Patients Achieving Crisis Resolution within 168 Hours

Group	MST-188	Placebo	P Value
All treated patients (n=249)	51.6%	36.6%	0.02
Patients <16 years old (n=73)	62.2%	27.8%	0.01



Source: JAMA, November 17, 2001 – Vol 286, No. 17

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## Lessons Learned

- Simplify endpoint to minimize protocol violations and missing (“left-censored”) data
- Follow subjects until hospital discharge to avoid truncated (“right- censored”) data
- Avoid subjective endpoints, which increase variability
- Standardize pain management practices across study sites
- Increase homogeneity in terms of cumulative disease burden (chronic pain)
- Control duration of crisis (“suffering at home”) prior to randomization
- Limit SCD genotypes

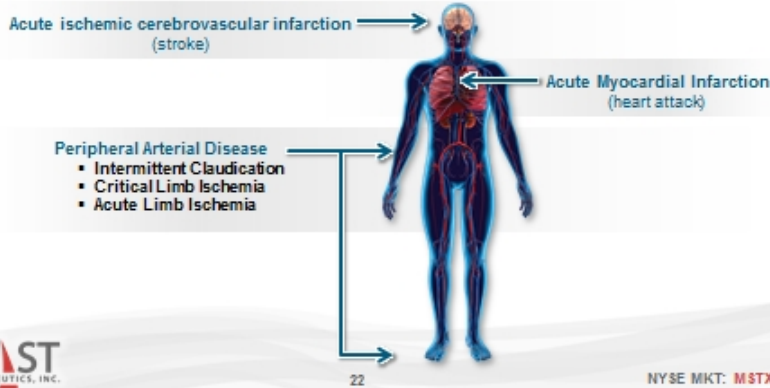
## Pivotal Phase 3 Trial (EPIC) Evaluation of Purified <sup>188</sup>In Children

- Study Design
  - Randomized, two-arm, double-blind, placebo controlled
  - 388 patients ages 8-17 from ~40 centers in the U.S.
  - 90% power
- Primary endpoint
  - Duration of crisis
  - Time from randomization to last dose of parenteral opioid
- Secondary endpoints
  - Re-hospitalization rate (for vaso-occlusive crisis) within 14 days
  - Acute chest syndrome within 120 hours of randomization
- Initiated: January 2013
- Expected Completion (enrollment): 2015

## Acute Limb Ischemia

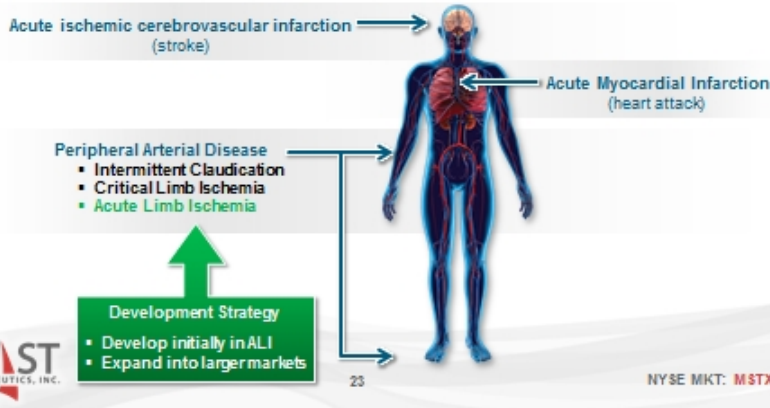
# Arterial Disease

- A progressive circulatory problem in which obstructed arteries reduce blood flow to tissue
  - Thrombolytic agents (tPA) used to treat acute complications
  - Significant morbidity and mortality



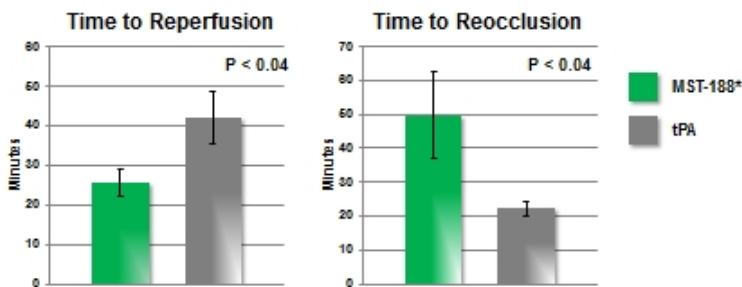
# Arterial Disease

- A progressive circulatory problem in which obstructed arteries reduce blood flow to tissue
  - Thrombolytic agents (tPA) used to treat acute complications
  - Significant morbidity and mortality



# MST-188 Improved tPA Effectiveness

Animals randomized to tPA (alteplase) (n = 10) or tPA + MST-188\* (n = 10)



# Planned Phase 2 Study

- **Generate Clinical Proof-of-Concept Data**
  - Biomarkers
  - Clinical outcomes
  - Protocol under development
- **Study Concept**
  - Design: randomized, double-blind, active-controlled
  - Population: Rutherford Class 2A / 2B and catheter-directed thrombolysis
  - Arms: tPA vs. tPA + MST-188
  - Sample Size: ~60 subjects
  - Evaluate multiple doses
- **Timing**
  - Initiation: late 2013/early 2014
  - Enrollment: 15 - 18 months



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## Resuscitation Following Major Trauma



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## MST-188 Improved Survival in Numerous Experimental Models

