
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):

June 5, 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 June 6, 2013, the information attached as Exhibit 99.1 to this report relating to Mast Therapeutics, Inc.(the "Company") and development of its lead product candidate, MST-188, will be presented from time to time by the Company at various 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, its Quarterly Report on Form 10-Q filed on May 15, 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.

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.

June 5, 2013

By: */s/ Brandi L. Roberts*

Name: Brandi L. Roberts
Title: Chief Financial Officer

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Mast Therapeutics, Inc. corporate overview slide deck, dated June 2013

Corporate Overview

NYSE MKT: MSTX



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 the prospectus included in our registration statement on Form S-1 (File No. 333-188870).

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 Overview

- **Developing MST-188 for “microcirculatory insufficiency”**
 - Platform technology targeting multiple indications
- **Initially focused on rare/orphan diseases**
 - Sickle Cell Disease (SCD)
 - Acute Limb Ischemia (ALI)
- **Currently enrolling subjects in a pivotal phase 3 study in SCD**
 - Most clinically-advanced new molecular entity in development for SCD
- **Planned expansion into larger markets**
 - Resuscitation Following Major Hemorrhage
 - Acute Decompensated Heart Failure
 - Transfusion (Storage Lesion)
 - Acute Ischemic Cerebrovascular Infarction (Stroke)

MST-188 Overview



API Structure:	$\text{HO} - (\text{CH}_2\text{CH}_2\text{O})_{80} - \underset{\text{CH}_3}{\text{CH}_2\text{CHO}}_{27} - (\text{CH}_2\text{CH}_2\text{O})_{80} - \text{H}$
Drug Product:	Formulated as a clear, citrate-buffered solution
CMC:	Large polymer (8,500 Daltons) manufactured by chemical synthesis and proprietary purification process
Administration:	~12-48 hour IV infusion in acute-care settings (hospital, ICU, specialized out-patient)

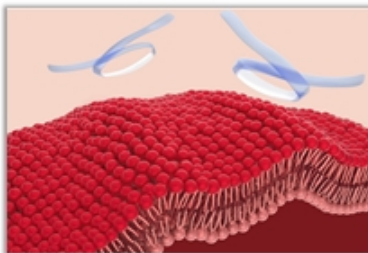


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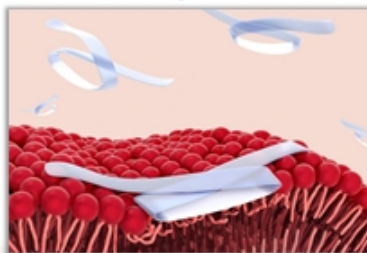
MST-188 Mechanism of Action

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

No Affinity for Healthy Cell Membranes



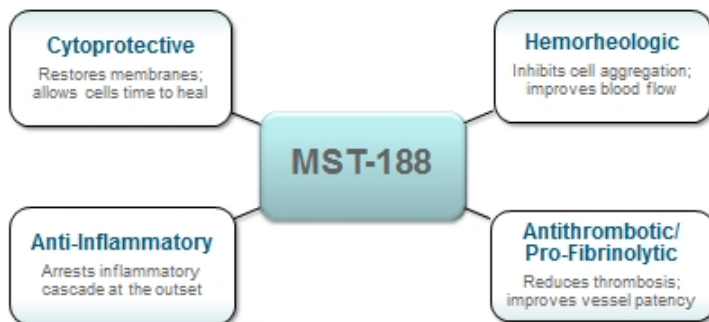
Adheres to Damaged Cell Membranes



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MST-188 Pharmacodynamics

- Single mechanism with numerous effects addresses multiple pathophysiologic processes



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The MST-188 Pipeline



	Preclinical	Phase 1	Phase 2	Phase 3
2013				
Sickle Cell Disease (orphan)	▶			
Acute Limb Ischemia (orphan)	▶			
Resuscitation of Shock following Major Trauma*	▶			
Acute Decompensated Heart Failure	▶			
Transfusion (storage lesion)	▶			

