
**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): September 3, 2015

Mast Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-32157

(Commission File Number)

84-1318182
(IRS Employer
Identification No.)

**3611 Valley Centre Drive, Suite 500,
San Diego, CA**
(Address of Principal Executive Offices)

92130
(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 (see General Instructions A.2. below):

- 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))
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Item 7.01 Regulation FD Disclosure.

The information attached as Exhibit 99.1 to this report relating to Mast Therapeutics, Inc. (the “Company”) and its development programs may be presented from time to time by the Company at various investor and analyst meetings, including on September 3, 2015 at the 4th Annual Sickle Cell Disease Therapeutics Conference.

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 immediately following the signature page of this report.

In accordance with General Instruction B.2. of Form 8-K, the information in Item 7.01 of this report and Exhibit 99.1 hereto 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 liability of that section, nor shall it be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

By filing this report, 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 24, 2015, Quarterly Report on Form 10-Q filed on August 12, 2015, 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, regulatory and commercialization strategies and plans for its investigational drug drugs, vepoloxamer (also known as MST-188) and AIR001, as well as the timing of activities and events related to those plans, including commencement and completion of clinical and nonclinical studies, and prospects for clinical, regulatory and commercial success. 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 uncertainty of outcomes in ongoing and future studies of its product candidates and the risk that its product candidates may not demonstrate adequate safety, efficacy or tolerability in one or more such studies, including vepoloxamer in the ongoing EPIC study; delays in the commencement or completion of clinical studies, including the EPIC study, the planned Phase 2 study of vepoloxamer in heart failure, and the ongoing Phase 2a studies of AIR001, 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, completing manufacturing process development activities, 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 for institutional review boards or the FDA or other regulatory agencies to require additional clinical or nonclinical studies prior to initiation of a planned clinical study; the risk that, even if clinical studies are successful, the FDA or another regulatory agency may determine they are not sufficient to support a new drug application; 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 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 its product candidates, including clinical studies, manufacturing, and regulatory activities for its product candidates and that such third parties may fail to perform as expected; the Company’s ability to obtain, as needed, 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 its product candidates 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 the FDA and regulatory agencies outside of the U.S. do not grant marketing approval of a product candidate, on a timely basis, or at all; 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 adequately protect its intellectual property rights and prevent competitors from duplicating or developing equivalent versions of its product candidates or

that the use or manufacture of its products or product candidates infringe the proprietary rights of others; 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 they are made. Mast Therapeutics does not intend to revise or update any forward-looking statement set forth in this report 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 Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended.

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.

Date: September 3, 2015

By: /s/ Brandi L. Roberts

Brandi L. Roberts

Chief Financial Officer and Senior Vice President

Exhibit Index

Exhibit Number	Description
99.1	Mast Therapeutics, Inc. corporate presentation, September 3, 2015



4th Annual SCD Therapeutics Conference

September 3, 2015

Forward-Looking Statements

This presentation includes forward-looking statements about our business prospects, financial position, and development of vepoloxamer and AIR001 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 our product candidates; and other risks and uncertainties more fully described in our press releases and our filings with the SEC, including our quarterly report on Form 10-Q filed with the SEC on August 12, 2015.

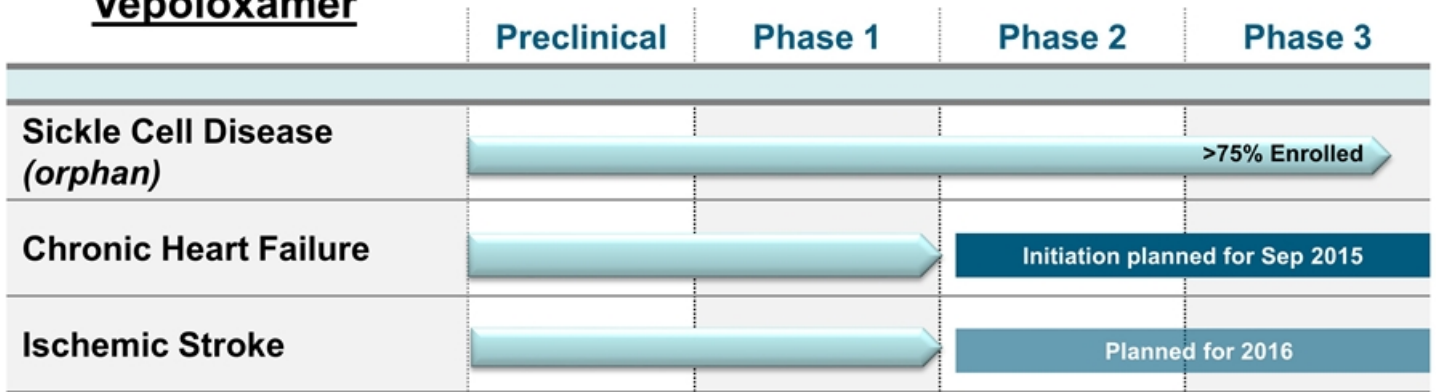
We caution you not to place undue reliance on any of these forward-looking statements, which speak only as of the date of this presentation. We do not intend to update any forward-looking statement included in this presentation to reflect events or circumstances arising after the date of the presentation,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



