### 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): January 11, 2016

#### 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)

П

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 250.425)

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 8.01 Other Events

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.

#### Item 9.01 Financial Statements and Exhibits

(d) Exhibite

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.

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 November 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

The Company 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 include, but are not limited to, statements regarding the Company's development, regulatory and commercialization strategies and plans for its investigational drugs, vepoloxamer (also known as MST-188) and AIRO01, as well as the timing of activities and events related to those groups are lated to those groups and formation of study results, submission of applications to regulatory authorities for marketing approval, and product launch, 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 the EPIC study, the Phase 2 study of vepoloxamer in heart failure, and the ongoing Phase 2a studies of AIRO01, 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 materials, completing manufacturing process development activities, being subject to a "clinical hold," and/or suspension or termination of a clinical studies are successful, successful; the FDA or another regulatory agency may determine they are not sufficient to support a new drug application; the potential for institutional review boards or the FDA or other regulatory agencies to require additional clinical studies prior to initiation of a planned clinical

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: January 11, 2016

By: /s/ Brandi L. Roberts
Brandi L. Roberts
Chief Financial Officer and Senior Vice President

Exhibit Number

99.1 Mast Therapeutics, Inc. corporate presentation, January 11, 2016

Exhibit 9



# Corporate Overview January 11, 2016

**Brian M. Culley, Chief Executive Officer** 

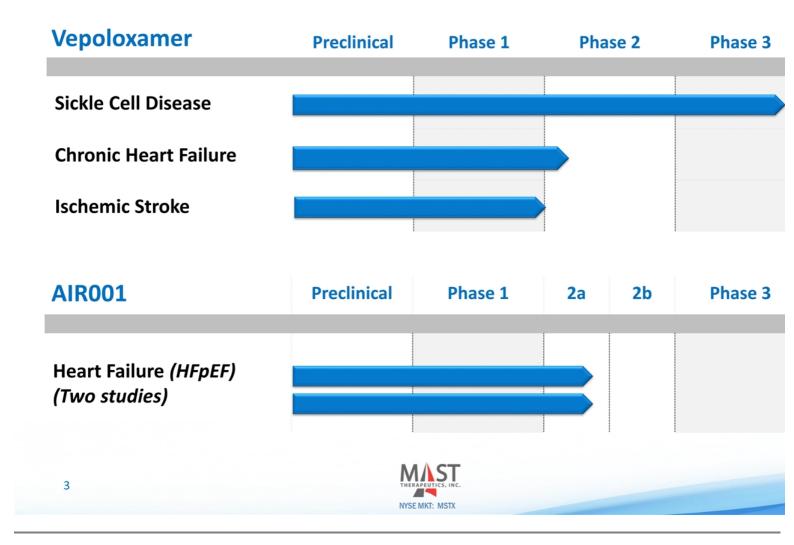
### **Forward Looking Statements**

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, a needed; our ability to repay outstanding debt as payments come due; our ability to establish an 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 reports of Form 10-Q filed with the SEC on August 12, 2015 and November 12, 2015.

We caution you not to place undue reliance on any of these forward-looking statements, which speconly 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.



## **Product Candidate Pipeline**



# Vepoloxamer: A Novel Proprietary Biophysical Agent

- Corrects imbalances in surface tension, an underlying feature of multiple diseases
- Biophysical mechanism of action offers lower development risk
  - · Targets damaged tissue; little or no activity in healthy tissue
  - Not metabolized; no active metabolites to track, no difference in fast vs slow metabolizers, less susceptible to drug-drug interactions
  - Less susceptible to genetic variation; independent of receptors, etc.



