



SeaStar Medical Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Updates

March 27, 2025

Webcast Today at 4:30 pm Eastern Time

DENVER, March 27, 2025 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life announced today financial results for the three months and year ended December 31, 2024, and provided business updates on key initiatives.

"Our significant accomplishments in 2024 position us well for a transformational year in 2025," said Eric Schlorff, SeaStar Medical CEO. "Last year, we not only received our first product approval for QUELIMMUNE and began our commercial launch, but we added 14 new clinical sites for our NEUTRALIZE AKI pivotal clinical trial, which has led to steady progress in enrollment with 94 of our anticipated 200 patients enrolled in the trial. We were also awarded our fourth Breakthrough Device Designation which should enable us to speed up the review and approval processes for our Selective Cytopheretic Device (SCD) therapy for these indications."

Mr. Schlorff continued, "And I am pleased to report that our momentum has continued this year. We have added new commercial customers and have a healthy pipeline of prospective customers in the process of adopting the QUELIMMUNE therapy. We activated two additional sites in our NEUTRALIZE AKI pivotal clinical trial, and the FDA approved a feasibility study for our SCD therapy as a treatment for cardiorenal syndrome as a bridge to left ventricular assist device. We secured additional capital to support planned operations and just last week the National Kidney Foundation announced that SeaStar Medical has been awarded its 2025 Corporate Innovator Award for our significant contribution to improving the lives of pediatric patients with AKI based on the approval and introduction of our QUELIMMUNE therapy. We are very pleased with our progress."

Key Business Highlights in 2024 and Beyond

During 2024, and into the first three months of 2025, SeaStar Medical's achievements have included the following:

- Granted approval by the FDA through a Humanitarian Device Exemption (HDE) for the QUELIMMUNE therapy for use in pediatric patients with acute kidney injury (AKI) due to sepsis or a septic condition requiring continuous renal replacement therapy (CRRT), an ultra-rare condition impacting approximately 4,000 pediatric patients annually.
- Launched the QUELIMMUNE therapy, achieving adoption by five customers to date, and expanded the pipeline of new customers in the process of adopting the QUELIMMUNE therapy.
- Successfully executed on the NEUTRALIZE AKI pivotal trial, enrolling 94 patients to date. Clinical sites, including the prestigious centers at Stanford Medical Center, Cleveland Clinic, and Mayo Clinic, are actively enrolling new patients in this trial that is designed to evaluate the safety and efficacy of the SCD therapy in 200 adults with AKI in the Intensive Care Unit (ICU) receiving CRRT.
- Awarded Breakthrough Device Designation to treat chronic systemic inflammation in end-stage renal disease (ESRD) patients who require chronic hemodialysis, also known as chronic dialysis.
- Announced that the National Institutes of Health awarded a \$3.6 million grant for a clinical trial to evaluate the SCD therapy as a bridging strategy to left ventricular assist device implantation in patients with chronic heart failure who have progressed to acute decompensated heart failure.
- Expanded awareness of the SCD therapy in the medical community through peer-reviewed publications in the European Journal of Heart Failure, Transplantation Direct, Nature Scientific Reports as well as presentations at the American Society of Nephrology's Kidney Week meeting.
- Awarded by the National Kidney Foundation the NKF 2025 Corporate Innovator Award for the significant contribution to improving the lives of pediatric patients with AKI based on the approval and introduction of the QUELIMMUNE therapy.
- Expanded the proprietary protection for the SCD through the award of U.S. Patent No. 11,866,730 with broad claims directed to methods of using the SCD therapy to treat subjects with inflammatory conditions and to process activated leukocytes and platelets, and through the Canadian Intellectual Property Office for issuance of Canadian Patent No. 2814586 covering broad claims for the SCD technology.
- Substantially improved the company's balance sheet through the addition of approximately \$31 million in capital as well as

a reduction in debt and liabilities.

Financial Results for the Year Ended December 31, 2024

Net revenue for the year ended December 31, 2024, was \$0.1 million, compared to no net revenue for the year ended December 31, 2023. The increase in net revenue is due to the initiation of sales of the QUELIMMUNE therapy in the third quarter of 2024, subsequent to its approval in the first quarter by the FDA to commercially sell the QUELIMMUNE pediatric selective cytopheretic device.

Research and development expenses for the years ended December 31, 2024, and 2023 were approximately \$9.1 million and \$6.0 million, respectively. The increase in research and development expenses was primarily driven by increases in clinical trial expenses and external services activities related to the NEUTRALIZE AKI Adult SCD clinical trial, as well as an increase in payroll and personnel expenses due to increased head count and equity grants.

General and administrative expenses for the years ended December 31, 2024, and 2023 were \$8.9 million and \$8.2 million, respectively. The increase in general and administrative expenses is due primarily to increased head count to support finance and commercial functions, increased legal expenses, and consulting expenses for various strategic and commercial endeavors, offset by a reduction in expenses for SEC related filings and compliance activities and certain external communications activities.