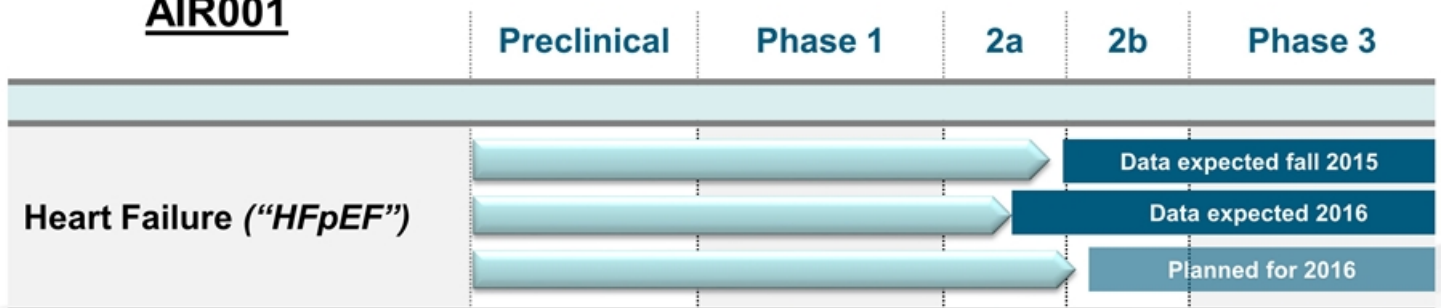
NYSE MKT: **MSTX**

Product Pipeline

Vepoloxamer



AIR001



NYSE MKT: **MSTX**

Vepoloxamer: A Biophysical Agent

Poiseuille's Law describes Newtonian flow

$$V = \frac{\pi}{8} \times \frac{1}{l} \times \frac{1}{\eta} \times \Delta P \times r^4$$

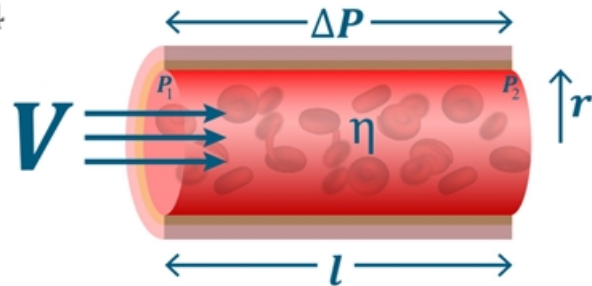
with V = flow (volume/time)

l = length of the capillary

η = viscosity of the media

ΔP = pressure drop over the length

r = radius of the capillary



➤ **Want lower viscosity?**

- Reduce friction by lowering adhesion and improving the deformability of cells

➤ **How?**

- Reduce surface tension with *vepoloxamer*

Vepoloxamer: A Biophysical Agent

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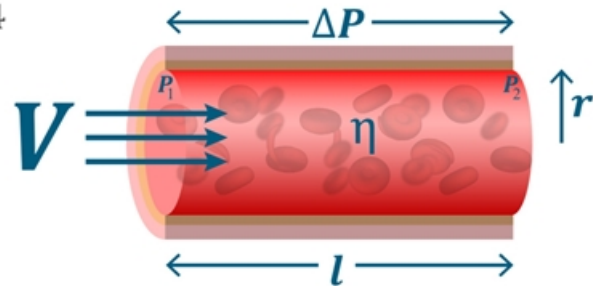
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Vepoloxamer Overview

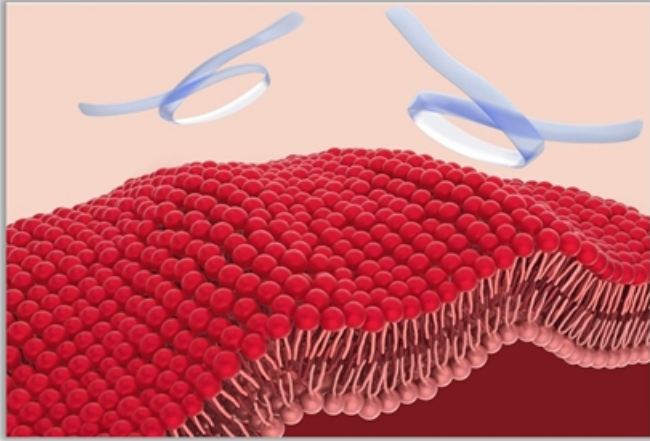


API Structure:	$\text{HO} - (\text{CH}_2\text{CH}_2\text{O})_{79} - (\text{CH}_2\text{CHO})_{30} - (\text{CH}_2\text{CH}_2\text{O})_{79} - \text{H}$ $\quad \quad \quad $ $\quad \quad \quad \text{CH}_3$
CMC:	<ul style="list-style-type: none">• Large, synthesized polymer with extraction process to remove undesirable (toxic) components• Composition of matter claims pending
Administration:	<ul style="list-style-type: none">• IV infusion
ADME:	<ul style="list-style-type: none">• Rapidly and predominantly cleared by kidneys (4-8h)• Ether linkages cannot be cleaved; no drug metabolites