* Contingent on U.S. government funding/other collaborator

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Sickle Cell Disease (vaso-occlusive crisis)



Sickle Cell Disease Overview



- **An inherited genetic disorder and orphan disease**
 - 90,000 to 100,000 people with SCD in the U.S.†
 - Characterized by severe deformation (i.e., "sickling") of red blood cells
 - Sickled cells cannot navigate the microcirculation
- **Presents as recurring episodes of extreme pain ("crisis")**
 - Episodes 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 death: ~40 years old
 - Standard of care; hydration and pain meds
 - ~100,000 hospitalizations/year for crisis
 - No approved agents to shorten duration or severity of crisis
- **Substantial recent interest from Big Pharma**
 - Pfizer: \$395 million* for phase 2 investigational drug (Oct 2011)
 - Novartis: \$650 million* for phase 2 investigational drug (Sep 2012)

† Source: Centers for Disease Control and Prevention
* Reported deal value

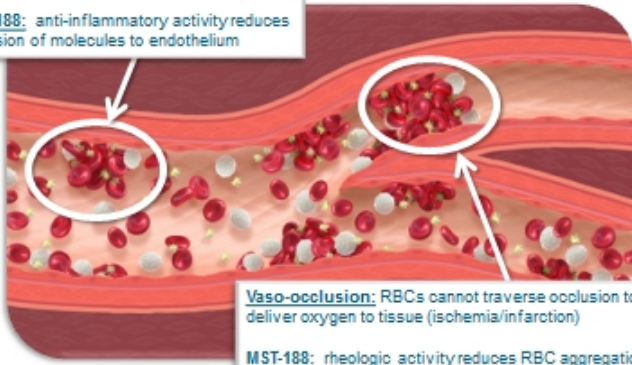
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Pathophysiology of SCD: Impaired Blood Flow

Early stages: adhesion of circulating blood products to endothelial cells

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

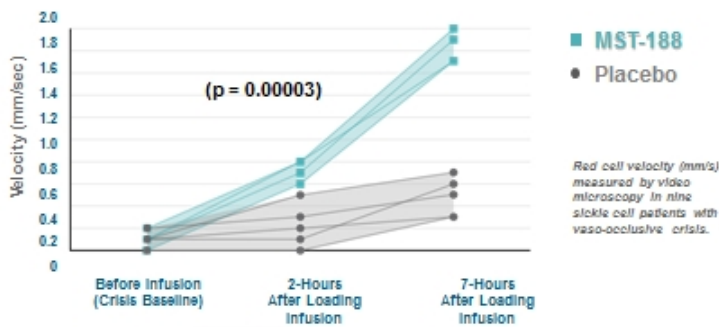


Vaso-occlusion: RBCs cannot traverse occlusion to deliver oxygen to tissue (ischemia/infarction)

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

MST-188 Improves Blood Flow

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



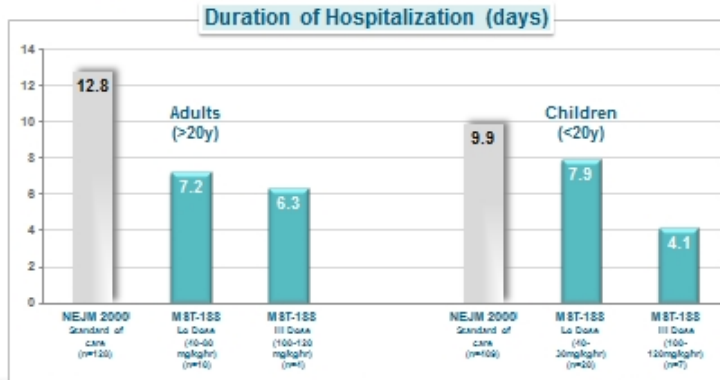
Completed Phase 2 Study in SCD

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

	Subjects who received ≥ 24 h infusion (n=45)		
	MST-188*	Placebo	Improvement
Duration of Crisis	60 hours	88 hours	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