- MST-188\* studied in 5 controlled models of hemorrhagic shock / resuscitation by 4 different investigator groups
- Consistently improved survival (reproducibility across studies)

<i>Resuscitation</i> (2011) (DARPA-funded)	MST-188 (n=7)	Control (n=16)	P value
Median Survival Time (min) (95% CI)	161 (80 - 180)	55.8 (36.5 - 86)	0.0186
<i>Shock</i> (2009)	MST-188 + Hextend	Hextend	P value
Survival time from onset of hemorrhage (min) (n=10/arm)	589±99	289±37	0.002

Sources: Resuscitation 22 (2011) 1463-1468; SHOCK, Vol 22, No. 4, pp. 442-460, 2009  
 \*Some studies evaluated 1<sup>st</sup> generation (non-purified) formulation



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# Planned Phase 2 Study & Funding

- **Generate Clinical Proof-of-Concept Data**
- **Study Protocol (complete)**
  - Design: randomized, double-blind, controlled
  - Population: admitted to ICU for resuscitation following major torso trauma
  - Arms: Standard resuscitation protocol (SRP) vs SRP + MST-188
  - Sample Size: ~60 subjects
  - Evaluate multiple doses
  - Enrollment: 18 - 24 months
- **Collaboration with University of Florida**
  - A leader in clinical research and trauma care
- **U.S. Government Funding**
  - MST-188 prior recipient of funding (DARPA)
  - Preparing / submitting new applications
  - Timeline: 9 - 12 months



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## Market Opportunities for MST-188

Therapeutic Area	U.S. Incidence (annual)	Ex-U.S.* Incidence (annual)
Sickle Cell Disease (vaso-occlusive crisis)	~100,000 hospitalizations	~70,000 hospitalizations
Peripheral Arterial Disease (thrombolysis)**	500,000 to 600,000	1.6 to 2.0 million
Resuscitation following Major Trauma	1.0 million	2.9 to 3.3 million
Acute Decompensated Heart Failure	1.0 million	3.1 to 4.1 million
Transfusion	4.5 million	20 to 22 million
Stroke	800,000	2.4 million

\*\*Includes all end-stage PAD (i.e. ALI, CLI, DVT and other thrombotic diseases) \* Includes developed countries



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## MST-188 Exclusivity

### Multiple Barriers to Entry

<b>Marketing Exclusivity</b>	<ul style="list-style-type: none"> <li>➤ SCD: orphan drug designation in U.S. and EU</li> <li>➤ ALI: orphan drug designation expected in U.S. and EU</li> </ul>
<b>Patents</b>	<ul style="list-style-type: none"> <li>➤ Filed applications cover:                             <ul style="list-style-type: none"> <li>▪ proprietary purification process</li> <li>▪ methods of using poloxamers</li> <li>▪ use of poloxamers in combination therapy</li> </ul> </li> <li>➤ Additional applications in-process</li> </ul>
<b>Trade Secrets</b>	<ul style="list-style-type: none"> <li>➤ Macromolecules difficult to characterize ("biosimilars")</li> <li>➤ Non-patented / non-published manufacturing steps</li> <li>➤ Proprietary specifications (in-take; in-process; release)</li> <li>➤ Evaluating proprietary analytical standards / bioassays</li> </ul>



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# Financial Overview

- Cash/investments at 12/31/12: ~\$36.5 million
- 46.3 million shares outstanding
  - Warrants for 16.5 million shares (10.6 million @ \$1.10)
- Average daily volume (3 mo): ~384,000\*
- No debt
- Opportunities for U.S. government funding
- Evaluating ex-U.S. partnerships to fund U.S. development



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\*As of April 1, 2013  
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# Recent and Upcoming Events

- ✓ Initiate Phase 3 Study in SCD
- ✓ Identify development plans outside SCD
- ✓ Secure orphan designation for MST-188 for SCD in EU
- ✓ Engage ex-U.S. partnering advisor
- ✓ Initiate tQT/QTc Study
  - Submit Applications for U.S. government funding for Phase 2 Study in Major Trauma
  - Request "rare pediatric disease" designation for SCD
  - Request Orphan Drug Designation for MST-188 for ALI in U.S.
  - Initiate Nonclinical Proof-of-Concept Study in Heart Failure
  - Report Data from tQT/QTc Study
  - File New Patent Applications
  - Open ex-U.S. Clinical Sites (EPIC)
  - Initiate mBF Sub-study
  - Initiate Phase 2 Study in ALI



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# Investment Highlights

- **Balanced Pipeline**
  - Mitigates corporate-level development risk
  - Multiple partnering opportunities
- **Staged Development Strategy**
  - Initial focus on rare diseases; planned expansion into larger markets
- **Late-Stage Program in Sickle Cell Disease**
  - Only company with NME in phase 3 development
  - Increase in Big Pharma dealmaking activity
- **Non-Dilutive Financing Opportunities**
  - U.S. government funding
  - Ex-U.S. partnerships to fund U.S. development
- **Attractive Valuation**
  - Market capitalization: \$34 million\*



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\*Based on closing price of \$0.73 on 3/29/2013  
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The logo for MAST Therapeutics, Inc. features the word "MAST" in a large, bold, sans-serif font. The letter "A" is stylized, with a red triangle pointing upwards and a grey triangle pointing downwards. Below "MAST" is the text "THERAPEUTICS, INC." in a smaller, all-caps, sans-serif font.

**MAST**  
THERAPEUTICS, INC.

(NYSE MKT: MSTX)