# SeaStar Medical Reports First Quarter 2023 Financial Results and Provides a Business Update

May 15, 2023

**DENVER, May 15, 2023 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation** (Nasdaq: ICU) ("SeaStar Medical" or the "Company"), a medical device company developing proprietary solutions to reduce the consequences of hyperinflammation on vital organs, reports financial results for the three months ended March 31, 2023 and provides a business update.

"Enrollment of the first patient in our pivotal NEUTRALIZE-AKI trial and activation of additional clinical trial sites are expected in the coming weeks. This trial is evaluating the safety and efficacy of our patented, first-in-class, cell-directed Selective Cytopheretic Device (SCD) extracorporeal therapy in critically ill adults with acute kidney injury (AKI) requiring continuous kidney replacement therapy (CKRT)," said Eric Schlorff, SeaStar Medical CEO. "Following the recent receipt of a non-approvable letter, we are working with the FDA to secure a Humanitarian Device Exemption (HDE) for use of the SCD to treat critically ill children with AKI, and are now targeting approval in late 2023."

SeaStar Medical provides the following updates on its clinical programs with its patented, first-in-class SCD, a cell-directed extracorporeal therapy for hospitalized patients with AKI requiring CKRT:

**Adult Acute Kidney Injury**

The first clinical site has been activated in our pivotal NEUTRALIZE-AKI (**NEUTR**ophil and Monocyte De**A**ctivation via Se**L**ective Cytopheret**I**c Device - a Randomi**ZE**d Clinical Trial in **A**cute **K**idney **I**njury) clinical trial to evaluate the safety and effectiveness of the SCD in critically ill adults with AKI in the intensive care unit (ICU) receiving CKRT. Approximately six million cases of adult AKI are diagnosed annually in the U.S., of which approximately 200,000 require CKRT.

- In 2022 the SCD received FDA Breakthrough Device Designation for adult use. This designation is awarded to a therapy to treat a serious or life-threatening condition with preliminary clinical evidence indicating it may demonstrate substantial improvement on clinically significant endpoints over available therapies. Breakthrough therapies receive many benefits, including a commitment by the FDA to expedite development and review.

- The NEUTRALIZE-AKI trial is expected to enroll up to 200 patients at up to 30 U.S. medical centers. The trial's primary endpoint is a composite of 90-day mortality or dialysis dependency of patients treated with SCD in addition to CKRT as the standard of care, compared with the control group receiving only CKRT standard of care. Secondary endpoints include mortality at 28 days, ICU-free days in the first 28 days, major adverse kidney events at Day 90 and dialysis dependency at one year. The study will also include subgroup analyses to explore the effectiveness of SCD therapy in AKI patients with sepsis and acute respiratory distress syndrome.

- The trial is expected to require 18 months to complete and report topline results. Based on this timeline, we expect to file a Premarket Approval application in the third quarter of 2024, with anticipated approval in the first half of 2025 and commercial launch in the second half of 2025.

**Pediatric Acute Kidney Injury**

We anticipate our first U.S. regulatory approval for the SCD will be for pediatric patients with AKI being treated in the ICU with CKRT. About one-half of children in the ICU with AKI who require CKRT survive, with those surviving at risk of long-term life-threatening conditions such as chronic kidney disease.

- In June 2022 we submitted an HDE application to the FDA, having met the criteria with clinical results showing safety and probable clinical benefit to critically ill children with AKI who have few treatment options. A non-controlled pivotal study funded by the FDA Office of Orphan Products Development showed that those treated with the SCD had no reported adverse events, a 50% reduction in mortality rate and no dialysis required at Day 60. The U.S. addressable population of about 4,000 pediatric patients is within the 8,000-patient HDE criteria.

- In May 2023 we received a letter from the FDA indicating that the application is not approvable in its current form and outlining specific guidance as to how the application may be amended and resubmitted. We believe that each defficiency cited in the letter is readily addressable and have put in place a plan with the goal of achieving pediatric HDE approval. In parallel we have initiated the administrative review and have a further option to appeal. We anticipate that this process could take between 90 and 120 days.

- With the license and distribution agreement with Nuwellis for the pediatric AKI indication in place, both team's have been

preparing for the initial commercial focus on the top 50 U.S. hospitals that treat pediatric AKI patients. Nuwellis' salesforce has established relationships with nephrologists and intensive care physicians who are trained in pediatric extracorporeal therapy. This agreement allows us to focus on additional clinical applications with the SCD without the expense of hiring and training a commercial team.

SeaStar Medical will continue to explore the application of our SCD technology across a broad range of indications where proinflammatory activated neutrophils and monocytes may contribute to disease progression or severity, in both acute and chronic indications.