Additional Clinical Data in SCD – Acute Chest Syndrome

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



Completed Phase 3 Study in SCD (Primary and post-hoc analyses)

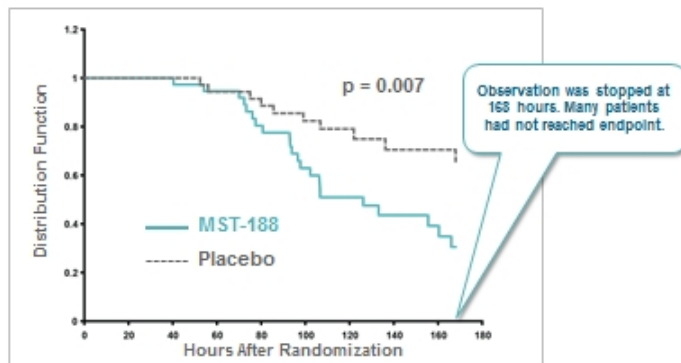
- Improvement in duration of crisis in SCD patients following treatment with MST-188

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 design required 350 patients.
 Reduced by almost 30% by prior sponsor (capital constraints).

Completed Phase 3 Study in SCD (Post-hoc analysis)

- Proportion of patients <16 years remaining in crisis over time (n=73)



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

Responder's analysis reached statistical significance for both adults and peds



Source: JAMA, November 17, 2011 – Vol 306, No. 22

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Lessons Learned

- Prior Phase 3 was the first large interventional study in SCD
- 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



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Pivotal Phase 3 Trial (EPIC)

Evaluation of Purified 188 in Children

- **Study design**
 - Randomized, two-arm, double-blind, placebo-controlled
 - 388 patients ages 8-17 from ~40 centers in the U.S. and ~30 centers outside the U.S.
 - 90% power to show 16h benefit versus standard of care
- **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
- **First Active Site: March 2013**
- **Expected enrollment completion and data read-out: 2015**



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MST-188 Phase 3 Trial Comparisons



	1248 (Prior Study)	EPIC (Ongoing)
Primary Endpoint	Duration of crisis	Duration of crisis
Assessment tool	Pain score plus	Last dose parenteral opioid
Secondary endpoint	Total analgesic use; Length of hospitalization	14-day rehospitalization rate; Acute chest syndromes
No. Patients	350 (255 actual)	388
Patient age	8-65	8-17
No. Centers	40 US	40 US + 30 ex-US
Power (alpha)	80% (0.05)	90% (0.05)



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Potential Competition in SCD



Drug	Sponsor	Challenges
GMI-1070 (Phase 2)	Glycomimetics (Pfizer)	<ul style="list-style-type: none"> Only blocks selectins; other adhesion molecules not affected Subjectivity of pain scores Variability inherent in hospital discharge as endpoint
Sel-G1 (Phase 1)	Selexys (Novartis)	<ul style="list-style-type: none"> MOA targets only 1 aspect of multi-factorial SCD pathophysiology; blocks P-selectin, one of many CAMs Early stage, no efficacy data (phase 1 was in healthy subjects)
Prasugrel (Phase 3)	Lilly (Daiichi)	<ul style="list-style-type: none"> MOA targets only 1 aspect of multi-factorial SCD pathophysiology Modest benefit (trend) observed in phase 2, and only in secondary endpoints, not in primary endpoint Risk of hemorrhage
LentiGlobin® (Phase 1/2)	bluebird bio	<ul style="list-style-type: none"> Early stage (phase 1/2 in beta-thalassemia to start July 2013) Regulation of expression control and insertion location Historical challenges related to gene therapy