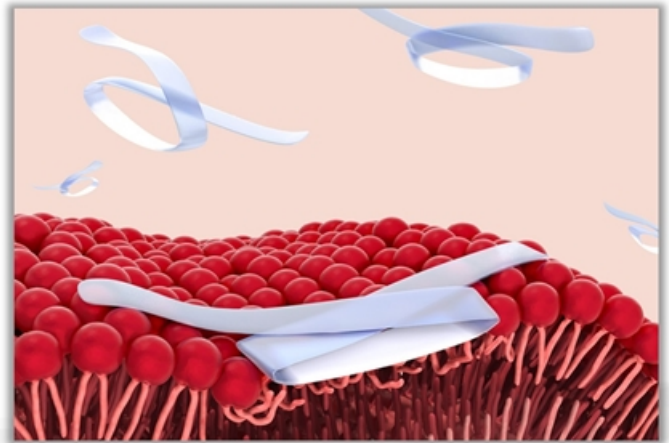
Vepoloxamer Mechanism of Action

Core of molecule adheres to hydrophobic domains on a cell surface, such as damaged membranes and adhesive proteins.

No Affinity for Healthy Cell Membranes...



But Adheres to Damaged Cell Membranes



Vepoloxamer Pharmacodynamics

Vepoloxamer adheres to hydrophobic domains on cells and lowers surface tensions



Viscosity is reduced
Lowers adhesion
Improves flow



Sickle Cell Disease:
Less occlusion,
reduced hemolysis