## Pathologies and Conditions Related to Imbalances in Surface Tension

### **Surface Tension Pathologies**

**Elevated blood viscosity** 

**Cellular aggregation** 

**Cellular adhesion** 

Loss of membrane barrier function / repair capacity

**Dysfunctional coagulation** 

Sickle Cell Disease
Heart Failure
Ischemic Stroke
Other Diseases



## Development of Vepoloxamer in Sickle Cell Disease

Objective: Improve blood flow to prevent ischemic injury and shorten the duration of crisis

Phase 3 ("EPIC") Study Ongoing



## **Vepoloxamer in Sickle Cell Disease (SCD)**

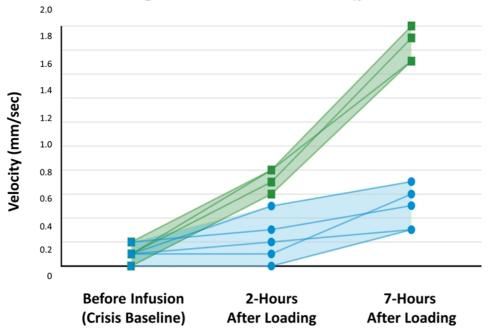
- ➤ The underlying pathology in vaso-occlusive crisis (VOC) is diminished blood flow
- Vepoloxamer improves blood flow by addressing multiple pathological mechanisms:
  - Adhesion
  - Hemolysis
  - Aggregation
  - Viscosity

Objective of treatment with vepoloxamer: Improve blood flow to prevent ischemic injury and shorten the duration of crisis



## Vepoloxamer Improved Blood Flow in Sickle Ce Patients

Vepoloxamer improved microvascular blood flow in sickle cell disease patients during vaso-occlusive crisis (prior Phase 3 sub-study)



- Vepoloxamer
- Placebo

of red cell velocity
(mm/s) measured by
video microscopy in ninsickle cell patients with
vaso-occlusive crisis
(p = .00003)



## **Vepoloxamer Development History**

- Over 100 nonclinical studies completed
- Phase 2 SCD statistically significant shorter crisis and less opioid use
- Phase 2 ACS\* approx. 50% shorter hospitalization stay vs. historical control
- Phase 3 SCD shorter duration of crisis (p-value = 0.07)
- Lessons learned from clinical history and applied to Mast's Phase 3 study "EPIC"
  - 1. Vepoloxamer has activity in SCD
  - 2. Study design is key to success (prior endpoint poorly designed)
  - 3. Key FDA feedback:
    - · Utilize a clinically meaningful endpoint
    - Use as objective an endpoint as possible
    - Avoid use of pain scores due to variability
    - Provide a plan to minimize data loss

(\*Acute chest syndrome, a serious complication of sickle cell cris



## The EPIC Study

#### **Evaluation of Purified Poloxamer 188 In Vaso-Occlusive Crisis**

#### Double-Blind, Placebo-Controlled, Multicenter

388 patients, randomized to standard of care +/- vepoloxamer

#### > Primary Endpoint

· Duration of crisis from time of randomization to last dose of parenteral opioid

#### > Secondary Endpoints

- Re-hospitalization for VOC within 14 days
- Occurrence of acute chest syndrome within 120 hours of randomization

#### Other Assessments

- Safety
- · Duration of hospitalization
- Biomarkers
- · Opioid requirements
- Sub-study outcomes



## **EPIC Study: Primary Endpoint**

- Duration of vaso-occlusive crisis
- > Definition: time from randomization to last dose of parenteral opioid
- > Advantages:
  - Aligns with FDA recommendations
    - Sensitive and specific data collection
    - Objective
    - Minimal data loss
  - Medical expert support
  - · Clinically meaningful



## **EPIC Study: Demographic Characteristics**

(As of December 31, 2015)

- ➤ Age
  - Average = 15 years
  - Range = 4 to 46 years
  - Patients over 18 = 29%
- Use of Hydroxyurea (HU) = 62%
- **➤** U.S. patients > 50%
- More than 80% of all sites have enrolled at least one patient
- Why are these demographics encouraging?
  - In the prior study, patients under the age of 16 had a benefit of 22 hours (p=.01) and those on HU had a benefit of 16 hours (p=.02).



