



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

November 14, 2023

DENVER, Nov. 14, 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 and nine months ended September 30, 2023 and provides a business update.

"Recent clinical and regulatory successes have significantly improved and strengthened our company's prospects," said Eric Schlorff, SeaStar Medical CEO. "We are addressing the remaining administrative steps outlined by the U.S. Food and Drug Administration (FDA) for approval of the Selective Cytopheretic Device Pediatric (SCD-PED) for children with acute kidney injury (AKI) and sepsis or septic condition requiring continuous kidney replacement therapy (CKRT). Preparations with our distribution partner Nuwellis are underway for commercial launch, which we expect to occur during the first quarter of 2024 following the receipt of the formal Approval Order from the FDA expected between December 2023 and January 2024. It is highly gratifying to be on the cusp of approval to bring the lifesaving benefits of our device to critically ill children.

"In our pivotal trial in adults with AKI, we have activated five clinical sites and enrolled seven patients to date. We are working diligently to qualify additional medical centers to join this trial and our goal is to enroll one patient per site per month," he added. "The addressable adult AKI population approximates 210,000 patients per year, which is about 50-times larger than the addressable pediatric AKI patient population.

"We are encouraged by the recent grant of Breakthrough Device Designation for the SCD in two additional indications – cardiorenal syndrome and hepatorenal syndrome. We view these grants as the FDA's further validation of the potential for dysregulating immune response in saving lives and improving outcomes," Mr. Schlorff concluded.

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

Adult Acute Kidney Injury

SeaStar Medical is conducting the pivotal [NEUTRALIZE-AKI \(NEUTRophil and Monocyte DeActivation via SeLective Cytopheretic Device - a RandomiZEd Clinical Trial in Acute Kidney Injury\)](#) clinical trial to evaluate the safety and effectiveness of the SCD-ADULT in adults with AKI in the intensive care unit (ICU) receiving CKRT.

- In 2022 the SCD-ADULT received FDA Breakthrough Device Designation for adult AKI . 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 over available therapies on clinically significant endpoints.
- 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-ADULT 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-ADULT therapy in AKI patients with sepsis and acute respiratory distress syndrome. A more complete description of the NEUTRALIZE-AKI trial design can be found in the journal [Nephron](#).
- SeaStar Medical expects regulatory approval for the SCD-ADULT in the first half of 2025 and commercial launch in the second half of 2025.

Pediatric Acute Kidney Injury

SeaStar Medical anticipates its first U.S. regulatory approval for the SCD-PED will be for pediatric patients with AKI and sepsis or septic condition weighing 10 kilograms or more who are being treated in the ICU with CKRT. Only 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 the Company submitted a humanitarian device exemption (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. The U.S. addressable population of about 4,000 pediatric patients falls within the 8,000-patient HDE criteria.

- In August 2023 a case series of three critically ill children with Shiga-toxin-associated hemolytic uremic syndrome (STEC-HUS), a cause of AKI, treated with the SCD in two different hospitals was published in the peer-reviewed journal *Blood Purification*. Each child showed gradual improvement following treatment and normalization or near normalization of kidney function at 60-day follow up.
- In October 2023 the Company received an Approvable Letter from CBER for use of the SCD-PED in children weighing 10 kilograms or more with AKI and sepsis or a septic condition requiring CKRT in the hospital ICU. The Company expects to complete the administrative action items outlined in the Approvable Letter in the coming weeks and to receive the formal approval letter between December 2023 and January 2024, with commercialization expected in the first quarter of 2024.
- With the license and distribution agreement in place with Nuwellis for the pediatric AKI indication, both teams are preparing for commercialization with an initial 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.

Additional SCD Indications

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

- In September 2023 the Company received Breakthrough Device Designation for the SCD for use in cardiorenal syndrome. This was only the ninth Breakthrough Device Designation granted by CBER since the program's inception in 2015. The Company plans to work in partnership with the University of Michigan to conduct additional clinical studies to gather further evidence to support a Premarket Approval (PMA) application.
- In October 2023 the Company received Breakthrough Device Designation for the SCD for use in hepatorenal syndrome. An ongoing pilot study in this indication at the University of Michigan is expected to provide valuable insight in the design and execution of a pivotal study.