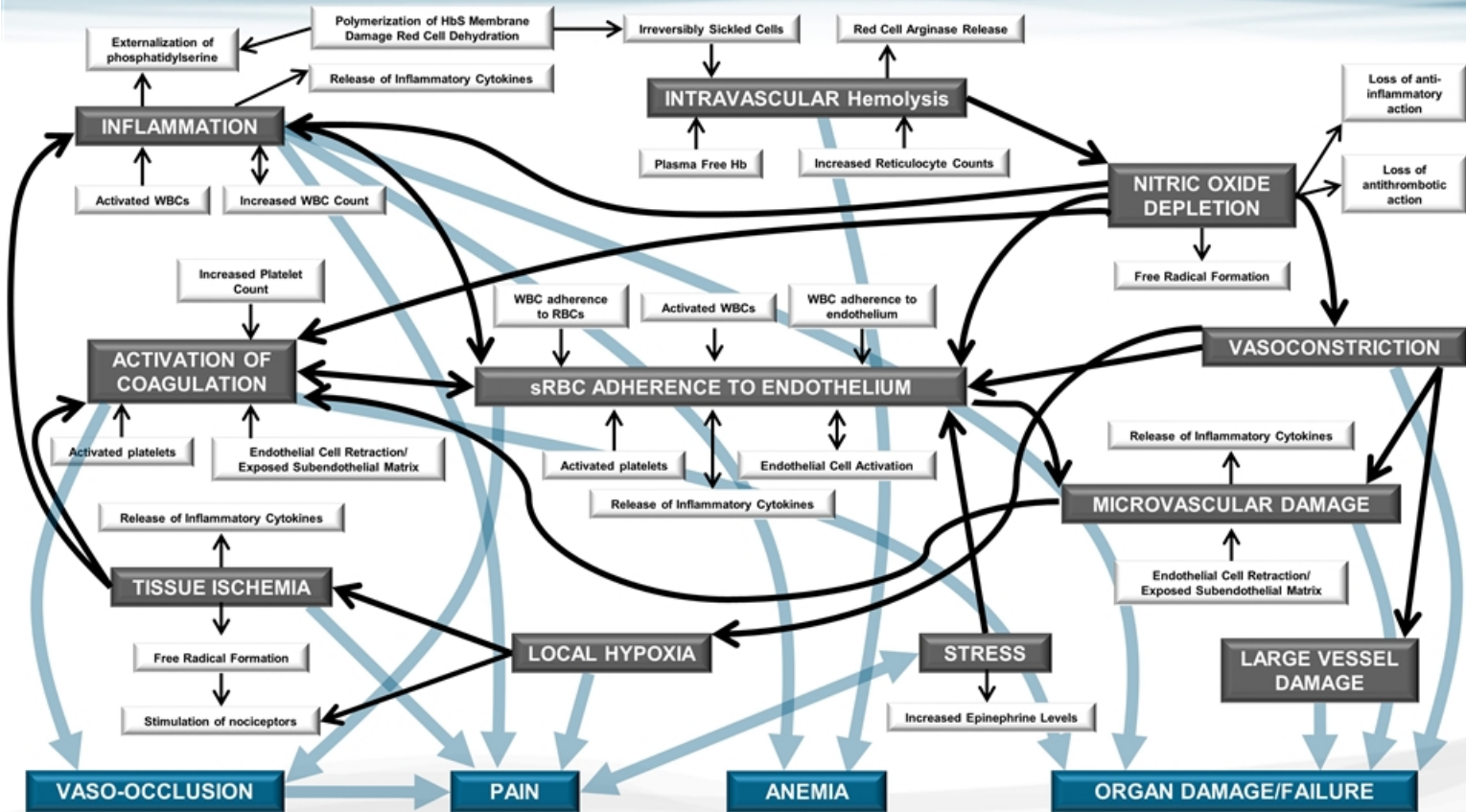


Membranes are sealed
Cell integrity maintained
Ca²⁺ influx reduced



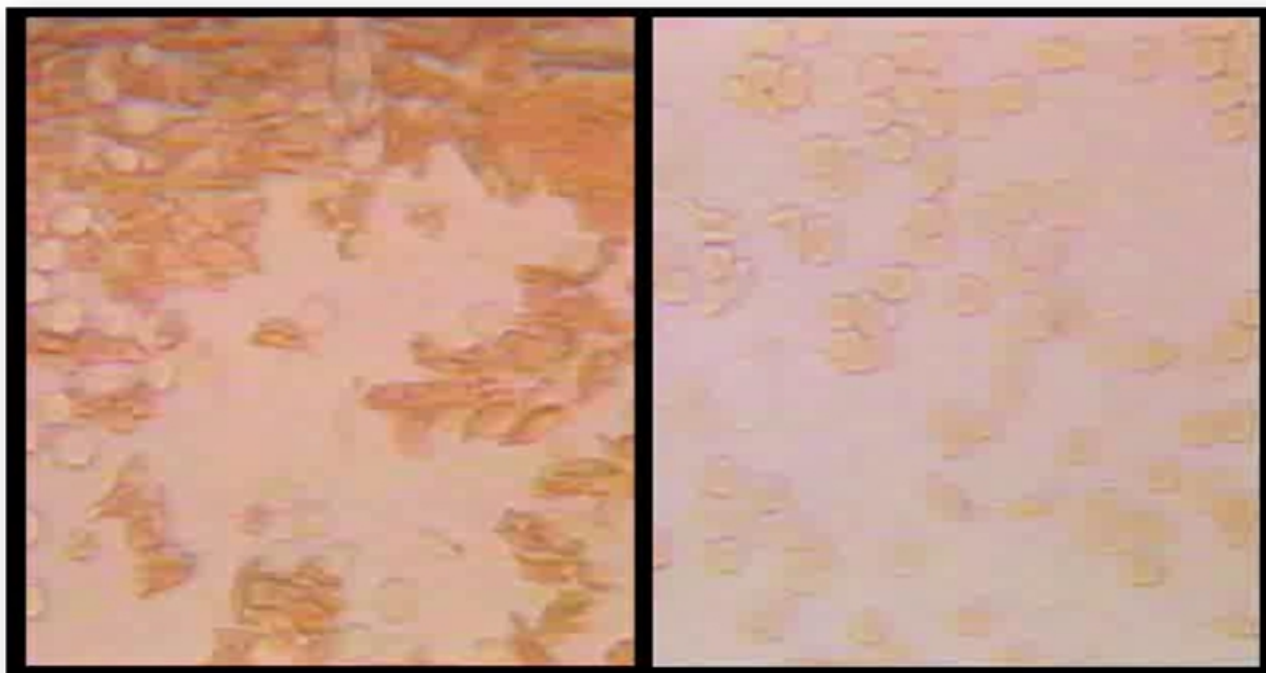
Heart Failure:
Membranes repair,
cells survive

SCD Pathophysiology (multiple points of intervention)



Vepoloxamer Effect on Sickle Cells

Lower surface tension improves flow and deformability (video)



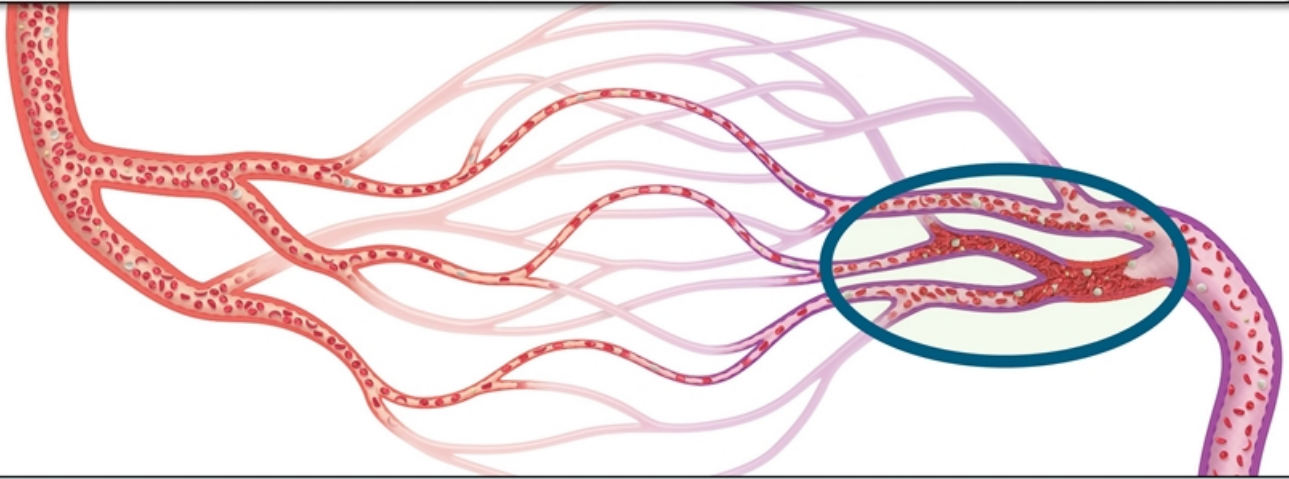
Before vepoloxamer

After vepoloxamer

Role of Vepoloxamer in Sickle Cell Disease

Vaso-Occlusive Crisis:

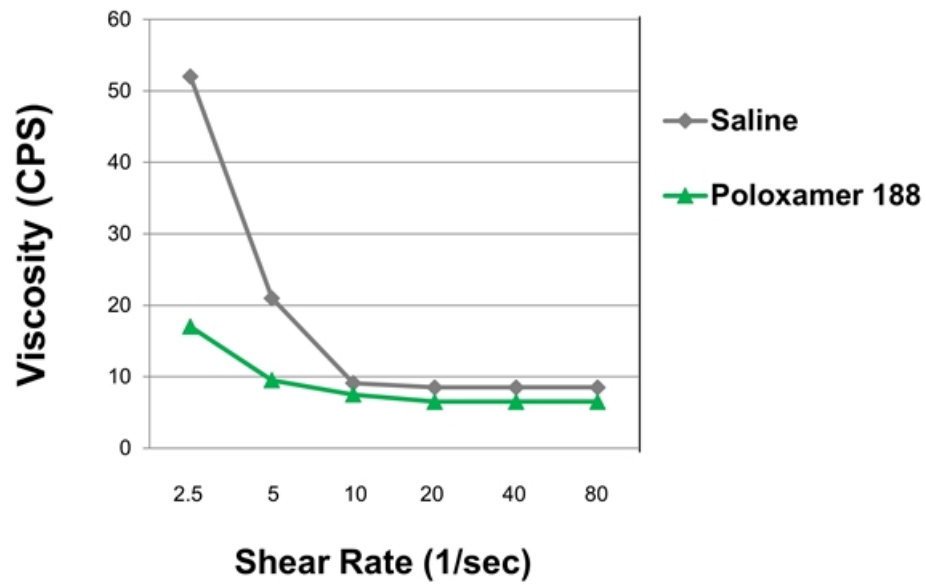
- Adhesion of poorly-deformable, “sticky” cells to endothelium and to each other leads to vessel obstruction
- Occluded RBC's cannot deliver oxygen, leading to ischemia, pain, organ damage



Vepoloxamer:

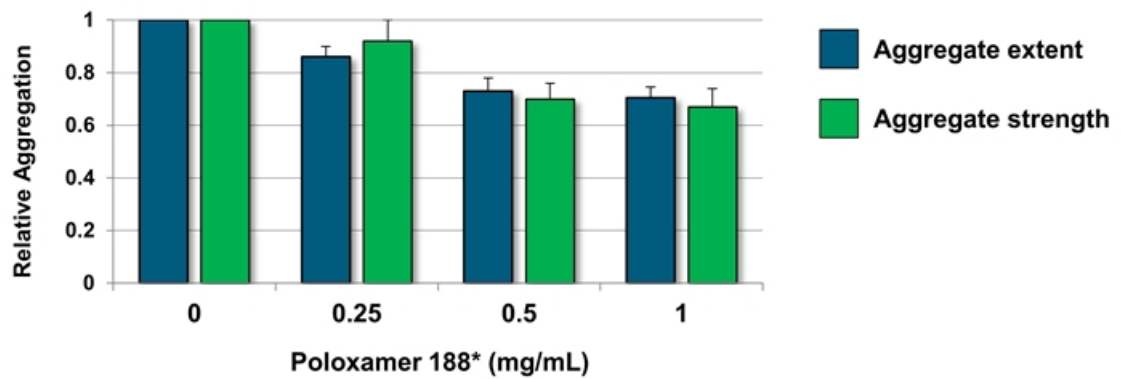
- Lowers viscosity, reduces adhesion of cells to endothelium, lowers RBC aggregation, improves RBC deformability and restores blood flow

Vepoloxamer Lowers Pathologic Blood Viscosity Under Low Shear Rates



Vepoloxamer Reduces RBC Aggregation (sickle cell patients)