## **EPIC Study: Safety**

#### > DSMB Evaluations

- Independent, unblinded DSMB (4 clinicians and 1 statistician)
- Meetings at 25, 58, 145 and 250 patients

#### > DSMB meeting held at 250 patients

- No unexpected safety signals identified
- DSMB members deemed no additional meetings were necessary



## **EPIC Study: Summary**

- > >90% enrolled; enrollment completion anticipated Feb 2016
- > Top-line data anticipated Q2 2016
- > Safety assumptions as predicted
- Age consistent with expectations
- Hydroxyurea use higher than expected
- ➤ At 250 patients, study performance consistent with statistical assumptions in study design (patient #s, avg. duration of crisis, coefficient of variation)
- > Minimal regional variability

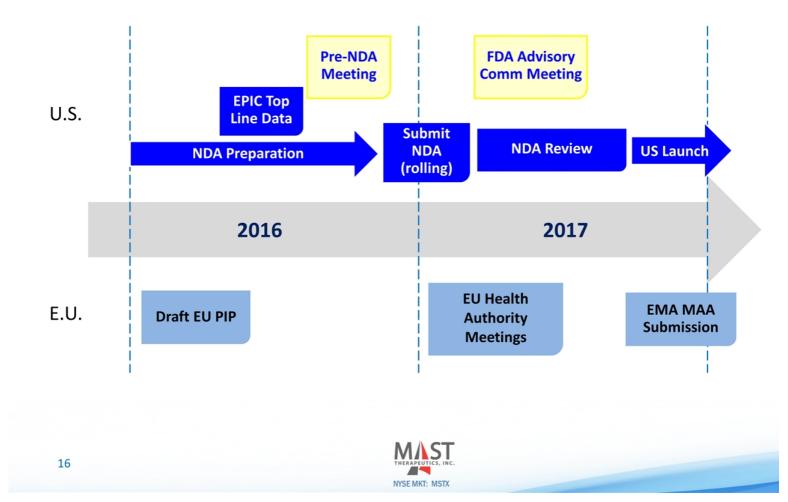


## **Vepoloxamer in SCD: Regulatory Consideration**

- Significant unmet need –no disease-modifying therapy for ongoing VOC
- > Support among medical / advocacy / patient communities
- > Orphan Drug Designation
- > Fast Track Designation
- > SCD is part of FDA "Patient-Focused Drug Development Initiative"
- > Healthcare disparity concerns
- > NDA-supportive clinical studies:
  - · Thorough QT study complete
  - · Repeat-administration study enrolling
  - · Special populations study enrolling



## **Vepoloxamer in SCD: Key Regulatory Activities**



## **SCD: A Lifetime of Complications**

"Sickle cell disease is a chronic disease that is punctuated by acute events and that shortens life."

- · Premature death
- Multiple organ damage and failure
- Acute papillary necrosis of the kidneys
- Leg ulcers
- · Pulmonary hypertension
- · Cholelithiasis (gallstones)
- · Patient may have early signs of renal disease
- · Chronic pain

#### Multiple hospitalizations for VOC per year

- · Avascular necrosis may start to occur as a result of ischemia
- Priapism and pregnancy complications
- · Annual eye exams recommended for retinopathy, hemorrhages, and retinal detachments
- Acute Chest Syndrome (common complication of VOC)
- · Transfusions may begin for cerebral infarction (stroke)
- Splenectomy (usually before age 8)
- Daily penicillin prophylaxis (through age 5)
- · Diagnosis (at birth)

Infant Childhood Adolescent Transition Young Adult Adult Mature Adult Senior

Source: Martin H. Steinberg, M.D., Management of Sickle Cell Disease, New Eng J Med: 1999; Vol 340, No 1