Third Quarter Financial Results

Research and development (R&D) expenses for the third quarter of 2023 were \$1.1 million, compared with \$0.7 million for the third quarter of 2022, with the increase primarily resulting from higher clinical trial expenses and an increase in payroll and personnel expenses, partially offset by a decrease in external services.

General and administrative (G&A) expenses for the third quarter of 2023 were \$1.8 million, compared with \$1.0 million for the third quarter of 2022, with the increase primarily due to increases in insurance expense, higher costs associated with SEC reporting, increases in payroll-related expenses and higher account and tax expenses.

Other expense for the three months ended September 30, 2023 was \$4.5 million, compared with other expense of \$0.1 million for the three months ended September 30, 2022. The increase primarily resulted from a change in interest expense, change in fair value of convertible notes and loss on extinguishment of convertible notes, partially offset by the change in fair value of warrants liability and other income.

The net loss for the three months ended September 30, 2023 was \$7.4 million, or \$0.37 per share, compared with a net loss of \$1.9 million, or \$0.26 per share, for the three months ended September 30, 2022.

Nine Month Financial Results

R&D expenses for the first nine months of 2023 were \$4.9 million, compared with \$1.7 million for the first nine months of 2022. G&A expenses for the first nine months of 2023 were \$6.4 million, versus \$2.2 million for the first nine months of 2022.

Other expense for the nine months ended September 30, 2023 was \$5.1 million, compared with other income of \$0.1 million for the nine months ended September 30, 2022. The difference primarily resulted from an increase in interest expense, the change in fair value of convertible notes, the change in fair value of forward option-prepaid forward contracts and the loss on extinguishment of convertible notes, partially offset by the change in fair value of warrants liability, a gain on sales of recycled shares, the change in fair value of notes payable derivative liability and other income.

The net loss for the nine months ended September 30, 2023 was \$16.4 million, or \$1.02 per share, compared with a net loss of \$3.8 million, or \$0.52 per share, for the nine months ended September 30, 2022.

The Company reported cash of \$73,000 as of September 30, 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 May 2023 closed on the second tranche of \$2.2 million. The Company issued two convertible notes each for \$0.5 million in August 2023 and a third convertible note for \$0.5 million in September 2023.

About Hyperinflammation and the Selective Cytopheretic Device

Hyperinflammation is 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 or damaging to vital organs, and can result in multi-organ failure and even death. This is known as the cytokine storm.

The Selective Cytopheretic Device (SCD) is a medical device that employs immunomodulating technology to selectively target pro-inflammatory neutrophils and monocytes during CKRT and disrupt the cytokine storm that causes inflammation, organ failure and possibly death in critically ill patients. Unlike pathogen removal and other blood-purification tools, the device works with hemofiltration systems to enable precise fluid and solute balance control to selectively target and transition pro-inflammatory monocytes to reparative and promote activated neutrophils to be less inflammatory. SCD selectively targets the most highly activated pro-inflammatory neutrophils and monocytes. These cells are then returned back into the body through the blood, and the body is signaled to focus on repair. This unique immunomodulation approach may reverse injury and eliminate the need for CKRT going forward.

Clinical Results with the SCD in AKI

The SCD is a patented, cell-directed, extracorporeal device intended to be used as an adjunct therapy that selectively targets and transitions pro-inflammatory monocytes to promote reparative processes and reduce the acute inflammatory and damaging effects of activated neutrophils. Pooled analysis from two non-controlled clinical studies, SCD-PED-01 (funded by the FDA Office of Orphan Products Development) and SCD-PED-02, [showed](#) that pediatric patients ≥ 10 kg with AKI requiring CKRT who were treated with the SCD had no device-related serious adverse events or infections, a 77% reduction in mortality rate and no dialysis dependency at Day 60. The SCD-PED-01 (weight range ≥ 15 kg) and PED-02 (weight range ≥ 10 kg) studies demonstrated 75% and 83% reductions in mortality, respectively.