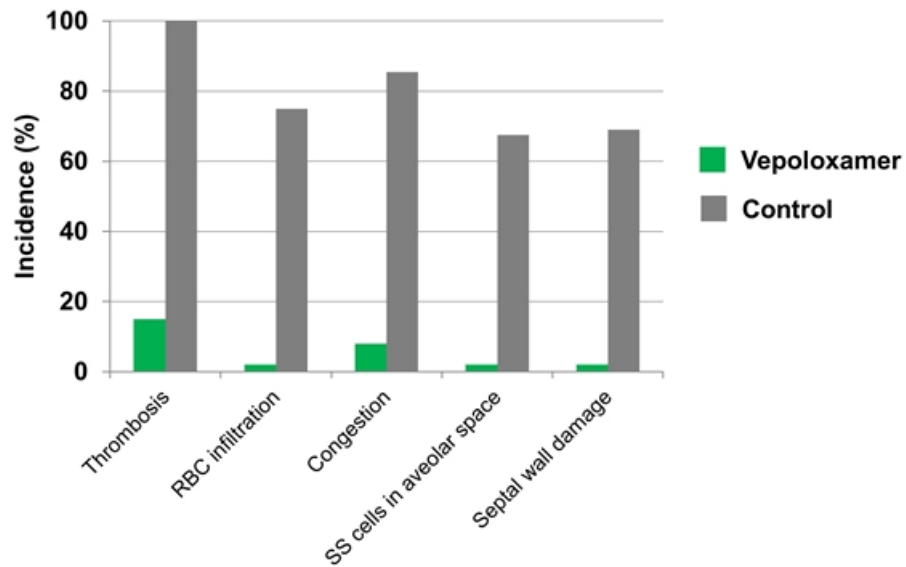
RBCs represent 99.9% of the volume of blood cells



- The effect of poloxamer 188 on sickle cell RBC aggregation determined by a Myrenne aggregometer
- Results represent the mean from 11 patients relative to PBS controls (Meiselman, et al.)

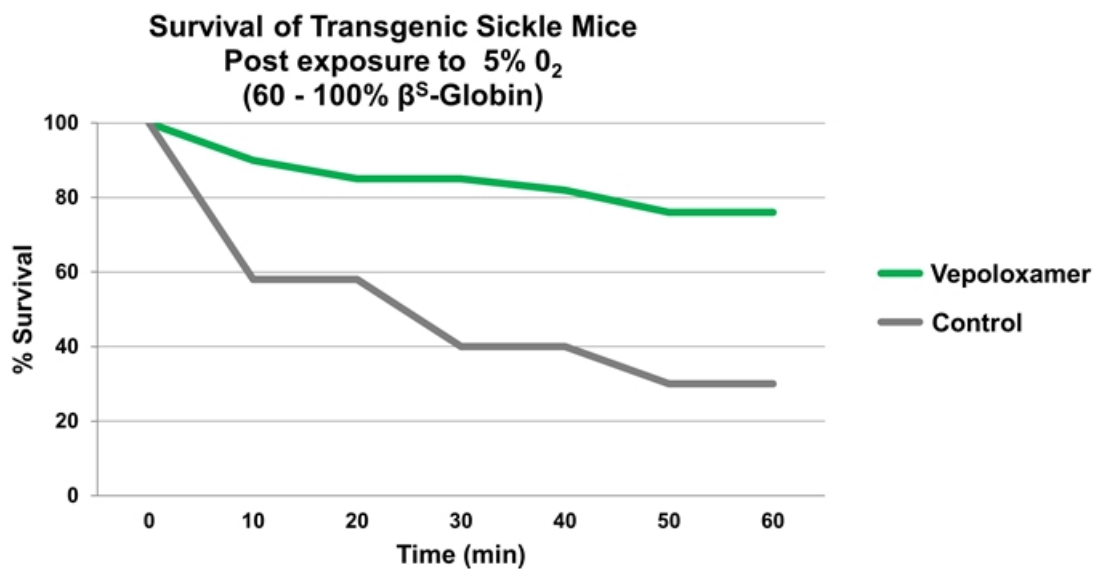
Vepoloxamer Reduced Organ Pathology in Transgenic Sickle Mice

Lung Pathology



Lung pathology was compared in transgenic mice pretreated with either vepoloxamer (400 mg/kg) or saline and subject to hypoxia (5% O₂). (Asakura, et al.)

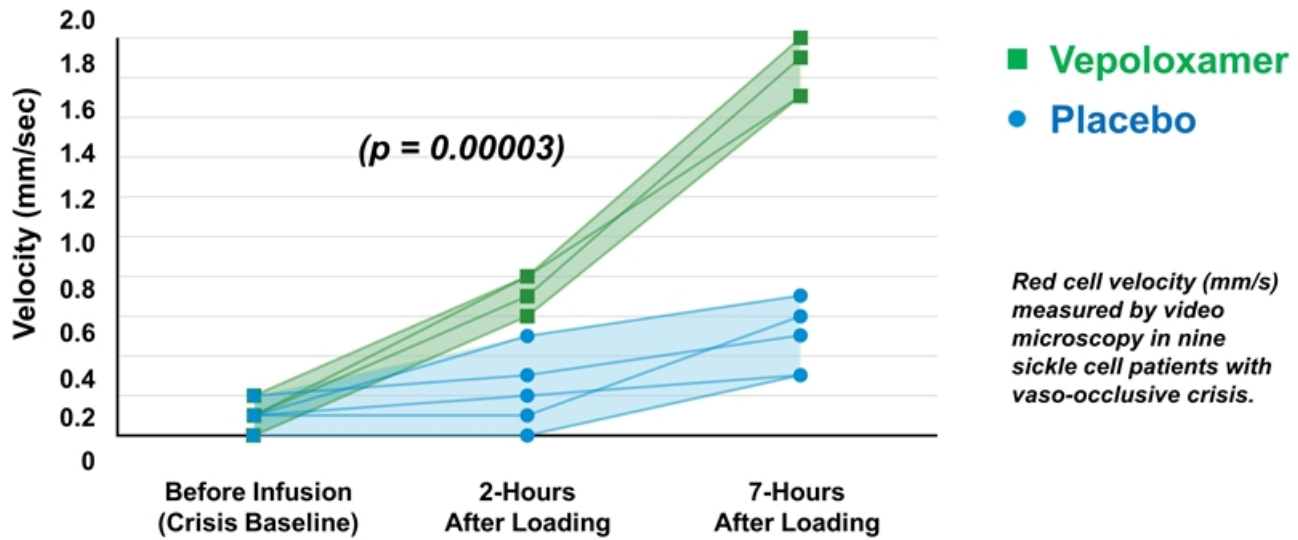
Vepoloxamer Increased Survival in Transgenic Sickle Mice