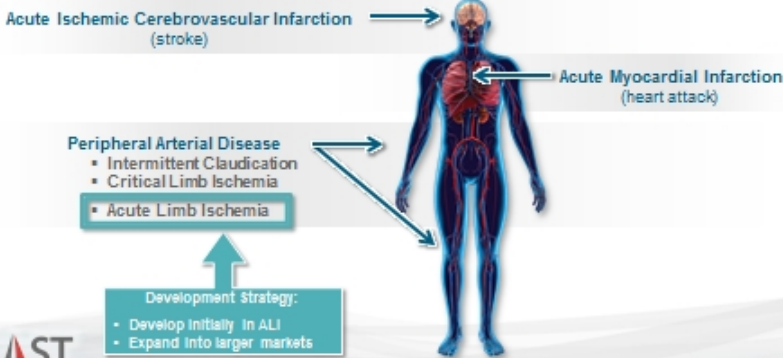
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Acute Limb Ischemia



Arterial Disease

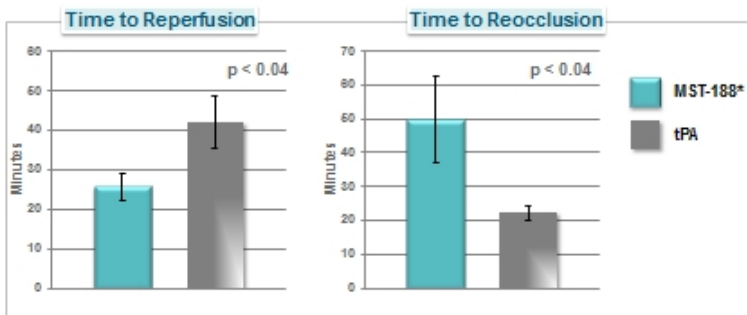
- A progressive circulatory problem in which obstructed arteries reduce blood flow to tissue
 - Thrombolytic agents (tPA) used to treat acute complications
 - Significant morbidity and mortality



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MST-188 Improved tPA Effectiveness

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



Source: Data on file
* 1st generation (non-purified) formulation

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Planned Phase 2 Study

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

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MST-188 Exclusivity



Multiple Barriers to Entry

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



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Financial Overview



- Cash/investments at 3/31/13: ~\$32.0 million
- Market capitalization: ~\$33 million*
- 46.3 million shares outstanding
 - Warrants for 16.5 million shares (10.6m @ \$1.10; 5.9m @ \$3.04*)
- Average daily volume (3 mo): ~215,500*
- No debt
- Opportunities for U.S. government funding
- Evaluating ex-U.S. partnerships to fund U.S. development

* Weighted average exercise price
* As of May 31, 2013



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2013 Activities



Event	Timing
Initiate tQT/QTc Study	Completed
Secure Orphan Designation for MST-188 for SCD in EU	Completed
Activate First Site in Phase 3 Study	Completed
File New Patent Applications	Completed
Request "Rare Pediatric Disease" Designation for SCD	Completed
Dose First Subject in Phase 3 Study	Completed
Report data from tQT/QTc Study	Q3
Submit Applications for U.S. Government Funding for Phase 2 Study in Resuscitation of Shock following Major Trauma	Q3
Request Orphan Designation for MST-188 for ALI in U.S.	Q3
Initiate Nonclinical Proof-of-Concept Study in Heart Failure	Q3
Open First Ex-U.S. Clinical Site in Phase 3 Study	Q4
Initiate mBF Sub-Study	Q4
Initiate Phase 2 Study in ALI	Q4 '13/Q1 '14



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Management and Board



Management Team

- Brian Culley, M.A., M.B.A. - Chief Executive Officer
- Patrick L. Keran, J.D. - President and Chief Operating Officer
- Santosh Vetticaden, M.D., Ph.D. - Chief Medical Officer
- Brandi Roberts, CPA, M.B.A. - Chief Financial Officer
- R. Martin Emanuele, Ph.D., M.B.A. - Senior VP, Development
- Gregory D. Gorgas, M.B.A. - Senior VP, Commercialization

Board of Directors & Affiliations

- Jack Lief - Chairman - Arena, Cephalon, Abbott
- Ted Love - Director - Onyx, Nuvelo, Theravance, Genentech
- David Ramsay - Director - Halozyme, Lathian, Valeant
- Lewis Shuster - Director - Kemia, Life Technologies, Pharmacopeia
- Brian Culley - CEO & Director - iTherx, Neurocrine, UC San Diego