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 1995. These forward-looking statements include, without limitation, SeaStar Medical's expectations with respect to the ability of SCD to treat patients with AKI and other diseases; the expected regulatory approval process and timeline for commercialization; and the ability of SeaStar Medical to meet the expected timeline. 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 Medical may not be able to obtain regulatory approval of its SCD product candidates; (ii) the risk that SeaStar Medical 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-party 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, (viii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (ix) 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. 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.

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SeaStar Medical Holding Corporation

Condensed Consolidated Balance Sheets
(in thousands, except for share and per-share amounts)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets		
Cash	\$ 73	\$ 47
Other receivables	—	12
Prepaid expenses	2,172	2,977
Total current assets	<u>2,245</u>	<u>3,036</u>
Forward option-prepaid forward contracts, net	—	1,729
Other assets	2	2
Total assets	<u>\$ 2,247</u>	<u>\$ 4,767</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	\$ 5,042	\$ 1,927
Accrued expenses	1,481	2,245
Contingent upfront payment for license agreement	100	—
Notes payable, net of deferred financing costs	—	1,178
Convertible notes	4,405	—
Warrants liability	1,400	—
Total current liabilities	<u>12,428</u>	<u>5,350</u>
Notes payable, net of deferred financing costs	<u>5,722</u>	<u>7,652</u>
Total liabilities	<u>18,150</u>	<u>13,002</u>
Commitments and contingencies		
Stockholders' deficit (1)		
Common stock - \$0.0001 par value per share; 500,000,000 and 100,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 27,201,087 and 12,699,668 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	3	1
Additional paid-in capital	99,776	91,089
Accumulated deficit	<u>(115,682)</u>	<u>(99,325)</u>
Total stockholders' deficit	<u>(15,903)</u>	<u>(8,235)</u>
Total liabilities and stockholders' deficit	<u>\$ 2,247</u>	<u>\$ 4,767</u>

(1) Retroactively restated to present effect of the reverse recapitalization

SeaStar Medical Holding Corporation
Condensed Consolidated Statements of Operations
(in thousands, except for share and per-share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	\$ 1,107	\$ 727	\$ 4,898	\$ 1,678
General and administrative	1,829	1,042	6,369	2,215
Total operating expenses	<u>2,936</u>	<u>1,769</u>	<u>11,267</u>	<u>3,893</u>
Loss from operations	(2,936)	(1,769)	(11,267)	(3,893)
Other income (expense), net				
Interest expense	(224)	(123)	(882)	(483)
Change in fair value of convertible notes	(291)	—	(291)	—

Change in fair value of warrants liability	825	—	1,305	—
Change in fair value of notes payable derivative liability	—	—	—	578
Change in fair value of forward option-prepaid forward contracts	—	—	(1,723)	—
Loss on extinguishment of convertible notes	(4,949)	—	(4,949)	—
Gain on sale of recycled shares	—	—	1,306	—
Other income	149	1	149	1
Total other income (expense), net	<u>(4,490)</u>	<u>(122)</u>	<u>(5,085)</u>	<u>96</u>
Loss before provision for income taxes	(7,426)	(1,891)	(16,352)	(3,797)
Provision for income taxes	—	1	5	1
Net loss	<u>\$ (7,426)</u>	<u>\$ (1,892)</u>	<u>\$ (16,357)</u>	<u>\$ (3,798)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.26)</u>	<u>\$ (1.02)</u>	<u>\$ (0.52)</u>
Weighted-average shares outstanding, basic and diluted, retrospectively restated to present effect of the reverse recapitalization	<u>20,048,473</u>	<u>7,238,767</u>	<u>16,028,118</u>	<u>7,238,767</u>

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Source: SeaStar Medical Holding Corporation