### Vaso-Occlusive Crisis is the Hallmark of SCD

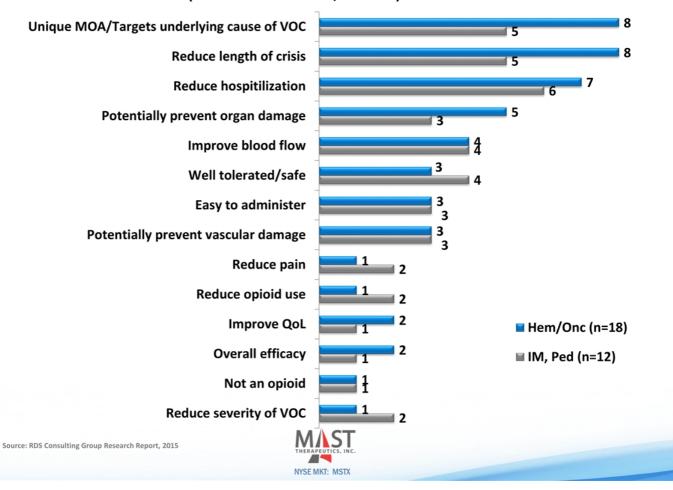
- 80-100k hospitalizations annually in the U.S.
- > Current treatment is palliative
  - · Consisting of hydration and IV opioids
  - Does not treat underlying pathophysiology of the disease
  - No VOC interventional therapy available
- Hospitalized on average for approximately 4-5 days
- > 40% of patients will have acute chest syndrome complication
- 12-41% are re-hospitalized within 30 days of hospital discharge
- > Shorter life expectancy due to ischemic injury (~45y)

Sources: Life-expectancy: Hassell, K. Am J Prev Med 2010; 38(4S): S512-521; Utilization data calculated from data in Brousseau, D., et al., Acute Care Utilization and Rehospitalizations for Sickle Cell Disease JAMA Apr 7 2010 and HCUP 2010-2012; SCD prevalent pop: Brousseau DC, Panepinto JA, Nimmer M, Hoffmann RG. The number of people with sickle-cell disease in the United States: national and state estimates. Am J Hematol 2010;85:77-8; Steinberg, M.H., Management of Sickle Cell Disease, New Eng J Med; 1999; Vol 340, No 13; Platt, et al., Mortality in Sickle Cell Disease (N Engl J Med 1994;330:1639-44)



### Market Research: Expected Features and Potential Benefit Align with Unmet Needs for VOC Treatment

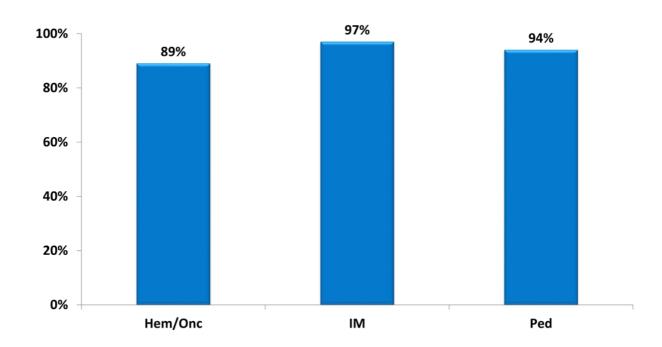
Key Advantages/Features of Vepoloxamer (# of ranked mentions, unaided)



## Market Research: Physicians Report a High Percent of Patients to be Treated with Vepoloxamer at Peak

Average % of Patients Treated with Vepoloxamer at Peak





MDs expect quick uptake and time to peak (~6 months)





## **Development Landscape in SCD**

## Vepoloxamer has the potential to be the first and only treatment to reduce the duration of an ongoing VOC

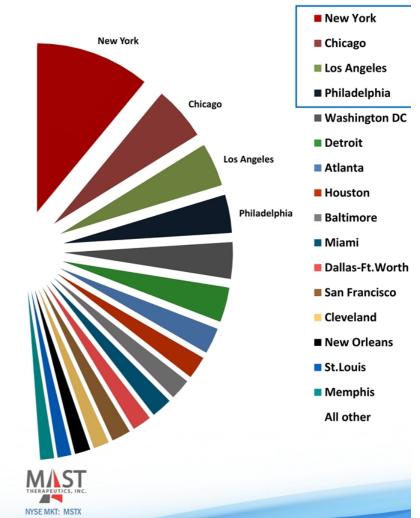
Stage	VOC Intervention	VOC Reduction	SCD Corrective Treatment
Marketed		Hydroxyurea	вмт
Phase 3	vepoloxamer rivipansel	L-Glutamine	
Phase 2		Aes-103 SANGUINATE Sevuparin SelG1	
Phase 1		GBT440 NiCord NKTT120 PF-04447943 SCD-101	LentiGlobin