Transgenic mice pretreated with either vepoloxamer (400 mg/kg) or saline, subject to hypoxia (5% O₂), and monitored for survival. (Asakura, et al.)

Veploxamer Improves Blood Flow

Veploxamer improved microvascular blood flow in SCD patients during vaso-occlusive crisis



Phase 2 Study

Randomized, double-blind, placebo-controlled, multi-center study in SCD patients hospitalized for vaso-occlusive crisis

	Subjects Who Received Full Dose [±]		
	Poloxamer 188* (n=18)	Placebo (n=13)	p value ^{±±}
Duration of Crisis	44 hours	80 hours	0.025
Duration of Hospitalization	5 days	7 days	0.111
Total Analgesic Use	34mg	145mg	0.045
Parenteral Analgesic Use	27mg	133mg	0.022

[±] Excludes patients who had drug administration errors or incomplete pain assessments (16), who withdrew consent (2) and who withdrew because of injection site pain after 15 minutes of infusion. Subjects were excluded equally (n=9) between poloxamer 188 and placebo.

^{±±} Proportional hazards model adjusted for baseline pain.

* Vepoloxamer is purified poloxamer 188

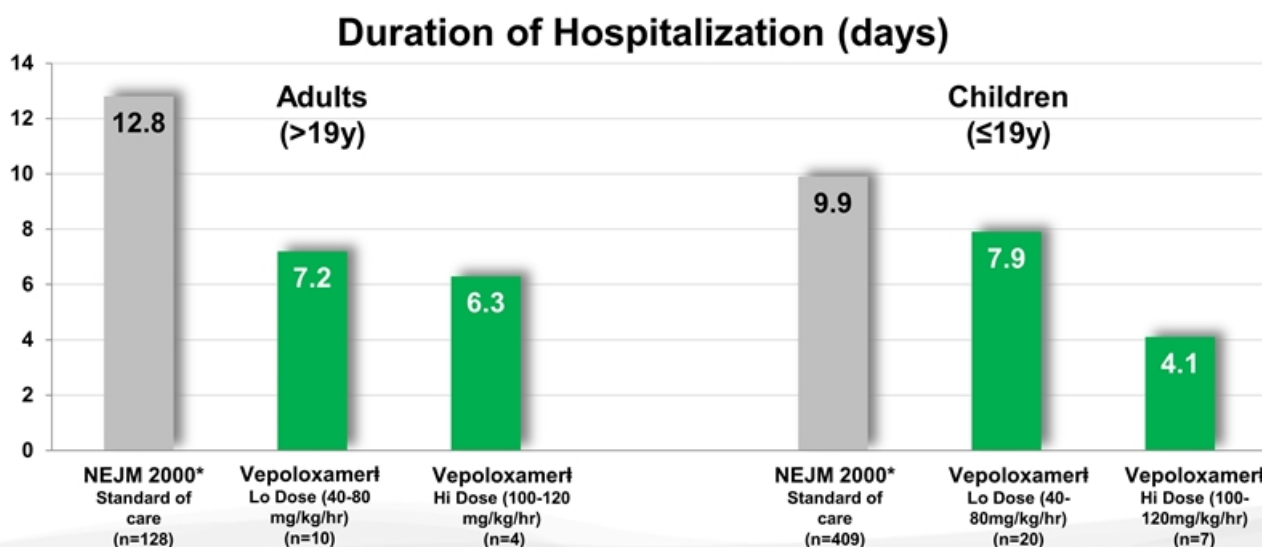
Source: Blood, September 1, 1997 – Vol 90, No. 5



NYSE MKT: **MSTX**

Acute Chest Syndrome Clinical Study

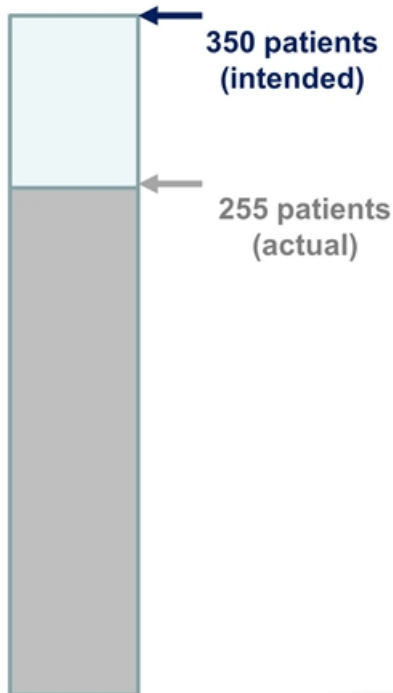
- **Acute Chest Syndrome (ACS)**
 - Serious complication of SCD that results in prolonged hospitalizations
 - A leading cause of death in SCD patients
- **Vepoloxamer reduced duration of hospitalization in SCD patients with ACS compared to standard of care**