**First Quarter Financial Results**

Research and development (R&D) expenses for the first quarter of 2023 were $1.8 million, compared with $0.4 million for the first quarter of 2022, with the increase primarily driven by an increase in clinical trial expenses of $0.6 million, an increase in the use of external services of $0.3 million and an increase in payroll and personnel expenses of $0.5 million.

General and administrative (G&A) expenses for the first quarter of 2023 were $3.0 million, compared with $0.5 million for the first quarter of 2022, with the increase primarily attributable to an increase in professional fees related to SEC reporting of $0.6 million, an increase in payroll-related expenses of $0.7 million, an increase in insurance expense of $0.4 million, expenses related to financial instruments of $0.3 million, cost of SEC reporting of $0.2 million, a legal settlement of $0.2 million and an increase in marketing expenses of $0.1 million.

Other expense for the first quarter of 2023 was $0.5 million, compared with other expense of $0.2 million for the first quarter of 2022. The increase primarily resulted from the change in fair value of forward option-prepaid forward contracts and tranche rights, and loss on issuance of convertible notes, partially offset by the change in fair value of convertible notes and a gain on sales of recycled shares.

The net loss for the first quarter of 2023 was $5.3 million, or $0.40 per share, compared with a net loss of $1.0 million, or $0.14 per share, for the first quarter of 2022.

The Company reported cash of $725,000 as of March 31, 2023, compared with $47,000 as of December 31, 2022. At the closing of the merger agreement in October 2022, the Company entered into forward purchase agreements of shares and warrants with the potential to generate up to $10 million in proceeds, depending on the market price of shares. The Company also entered into a $100 million equity line of credit. In March 2023 the Company closed a $3.3 million first tranche of a $9.8 million private placement convertible debt offering, and in recently closed on the second tranche of $2.2 million.

**About Hyperinflammation and the Selective Cytopheretic Device (SCD)**
SeaStar Medical has identified a clear, urgent, unmet clinical need for technology that addresses hyperinflammation, the overproduction or overactivity of inflammatory cells that can lead to damage of vital organs. It occurs when the body overproduces inflammatory effector cells and other molecules that can be toxic, damaging to vital organs and result in multi-organ failure and even death. This is known as the cytokine storm. Current treatment options have shown limited efficacy in managing a cytokine storm with many simply treating symptoms instead of stopping the inflammatory effector cells that cause the cytokine storm.

The Selective Cytopheretic Device, or SCD, is a first-in-class, cell-directed extracorporeal therapy. Unlike pathogen removal and other blood-purification tools, the SCD selectively targets the most highly activated proinflammatory neutrophils and monocytes. The Company has observed that these most highly activated immune cells are turned off in a low calcium environment. The SCD is integrated into existing hemodialysis equipment that is widely available in ICUs across the U.S. It requires less than 15 minutes for physicians or hospital staff to attach. The SCD therapy mimics nature by creating a unique micro-environment, attracting these highly activated effector cells and neutralizing them in a low calcium setting, with these cells then returned into the body through the blood, and the body is signaled to focus on repair.

**Clinical Results with the SCD in AKI**
SCD therapy has produced favorable clinical results in critically ill adults and children with AKI in the ICU being treated with CKRT, today's standard of care. The SCD has reduced mortality rates by up to 50% in four non-COVID clinical trials in which adult and pediatric AKI patients had on average three organ failures and with a significant number of patients also being septic. A similar reduction in mortality was observed in a study of 22 COVID-19 patients with AKI and/or acute respiratory distress syndrome.

**About SeaStar Medical**
SeaStar Medical is a medical technology company that is redefining how extracorporeal therapies may reduce the consequences of excessive inflammation on vital organs. SeaStar Medical's novel technologies rely on science and innovation to provide life-saving solutions to critically ill patients. The Company is developing and commercializing cell-directed extracorporeal therapies that target the effector cells that drive systemic inflammation, causing direct tissue damage and secreting a range of pro-inflammatory cytokines that initiate and propagate imbalanced immune responses. For more information visit www.seastarmedical.com or visit us on LinkedIn or Twitter.