## Concentration of SCD Treatment in the U.S. Offers an Attractive Commercial Opportunity

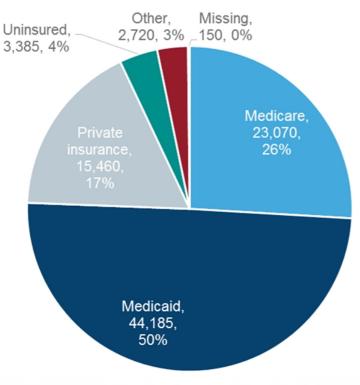
- ~50% of SCD patients in the U.S. are treated in the top 16 metropolitan areas
- Top four metropolitan areas account for 24% of the market
- <200 hospitals in the U.S. serve the majority of SCD patients</p>
- Target audience: Hematologist, hospitalist, other physicians who routinely care for SCD
- Effective field promotion with small hospital sales force (~30)

Sources: Hassell KL. Population estimates of sickle cell disease in the U.S. Am J Prev Med 2010;38(4 Suppl):S512-21; Data on file, Mast Therapeutics 2015



## **U.S. Sickle Cell Disease Hospital Payer Mix**

## Sickle Cell Disease, Payer Mix 2012 HCUP data



- Inpatient prospective payment system (IPPS)
- Patients with public insurance have minimal share of costs
- Medicaid plans may seek additional funding via CHIP, per diem rates, or modified FFS rates
- Vepoloxamer expected to meet criteria for additional Medicare payment (NTAP)



## Significant Potential Outside the U.S.

#### Over 12 million patients worldwide

#### Europe

- Approximately 40,000 patients
- 54% reside in two countries: UK and France
- Most patients concentrated in large metro areas: Paris and London

#### > MENA

- Over 850,000 with SCD
- Many treatment centers provide care on par with standard of the U.S. and E.U.



Sources: Hassell KL. Population estimates of sickle cell disease in the U.S. Am J Prev Med 2010;38(4 Suppl):S512-21; Data on file, Mast Therapeutics 2015; VOI Consulting analysis, 2015

### **Vepoloxamer Positioned for Success in SCD**

#### > Novel therapy for a genetic disease with high unmet needs

- Unique and relevant mechanism of action
- No approved disease-modifying therapies available for VOC intervention

#### Significant first-to-market advantage in multiple territories

- Clinical development >2 years ahead of other SCD programs
- Orphan Drug Designation in U.S. and E.U.
- Expansion opportunity
  - · Planning E.U. launch
  - Partner MENA region and ROW

#### Concentrated market

- 50% of U.S. SCD patients live in 16 metropolitan areas
- 96% of SCD patients in the U.S. have insurance coverage

#### Research supports rapid adoption & significant market penetration

- Ranked 4.4 out of 5 as a "breakthrough medical innovation" by pharmacy directors at key SCD institutions
- KOLs and community physicians express high intent to use



## Development of Vepoloxamer in Heart Failure

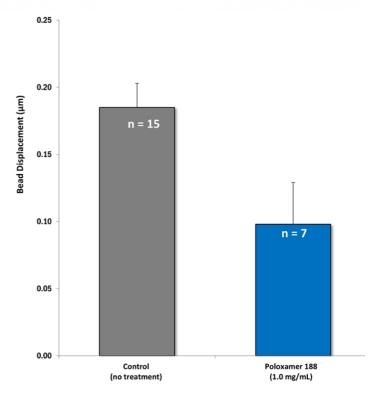
## Objective: Restore Membrane Integrity To Improve Cardiac Performance