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Investment Summary



- **Balanced Platform Pipeline**
 - Mitigates corporate-level development risk
 - Multiple partnering opportunities
- **Multi-Stage Development Strategy**
 - Initial focus on rare diseases; expand into larger markets
- **Late-Stage Program in Sickle Cell Disease**
 - Only company with new drug in phase 3 development
 - Increasing trend for Big Pharma deal-making
- **Non-Dilutive Financing Opportunities**
 - U.S. government funding
 - Ex-U.S. partnerships to fund U.S. development
- **Attractive Valuation**
 - Market capitalization: ~\$33 million*



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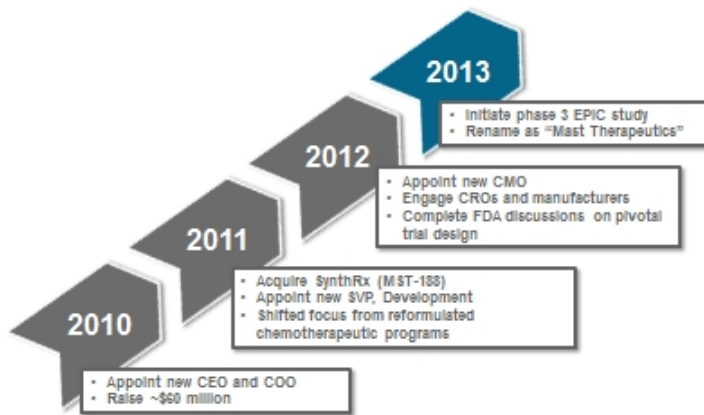
* Based on closing price of \$0.71 on May 31, 2015

Additional Slides



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Corporate Evolution



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Phase 3 CRO/CMOs



- **Theradex**
 - 30 year collaboration with National Cancer Institute
 - Experience with pediatric trials, minority populations, and sickle cell disease trials, including phase 3
- **Pierre-Fabre Medicament**
 - Manufacturing active ingredient in MST-188
 - Second largest independent pharmaceutical group in France
 - Supercritical Fluids Division has expertise and specialized facilities for purification of products via supercritical extraction
- **Patheon**
 - Formulation, fill and finish of MST-188
 - A leading global provider of manufacturing services



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MST-188 Safety Data



- **MST-188: generally well-tolerated**
 - Transient elevations in liver function tests, return to baseline during follow-up
- **Evaluated in 6 clinical studies***
 - 255-subject phase 3 randomized, controlled study in sickle cell disease
 - ~250 subjects* exposed to active drug
- **Thorough QT/QTc Study**
 - Standard design to assess cardiac repolarization (QT interval)
 - Initiated: Jan 2013

* Numbers include only subjects exposed to 2nd generation (purified) formulation. Over 2,250 additional subjects exposed to 1st generation (non-purified) formulation.



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Thorough QT/QTc Clinical Study

- Four-period, four-way cross-over, placebo- and positive-controlled, double-blind randomized trial in 60 healthy volunteers
- Subjects receive each of four treatments:
 - Placebo (saline)
 - Positive control
 - MST-188 therapeutic dose
 - MST-188 supra-therapeutic dose
- Primary objective: evaluate the effect of MST-188 on cardiac ventricular repolarization (specifically the QT interval)