Other expenses, net for the years ended December 31, 2024, and 2023 was \$7.0 million and \$12.0 million, respectively, due primarily to non-cash changes. As a result of deleveraging the balance sheet during fiscal 2024, the only non-operating cash outflows, interest, declined to \$0.6 million for fiscal 2024 compared to \$1.1 million for fiscal 2023.

Net loss for the year ended December 31, 2024, was \$24.8 million compared to a net loss for the year ended December 31, 2023, of \$26.2 million. Net loss per basic and diluted share was \$6.63 for the year ended December 31, 2024, compared to \$30.26 for the year ended December 31, 2023.

Cash, cash equivalents and short term investments at December 31 2024, were \$1.8 million, which does not include proceeds from the company's \$6 million registered direct financing that was completed in on February 3, 2025.

SeaStar Medical Fourth Quarter and Year-End 2024 Financial Results Conference Call

Date/Time:	Thursday, March 27, at 4:30 p.m. ET / 1:30 p.m. PT
Webcast:	The live webcast and replay can be found here .
Conference ID:	2078693
Dial-in numbers:	1 (800) 715-9871 within the U.S. 1 (646) 307-1963 from outside the U.S.

A replay of the call will be available after 7:30 pm ET and can be accessed as follows:

- The webcast replay is available [here](#).
- The call replay number is 1 (609) 800-9909 and will be available through April 3, 2025.

About QUELIMMUNE

The QUELIMMUNE™ therapy is being commercialized for children with AKI and sepsis or septic condition weighing 10 kilograms or more who are being treated in the ICU with KRT. The QUELIMMUNE therapy was approved in February 2024 under a HDE application, having met the applicable criteria with clinical results showing safety and probable clinical benefit in a limited population of critically ill children with AKI who have few treatment options. In January 2025, SeaStar Medical was awarded the 2025 Corporate Innovator Award by the National Kidney Foundation its significant contribution to improving the lives of pediatric patients with AKI based on the approval and introduction of the QUELIMMUNE therapy.

About NEUTRALIZE-AKI Pivotal Trial

The [NEUTRALIZE-AKI](#) (NEUTrophil and monocyte deActivation via SeLective Cytopheretic Device – a randomIZEd clinical trial in Acute Kidney Injury) pivotal trial is evaluating the safety and efficacy of the SCD therapy in 200 adults with AKI in the ICU receiving CRRT. The trial's primary endpoint is a composite of 90-day mortality or dialysis dependency of patients treated with SCD in addition to CRRT as the standard of care, compared with the control group receiving only CRRT 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.

About Acute Kidney Injury (AKI) and Hyperinflammation

AKI is characterized by a sudden and temporary loss of kidney function and can be caused by a variety of conditions such as

COVID-19, sepsis, severe trauma and surgery. AKI can cause hyperinflammation, which is the overproduction or overactivity of inflammatory effector cells and other molecules that can be toxic. Damage resulting from this extreme hyperinflammation in AKI can progress to other organs, such as the heart or liver, and potentially to multi-organ dysfunction or even failure that could result in worse outcomes, including increased risk of death. Even after resolution, these patients may face complications including chronic kidney disease or end-stage renal disease requiring dialysis. Extreme hyperinflammation may also contribute to added healthcare costs, such as prolonged ICU stays and increased reliance on dialysis and mechanical ventilation.

About the SeaStar Medical Selective Cytopheretic Device Therapy

The Selective Cytopheretic Device (SCD) is a patented cell-directed extracorporeal device that employs immunomodulating technology to selectively target proinflammatory neutrophils and monocytes during CKRT and reduces the hyperinflammatory milieu including the cytokine storm. Unlike pathogen removal and other blood-purification tools, the SCD is integrated with CKRT hemofiltration systems to selectively target and transition proinflammatory monocytes to a reparative state and promote activated neutrophils to be less inflammatory. This unique immunomodulation approach may promote long-term organ recovery and eliminate the need for future KRT, including dialysis.

About SeaStar Medical

SeaStar Medical is a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life. SeaStar's first commercial product, QUELIMMUNE (SCD-PED), was approved in 2024 by the U.S. Food and Drug Administration (FDA). It is the only FDA approved product for the ultra-rare condition of life-threatening acute kidney injury (AKI) due to sepsis or a septic condition in critically ill pediatric patients. SeaStar's Selective Cytopheretic Device (SCD) therapy has been awarded Breakthrough Device Designation for four therapeutic indications by the FDA, enabling the potential for a speedier pathway to approval and preferable reimbursement dynamics at commercial launch. The company is currently conducting a pivotal trial of its SCD therapy in adult patients with AKI requiring continuous renal replacement therapy, a life-threatening condition with no effective treatment options that impacts over 200,000 adults in the U.S. annually.

For more information visit www.seastarmedical.com or visit us on [LinkedIn](#) or [X](#).

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 anticipated patient enrollment and the expansion of the clinical trial sites; the amount and timing of future QUELIMMUNE commercial sales; commercial acceptance of QUELIMMUNE; 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 current or future 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 secure additional financing on acceptable terms; (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 assumes 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.