**Phase 2 Study Ongoing** 



## **Development Rationale in Heart Failure**

- Elevated wall tension in dilated (failing) heart impairs normal membrane repair process
- Permeabilized membranes allow unregulated calcium influx and cardiac troponin leak
- Vepoloxamer reduces surface tension, facilitating membrane repair and inhibiting unregulated calcium entry



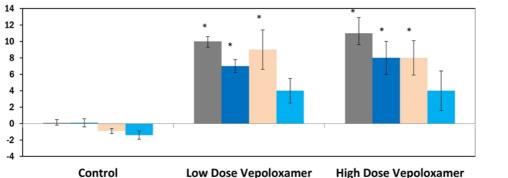
Effect of poloxamer 188\* on cell surface tension (bead displacement). Cells treated with 1.0 mg/mL poloxamer 188 had significantly reduced membrane tension.



\*Vepoloxamer is purified poloxamer 188.

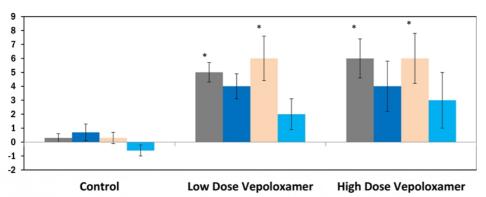
## Heart Failure Model – Functional Improvement (single administration)

#### Δ LV Ejection Fraction (%)





#### Δ Stroke Volume (mL)



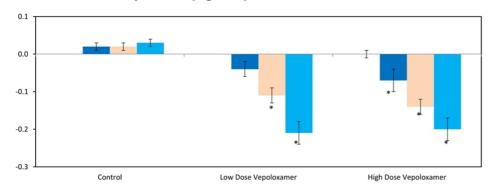
Vepoloxamer elicited improvements in LV systolic and diastolic function that lasted for at least one week

Study conducted by: Hani N. Sabbah, Henry Ford Health System



## Heart Failure Model – Biomarkers (single administration)

#### Δ Plasma Troponin-I (ng/mL)



#### 2 Hours Post

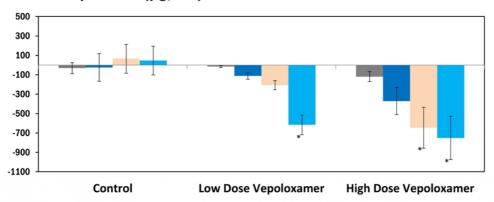
24 Hours Post

1 Week Post

2 Weeks Post

\* p < 0.05 vs. Control

#### Δ nt-pro BNP (pg/mL)



- Troponin data suggests vepoloxamer can preserve cardiomyocyto by limiting calcium entri into the cell.
- Functional improvemer supported by significan reductions of NT-proBN for up to 2 weeks.

Study conducted by: Hani N. Sabbah, Henry Ford Health System



## **Heart Failure Phase 2 Study Design**

- Randomized, double-blind, placebo-controlled, multi-center Phase 2 study in chronic heart failure initiated Q4 2015
- ➤ N=150 patients, 3 dose arms, single dose (3-hour IV administration)
- > Efficacy assessments:
  - · Cardiac function
  - Biomarkers
- > Study is testing a new formulation of vepoloxamer designed to be more suitable for a heart failure patient population
- Patent applications filed on new vepoloxamer formulation and methods of use in heart failure



## **Development of Vepoloxamer in Ischemic Strok**

## Objective: Accelerate time to reperfusion and reduce reperfusion injury

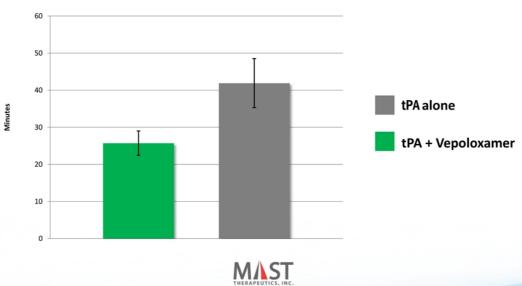
**Phase 2a Ready** 



## **Vepoloxamer in Ischemic Stroke**

- In stroke, restoring blood flow is critical ("time is tissue")
  - · Vepoloxamer improves blood flow as a stand-alone agent
  - In combination with a thrombolytic, vepoloxamer shortens time to thrombolysis b up to 40%
  - · Seals and protects ischemia-injured tissue
    - Neuronal tissue
    - Blood brain barrier integrity