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VOC Market Summary

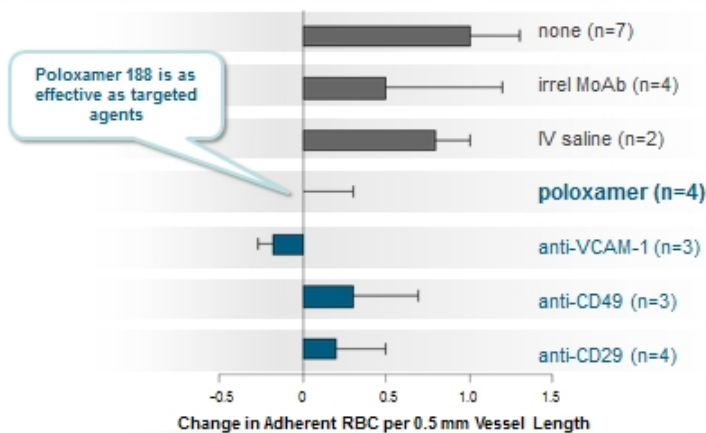
Preclinical	Phase I	Phase II	Phase III	Marketed
SHAPE platform	Aes-103	Vorinostat	MST-188	Hydroxyurea
Enxoy	MP4CO	Decitabine	L-glutamine	
Sanguinate	Gene Therapy	HQK 1001	Prasugrel	
CLT 001	Pomalidomide	GMI-1070		
Gene Therapy	Panobinostat	Regadenoson		
Zinc Finger	3aIG1	Eptifibatid		
ACP-501		LMVVH		
Piper Genus Botanical Extract		Antioxidant Therapy		
		Immune Globulin		
		Magnesium sulfate		

Intervention	◆ Physiological enhancer
	◆ Anti-inflammatory
Prevention	◆ Anticoagulant
	◆ Oxygenator
Prevention	◆ Dietary supplement
	◆ HbF stimulant
	◆ Gene correction (curative)
	◆ Other/TBA



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Effect of IV blocking agents on RBC adhesion following topical LPS



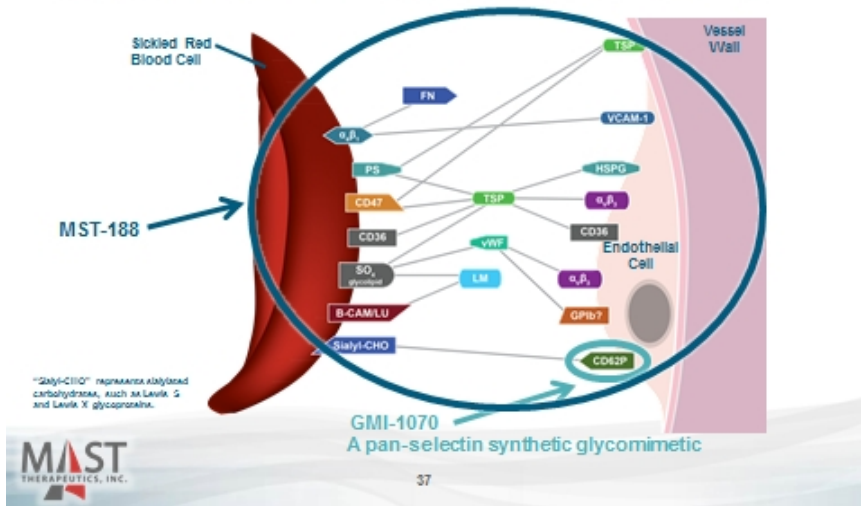
Source: Microcirculatory Effects Of Blocking Cell Adhesion Molecules In Transgenic Sickle Cell Mice, Dr. L.L. Hsu



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MST-188 vs. GMI-1070 (Glycomimetics)

- Sickle cell adhesion to endothelium: MST-188 vs. GMI-1070



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)

Resuscitation (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
Shock (2009)	MST-188 + Hextend	Hextend	p Value
Survival time from onset of hemorrhage (min) (n=10/arm)	589±99	289±37	0.002

Source: Resuscitation 82(2011) 1462-1468, SHOCK, Vol 32, No. 4, pp. 442-450, 2009
*Some studies evaluated 1st generation (non-purified) formulation

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Resuscitation of Shock following Major Trauma Planned Phase 2 Study & Funding

- Generate Clinical Proof-of-Concept Data
- Study Protocol (complete)
 - Design: dose-ranging, 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
 - 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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Contact Info:

Brian M. Culley
Chief Executive Officer
culley@mastthera.com

Brandi Roberts
Chief Financial Officer
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Ph: (858)-768-6325