*Source: NEJM, June 22, 2000, Vol 342, No 25
† Data on file

Prior Sponsor's Phase 3 Study

ENROLLMENT



➤ **Flawed endpoint selection and premature termination led to loss of power**

➤ **Proportional analysis positive:**

- **All ages: 52% vs. 37% (n=249, p=0.02)**
- **Under 16y*: 60% vs. 28% (n=73, p=0.009)**

➤ **Lessons learned for Mast's Phase 3 study:**

1. **Vepoloxamer has activity in SCD**
2. **Incorporate FDA, physician, and patient input**
3. **Pain scores confounded by analgesia use**
4. **Use a clinically-relevant, objective endpoint**
5. **Anticipate and address data loss**



*Average age of patients in Mast's Phase 3 trial (EPIC) as of August 2015: ~15 years

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

NYSE MKT: **MSTX**



Current Phase 3 Study “EPIC” (Mast study)

- **Largest Interventional SCD Trial Ever Conducted**
 - 388 patients, randomized 1:1 (standard of care +/- vepoloxamer)
 - Double-blind, placebo-controlled, international (2/3rd U.S. sites)

- **Primary Endpoint: Duration of crisis**
 - Assessed from randomization to last dose of parenteral opioid
 - Clinically relevant (no IV meds = readiness for discharge)
 - Sensitive data collection (patient-controlled analgesia device)
 - Reduction in data loss (PCA device)

- **Secondary Endpoints and Other Assessments:**
 - Re-hospitalization for crisis within 14 days
 - Occurrence of acute chest syndrome
 - Duration of hospitalization
 - Tissue oxygenation
 - Biomarkers

- **Power Calculations**
 - 90% power to detect a 16-hour difference (17% benefit, $p=0.05$, CV >50%)



NYSE MKT: **MSTX**

- **Enrollment on-track**
 - Enrollment >75% complete
 - Top-line data anticipated Q1 2016

- **Most Advanced New Drug in SCD**
 - Potential to be 1st drug ever approved to treat on-going vaso-occlusive crisis
 - Substantial head start versus other drugs in development

- **Considerations for Regulatory Decision-Making**
 - Significant unmet need – standard of care unchanged for years
 - Increased reliance on disease experts in rare diseases
 - Support among medical / advocacy communities
 - Fast Track designation
 - Orphan Drug designation
 - Healthcare disparity concerns
 - Supportive clinical studies: Thorough QT, repeat-admin, special populations

SCD Market Opportunity

United States

- Approximately 100,000 hospitalizations annually
- ~50% of events occur in just 16 metropolitan areas
- Effective coverage with small, targeted field force



Europe

- Approximately 40,000 patients
- ~50% of patients reside in 2 cities:
 - Paris and London

Vepoloxamer Market Opportunity

Approximately 100,000 Hospitalizations Annually for Crisis (U.S.)

Bone Marrow
Transplant (1%)



Gene Therapy
(<25%*)



Crisis Intervention
(100%)



Addressable market for vepoloxamer is substantially larger than for current gene corrective approaches (e.g. not limited to just “severe” patients)

Vepoloxamer Positioned for Success in SCD

- **Novel Therapy for Rare Disease with High Unmet Need**
 - Unique mechanism
 - Orphan Drug Designation (U.S. and EU)
 - New composition of matter patent application pending
 - No approved therapies available for crisis intervention
- **First-To-Market Advantage**
 - Clinical development >2 years ahead of nearest competitor
- **Concentrated, In-Patient Setting**
 - 50% of U.S. patients live in just 16 metropolitan areas
 - 80% public payer (NTAP, DRG, DSH considerations)
- **Pharmacy Director Support**
 - Based on qualitative market research, perceived as a 4.4 out of 5; e.g. a “breakthrough medical innovation”

Mast Therapeutics Summary

➤ An Emerging Cardiovascular Company

- **Sickle Cell Disease**
 - Most clinically-advanced new drug in development
- **Heart Failure**
 - Two distinct programs with novel mechanisms
- **Stroke**
 - Encouraging nonclinical data, phase 2 planned for 2016

➤ Mast Therapeutics is committed to:

- **Bringing the first new SCD therapy to market in over 17 years, and**
- **Showing the clinical benefit of improving blood flow and sealing cell membranes in dysfunctional circulatory conditions.**



NYSE MKT: **MSTX**

MSTX Financial Overview

- **Cash/investments at 6/30/15: \$43.4 million**
- **Market capitalization: ~\$72 million***
- **Shares outstanding: 164 million***
- **Average daily volume (3 mo): ~700,000***



* As of August 26, 2015

NYSE MKT: **MSTX**