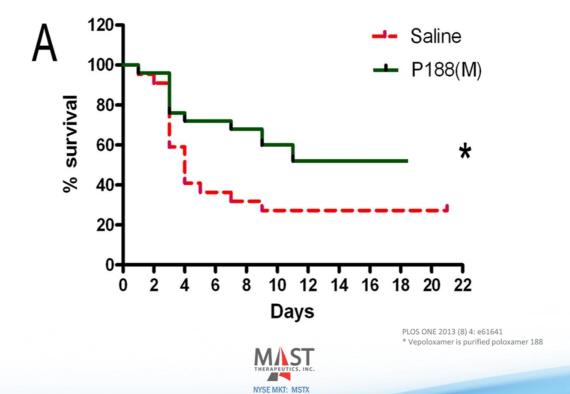




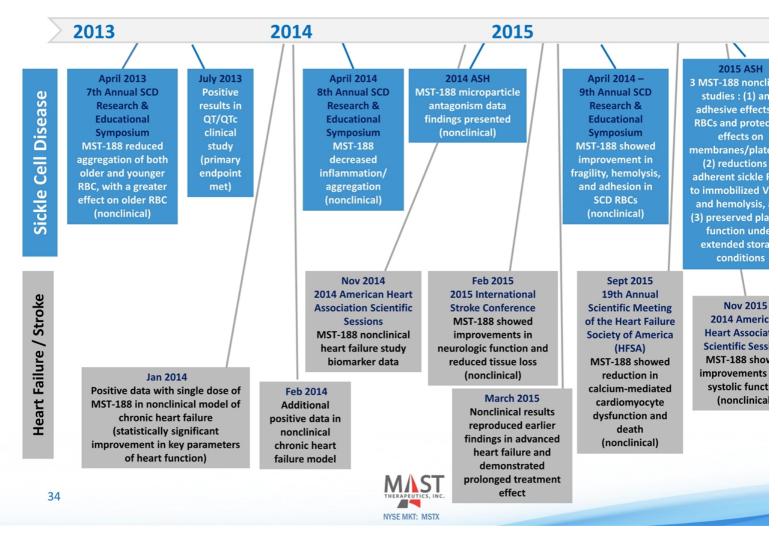
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## Vepoloxamer Alone or with tPA Improves Outcomes in Experimental Stroke Models

- > Two hour occlusion of MCA with silicon coated nylon suture
- Only 27% of control mice survived vs. 52% of mice treated with poloxamer 188\* (n=51)



# Vepoloxamer Data Announcements Following Acquisition by MAST



# **Vepoloxamer Market Exclusivity**

Form of Protection	Indication	Status	
Orphan Drug Designation (Market Exclusivity)	SCD	Granted (US/EU)	
Patents – Composition of matter	SCD, HF, IS	Filed, pending w/w	
Patents – New formulation	HF	Provisional filed	
Patents – Methods of use	SCD, HF, IS	Filed, pending w/w	
Data Exclusivity	SCD, HF, IS	Eligible (US/EU)	
Trade Secret & Know-How	SCD, HF, IS	CD, HF, IS Varies	
		SCD = sickle cell disease HF = heart failure	



IS = ischemic stroke

## **Development of AIR001 in Heart Failure**

# Objective: Improve exercise tolerance and hemodynamics in HFpEF patients

**Phase 2a Studies Ongoing** 



### **AIR001 Overview**

#### AIR001 is nitrite\* for intermittent inhalation

- · Delivered via a proprietary handheld nebulizer
- · Activity includes dilation of blood vessels and reduced inflammation
- Hemodynamic benefits include reductions in:
  - Pulmonary capillary wedge pressure
  - Right atrial pressure
  - Mean pulmonary arterial pressure
- Safety data available in 124 subjects (well-tolerated) including exposures beyond 52 weeks
- Activity (mechanism) not limited to role as a nitric oxide donor as nitrite has direct mitochondrial oxygen sparing activity

\* Note: Nitrite is a different molecule and has separate activ compared to organonitrates or nitric oxide.



