

Nasdaq: ICU www.seastarmedical.com

Recent Stock Price (07/20/23) \$0.52
Market Capitalization \$7.0M
Common Shares Outstanding 13.5M
Avg. Daily Trading Volume 707,000

#### Innovative Solutions for the Consequences of Hyperinflammation

**SeaStar Medical** is developing and commercializing proprietary extracorporeal therapies that target the effector cells that drive systemic inflammation and damage vital organs. SeaStar Medical's novel technologies rely on science and innovation to provide life-saving solutions to critically ill patients in multiple underserved indications.

Targeting FDA approval of the Selective Cytopheretic Device (SCD) for pediatric acute kidney injury (AKI) by 2023 year end under the humanitarian device exemption (HDE) process,

Enrolling patients in the NEUTRALIZE-AKI (<u>NEUTR</u>ophil and monocyte de<u>A</u>ctivation via Se<u>L</u>ective Cytopheret<u>I</u>c Device – a randomiZEd clinical trial in Acute Kidney Injury) with interim results expected in 4Q23

#### **Investment Highlights**



Selective Cytopheretic Device (SCD) quells the hyperinflammatory process and cytokine storm by targeting and neutralizing activated effector cells

- SCD addresses hyperinflammation in multiple acute and chronic indications, all highvalue and large markets
- SCD's unique method of mechanism of action provides cell-directed extracorporeal therapy at the patient point of care under an FDA medical device regulatory pathway
- Initial work in pediatric and adult AKI generated clinical results demonstrating vastly reduced mortality and the elimination of dependency on hemodialysis
- Multiple near-term regulatory and clinical milestones provide potential to create significant value for shareholders
- Seasoned leadership team with highly relevant business experience and a proven track record of execution

### Hyperinflammation is a Serious Condition that Can Lead to Permanent Organ Damage and Death

Hyperinflammation develops when the immune system responds too aggressively to injury, subsequently creating a cytokine storm

**Key Drivers of Hyperinflammation:** bacterial and viral infections, trauma and surgery can lead to pulmonary infiltrates, lung injury, acute respiratory distress syndrome (ARDS), cardiovascular shock, disseminated intravascular coagulant or renal failure

Hyperinflammation can Result in End-Organ Damage and Failure, with the Potential for Permanent Organ Damage or Death

### Current Treatment Options Have Limited Efficacy











Transfusion

Therapeutic approaches intended to block soluble mediator targets – such as cytokines or free radicals – have not been proven to be efficacious

There is an urgent need to address hyperinflammation at its source

### SCD: Innovative Cell-directed Extracorporeal Therapy Works to Restore Immune System Homeostasis



\*SCD is currently under investigation and has not been approved. There is no guarantee that the product will receive authority approval and become commercially available for the uses being investigated.

SCD is not a filter; it creates a microenvironment to neutralize hyperactive neutrophils and transform monocytes

The FDA granted Breakthrough Device designation to SCD for adult AKI in Q2 2022

## Significantly Reduced Mortality and Elimination of Dialysis Dependency Demonstrated Across Multiple AKI Clinical Studies

		Mortality Rate (60 Days)			Dialysis Dependency (60 Days)	
Non-COVID AKI Studies	Patients Treated	Mortality Reduction	SCD	Control	SCD	Control
OUS Study	9	56%	22%	78%1	0%	25%
U.S. Adult Pilot 002	35	19%	31%	50%3	0%	25%
U.S. Adult ARF 003	19/272	25%	16%	41%	0%	25%
U.S. Peds SCD 001	16	25%	25%	50%³	0%	15%-25%

Note: All subjects in these studies were patients with AKI

- 1. Case-matched controls based on SOFA Scores and age
- 2. Treated per protocol (iCa in therapeutic range using citrate)
- 3. Historical control based on published studies ARF = Acute Renal Failure

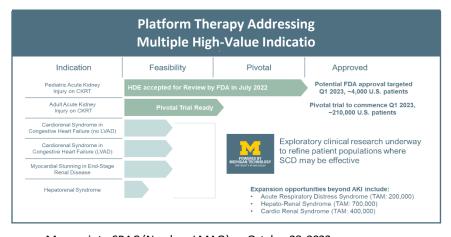
#### **Positive Results in Pivotal Pediatric AKI Study**

Open-label, multicenter pilot study assessed the safety and feasibility of SCD in 16 pediatric patients with AKI and multi-organ dysfunction requiring continuous kidney replacement therapy

Primary Endpoints: Treatment-related adverse events occurring during treatment and Day 60 post-treatment initiation

#### Results:

- ✓ No SCD-related adverse events
- ✓ 94% of patients survived SCD therapy
- ✓ 75% of patients survived to ICU discharge
- √ 100% of ICU survivors were dialysis independent and had normal kidney function at Day 60



- Merger into SPAC (Nasdaq: LMAO) on October 28, 2022
- At merger closing entered into forward purchase agreements of shares and warrants with the potential to generate up to \$10 million in proceeds
- \$100 million equity line of credit
- Closed \$3.3 million first tranche in March and \$1.75 million second tranche in May of a \$9.8 million private placement

## What Types of Patients Have Been Treated with the SCD?

3 Organ Failure



50%-60% Sepsis

Among patients

Comorbidities include (but not limited to) morbidly obese and COVID-19 positive – all patients were in the ICU

#### **Pediatric AKI Commercial Overview**

#### Market:

yee

**220 Children's Hospitals**: ~4,000 AKI pediatric patients; ~7,200 ICU beds

**Top 50 Children's Hospitals**: ~2,200 AKI pediatric patients; ~4,030 ICU beds

**Commercial Preparations:** 

Product manufacturer



Pediatric SCD license & distribution partner



# Key Upcoming Value-Creating Milestones

YE 2023
FDA Approval

**YE 2023** 

Commercial Launch

Adult Acute Kidney Injury

**Interim Results** 

Q2 2023

**Pivotal Trial** 

Q4 2023 Pivotal Study Q3 2024

Pivotal Study Topline Results

Q3 2024

PMA Submission H1 2025 PMA Approval

H2 2025
Commercial
Launch

#### **Investor Contact**

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July 2023