Contact:

IR@SEASTARMED.COM

— Financial Tables to Follow —

	As of December 31, 2024	As of December 31, 2023
ASSETS		
Current assets		
Cash	\$ 1,819	\$ 176
Accounts receivable	112	—
Prepaid expenses	1,835	2,132
Total current assets	3,766	2,308
Other assets	892	1,205
Total assets	<u>\$ 4,658</u>	<u>\$ 3,513</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	\$ 3,046	\$ 4,372
Accrued expenses	3,188	1,523
Contract liabilities	—	100
Notes payable, net of deferred financing costs	574	565
Convertible notes, current portion	—	4,179
Liability classified warrants	33	2,307
Total current liabilities	6,841	13,046
Notes payable, net of deferred financing costs	—	4,143
Convertible notes, net of current portion	—	194
Total liabilities	<u>6,841</u>	<u>17,383</u>
Commitments and contingencies		
Stockholders' deficit		
Preferred stock - \$0.0001 par value, 10,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock - \$0.0001 par value per share; 500,000,000 shares authorized at December 31, 2024 and 2023; 5,977,246 and 2,016,045 shares issued and outstanding at December 31, 2024 and 2023, respectively	2	1
Additional paid-in capital	137,379	100,863
Accumulated deficit	(139,564)	(114,734)
Total stockholders' deficit	<u>(2,183)</u>	<u>(13,870)</u>
Total liabilities and stockholders' deficit	<u>\$ 4,658</u>	<u>\$ 3,513</u>

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

	Three Months Ended December 31, (unaudited)		Year Ended December 31,	
	2024	2023	2024	2023
Net revenue	\$ 67	\$ —	\$ 135	\$ —
Cost of goods sold	—	—	—	—
Gross profit	67	—	135	—
Operating expenses				
Research and development	2,738	1,175	9,105	5,973
General and administrative	2,096	1,762	8,872	8,237
Total operating expenses	<u>4,834</u>	<u>2,937</u>	<u>17,977</u>	<u>14,210</u>
Loss from operations	<u>(4,767)</u>	<u>(2,937)</u>	<u>(17,842)</u>	<u>(14,210)</u>
Total other income (expense)	348	(6,525)	(6,985)	(12,022)

Loss before income tax provision	(4,419)	(9,462)	(24,827)	(26,232)
Income tax provision (benefit)	—	(5)	3	—
Net loss	<u>\$ (4,419)</u>	<u>\$ (9,457)</u>	<u>\$ (24,830)</u>	<u>\$ (26,232)</u>
Net loss per share of common stock, basic and diluted	\$ (0.90)	\$ (6.17)	\$ (6.63)	\$ (30.26)
Weighted-average shares outstanding, basic and diluted	4,920,156	1,532,418	3,743,554	866,813

SeaStar Medical Holding Corporation
Condensed Consolidated Statement of Cash Flow
(in thousands, except for share and per-share amounts)

	Year Ended December 31	
	2024	2023
Cash flows from operating activities		
Net loss	\$ (24,830)	\$ (26,232)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of deferred financing costs	102	48
Change in fair value of convertible notes	6,145	5,380
Change in fair value of forward purchase agreement derivative liability	—	1,308
Change in fair value of liability classified warrants (exercised and outstanding)	697	(545)
Stock-based compensation	887	1,930
Loss on extinguishment of convertible notes	—	4,949
Change in operating assets and liabilities		
Account receivable	(112)	—
Other receivables	—	12
Prepaid expenses	297	(97)
Other assets	313	—
Accounts payable	(1,390)	2,445
Accrued expenses	1,984	517
Other liabilities	(100)	—
Net cash used in operating activities	<u>(16,007)</u>	<u>(10,285)</u>
Cash flows from financing activities		
Proceeds from issuance of convertible notes	979	8,000
Payment of convertible notes	(700)	(400)
Proceeds from issuance of notes payable	713	800
Payment of notes payable	(5,402)	(4,870)
Proceeds from issuance of shares, net of offering costs	17,441	4,742
Proceeds from exercise of convertible note warrants	853	592
Proceeds from issuance of pre-funded warrants	3,766	—
Proceeds from exercise of additional warrants	—	180
Payment of commitment fee - equity line of credit	—	(500)
Proceeds from sale of recycled shares	—	1,870
Net cash provided by financing activities	<u>17,650</u>	<u>10,414</u>
Net increase in cash	1,643	129
Cash, beginning of period	176	47
Cash, end of period	<u>\$ 1,819</u>	<u>\$ 176</u>

Supplemental disclosure of cash flow information

2024

2023

Cash paid for income taxes	\$	3	\$	—
Cash paid for interest	\$	553	\$	1,126
Exercise of liability classified warrants	\$	3,106	\$	—
Shares issued as payment of convertible notes	\$	10,210	\$	10,411
Shares issued to settle forward option-prepaid forward contracts	\$	—	\$	1,870
Board compensation settled in shares of common stock in-lieu-of-cash	\$	210	\$	—
Offering costs incurred but not paid	\$	45	\$	—
Issuance of convertible note warrants	\$	586	\$	2,705

###



Source: SeaStar Medical