### **AIR001 Clinical Data**

#### Three Phase 1 studies

- Established Maximum Tolerated Dose (MTD)
- Acute improvements in hypoxia-induced pulmonary hypertension
- No drug-drug interaction with sildenafil

#### One Phase 2 study

- Well-tolerated; no treatment-related serious adverse events
- Improvements seen in median pulmonary vascular resistance (PVR) and median distances in 6-minute walk test
- Methemoglobin levels remained normal (<1.5%)</li>



## **AIR001 Clinical Development**

- ➤ Heart Failure with Preserved Ejection Fraction (HFpEF)
  - Responsible for ~50% of heart failure hospitalizations
  - 80% develop pulmonary hypertension
  - · No approved medications
- Supporting two institutional-sponsored Phase 2a studies to:
  - Evaluate acute effects versus placebo on submaximal oxygen consumption an exercise hemodynamics
  - Evaluate hemodynamic effects of AIR001
- Initial observations from ongoing Phase 2a studies are encouraging
- > Top-line data from first of two Phase 2a studies in HFpEF anticipated Jan 2016 (enrollment completed Dec 2015)



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## **MSTX Financial Overview**

- > Cash/investments at 12/31/2015: ~\$41M
- ➤ Market capitalization: \$70 million\*
- > Shares outstanding: ~ 164 million\*
- > Average daily volume (3 mo.): ~ 1.1 million



## **Management Team and Board of Directors**

#### Management Team

Brian Culley, CEO Immusol, UC San Diego, Neurocrine, Scripps Research Inst

Ed Parsley, CMO Aires, Pfizer, CLS, Encysive, U. Texas Medical

Brandi Roberts, CFO Alphatec, Artes, Stratagene, Pfizer, PWC

Martin Emanuele, SVP Development DaVita, SynthRx, Kemia, Avanir, DuPont

Greg Gorgas, SVP Commercial Theragence, Biogen Idec, Chiron, Cetus, Upjohn Co.

Mark Longer, VP Regulatory AstraZeneca, Amylin, Pfizer

#### Board of Directors

NEW – Matthew Pauls, CEO StrongBridge Biopharma

NEW – Peter Greenleaf, CEO Sucampo Pharmaceuticals

Lew Shuster, CEO Shuster Capital

Howard Dittrich, EIR, CMO Frazier Healthcare Partners

David Ramsay, CFO (ret.) Halozyme



## **Mast Therapeutics: Key Takeaways**

- Vepoloxamer has the potential to be a first-in-class disease-modifying therapy for SCI
- > EPIC average age is 15, majority of patients are from U.S., and hydroxyurea use is >60
- Blinded analysis suggests EPIC actual performance is consistent with statistical assumptions in study design
- > No unexpected safety signals after 250 patients and no further DSMB meetings needs
- Concentration of patients in the U.S. and E.U. provides an attractive market opportunity
- > Vepoloxamer has potential in serious vascular diseases, such as heart failure and stro
- ➤ Encouraging observations in ongoing AIR001 studies support further development in HFpEF



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## **Investment Highlights**

#### > Anticipated milestones in 1H 2016

- Top-line results from first of two ongoing AIR001 Phase 2a studies
- Completion of enrollment in EPIC study
- Q4 & FYE 2015 financial results & update
- EPIC study final patient's 30-day observation period & follow-up
- Q1 2016 financial results & update
- Preliminary results from initial cohort in second AIR001 Phase 2a study
- Completion of enrollment in vepoloxamer Phase 1 special population PK study
- Top-line results from EPIC study