**Forward-Looking Statements**
This press release contains certain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1955. These forward-looking statements include, without limitation, the FDA letter and SeaStar's intent to pursue appeal options and other actions in response to such letter; the ability of SeaStar to address

deficiencies raised by the FDA; the ability of SCD to treat pediatric patients with AKI, and the potential benefits of SCD to treat other diseases. Words such as “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “strategy,” “future,” “opportunity,” “plan,” “may,” “should,” “will,” “would,” “will be,” “will continue,” “will likely result,” and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside SeaStar Medical’s control and are difficult to predict. Factors that may cause actual future events to differ materially from the expected results include, but are not limited to: (i) the risk that SeaStar may not be able to obtain regulatory approval of its SCD product candidates; (ii) the risk that SeaStar may not be able to raise sufficient capital to fund its operations, including clinical trials; (iii) the risk that SeaStar Medical and its current and future collaborators are unable to successfully develop and commercialize its products or services, or experience significant delays in doing so, including failure to achieve approval of its products by applicable federal and state regulators, (iv) the risk that SeaStar Medical may never achieve or sustain profitability; (v) the risk that SeaStar Medical may not be able to access funding under existing agreements, including the equity line of credit and forward purchase agreements; (vi) the risk that third-parties suppliers and manufacturers are not able to fully and timely meet their obligations, (vii) the risk of product liability or regulatory lawsuits or proceedings relating to SeaStar Medical’s products and services, (xiii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (xi) other risks and uncertainties indicated from time to time in SeaStar Medical’s Annual Report on Form 10-K, including those under the “Risk Factors” section therein and in SeaStar Medical’s other filings with the SEC. (iii) The foregoing list of factors is not exhaustive. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and SeaStar Medical assume no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise.

**Contacts:**
Media
PSC Consulting
Patty Caballero
(973) 348-5055
**patty@pscconsulting.net**

Investors
LHA Investor Relations
Jody Cain
(310) 691-7100
**Jcain@lhai.com**

Financial Tables to Follow

**SeaStar Medical Holding Corporation**
**Consolidated Balance Sheets**
**As of December 31, 2022 and 2021**
**(in thousands, except for share and per-share amounts)**
**Unaudited**

| | March 31, 2023 | December 31, 2022 |
|---|---|---|
| ASSETS | | |
| Current assets | | |
| Cash | $ 725 | $ 47 |
| Other receivables | — | 12 |
| Prepaid expenses | 2,659 | 2,977 |
| Total current assets | 3,384 | 3,036 |
| Forward option-prepaid forward contracts, net | - | 1,729 |
| Other assets | 2 | 2 |
| Total assets | $ 3,386 | $ 4,767 |
| LIABILITIES AND STOCKHOLDERS' DEFICIT | | |
| Current liabilities | | |
| Accounts payable | $ 3,022 | $ 1,927 |
| Accrued expenses | 1,531 | 2,245 |
| Contingent upfront payment for license agreement | 100 | — |
| Notes payable | 493 | 1,178 |
| Convertible note | 2,390 | — |
| Warrants liability | 500 | — |
| Total current liabilities | 8,036 | 5,350 |

| | | |
|---|---|---|
| Forward option-prepaid forward contracts, net | 489 | - |
| Notes payable, net of deferred financing costs | 5,745 | 7,652 |
| Total liabilities | 14,270 | 13,002 |
| Commitments and contingencies | | |
| Stockholders' deficit (1) | | |
| Common stock - $0.0001 par value per share; 100,000,000 shares authorized; 13,296,516 and 12,699,668 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively | 1 | 1 |
| Additional paid-in capital | 93,702 | 91,089 |
| Accumulated deficit | (104,587) | (99,325) |
| Total stockholders' deficit | (10,884) | (8,235) |
| Total liabilities and stockholders' deficit | $ 3,386 | $ 4,767 |

(1) Retrospectively restated to give effect to the reverse recapitalization

**SeaStar Medical Holding Corporation**
**Consolidated Statements of Operations**
**For the Years Ended December 31, 2022 and 2021**
**(in thousands, except for share and per-share amounts)**
**Unaudited**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Operating expenses | | |
| Research and development | $ 1,784 | $ 355 |
| General and administrative | 2,957 | 457 |
| Total operating expenses | 4,741 | 812 |
| Loss from operations | (4,741) | (812) |
| Other income (expense), net | | |
| Interest expense | (273) | (169) |
| Change in fair value of convertible note | 100 | — |
| Change in fair value of notes payable | — | (23) |
| Change in fair value of forward option-prepaid forward contracts | (1,654) | — |
| Gain on sale of recycled shares | 1,306 | — |
| Total other expense, net | (521) | (192) |
| Loss before income tax provision (benefit) | (5,262) | (1,004) |
| Income tax provision (benefit) | — | — |
| Net loss | $ (5,262) | $ (1,004) |
| Net loss per share of common stock, basic and diluted | $ (0.40) | $ (0.14) |
| Weighted-average shares outstanding, basic and diluted (1) | 13,025,852 | 7,238,767 |

(1) Retroactively restated to give effect to the reverse recapitalization

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Source: SeaStar Medical Holding Corporation