SeaStar Medical Reports First Quarter 2025 Financial Results and Provides Business Updates

May 14, 2025

- *QUELIMMUNE adoption drives four-fold increase in sequential quarter net revenue*
- *NEUTRALIZE AKI trial exceeds 50% enrollment, triggers start of Interim Analysis*
- *Webcast Today at 4:30 pm Eastern Time*

DENVER, May 14, 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 ended March 31, 2025, and provided business updates on key initiatives.

“This is our second full quarter of the QUELIMMUNE launch and we believe our four-fold increase in revenue represents the strong commitment by our customers to improve outcomes in their pediatric patients with Acute Kidney Injury (AKI) with this potential life-saving therapy,” said Eric Schlorff, CEO of SeaStar Medical. “We also continue to attract new customers, including a nationally recognized children’s medical center that just completed Institutional Review Board (IRB) approvals and placed its first order for the QUELIMMUNE therapy.”

Mr. Schlorff continued, “Importantly, we are now looking to expand access to our promising technology into the adult AKI market, where this is also a very high unmet need. Our NEUTRALIZE-AKI trial in adult AKI patients is now 50% enrolled and we look forward to completing the trial and potentially filing the Premarket Approval (PMA) application in 2026. Our team is already actively engaging with health care providers in peer-to-peer nephrology venues to provide education and awareness of our Selective Cytopheretic Device (SCD) therapy. Given the same mechanism of action as QUELIMMUNE, albeit a larger device for the adult SCD therapy, we are excited to unveil results from this trial in 2026.”

Key Business Highlights in 2025

Since the beginning of 2025, SeaStar Medical’s key business updates include the following:

- Reported a four-fold increase in QUELIMMUNE net product revenue in the first quarter of 2025 to approximately $293 thousand compared to approximately $68 thousand in the fourth quarter of 2024.
- Broadened the QUELIMMUNE customer base, securing three new customers in 2025, including a nationally recognized children’s medical center that recently completed IRB approvals and placed an initial order for QUELIMMUNE therapy.
- Achieved 50% enrollment in the NEUTRALIZE-AKI pivotal trial, triggering the initiation of the prespecified, per protocol Interim Analysis by the trial’s independent Data Safety Monitoring Review Board (DSMB). SeaStar Medical anticipates the DSMB will report its findings to the company in the third quarter of 2025.
- Awarded two new Breakthrough Device Designations for use of the SCD therapy to treat systemic inflammatory response in 1) adult patients undergoing cardiac surgery and 2) pediatric patients undergoing cardiac surgery towards prevention of post-operative adverse complications and outcomes. This brings SeaStar Medical’s total Breakthrough Device Designations to six therapeutic indications, enabling a potential for a speedier pathway to approval and preferable reimbursement dynamics at commercial launch.
- Successfully completed an FDA site inspection of SeaStar Medical’s facility for QUELIMMUNE kitting operations, eliminating its contract manufacturer and enabling internal controls over the entire kitting process.
- Received from the FDA an Investigational Device Exemption (IDE) for a clinical trial to evaluate the SCD therapy as a bridging strategy to left ventricular assist device (LVAD) implantation in patients with chronic heart failure who have progressed to acute decompensated heart failure. This indication has been granted Breakthrough Device Designation by the FDA. It represents a market where there is serious unmet need for effective treatments.
- Awarded the NKF 2025 Corporate Innovator Award by the National Kidney Foundation for its significant contribution to improving the lives of pediatric patients with AKI based on the approval and introduction of the QUELIMMUNE therapy.

Financial Results for the First Quarter 2025

Net revenue for the three months ended March 31, 2025, was approximately $0.3 million, reflecting sales of the QUELIMMUNE

pediatric SCD therapy that was approved under a Humanitarian Device Exemption in February 2024 and launched as a commercial product by SeaStar Medical in July 2024.

Research and development expenses for the three months ended March 31, 2025, and 2024, were $2.4 million and $1.7 million, respectively. The increase in research and development expenses was primarily driven by an increase in clinical trial costs related to the NEUTRALIZE-AKI pivotal trial, as well as medical affairs and personnel costs, partially offset by a decline in costs for external services.

General and administrative expenses for the three months ended March 31, 2025, and 2024, were approximately $1.7 million and $2.3 million, respectively. The decrease in general and administrative expenses was the result of a decline in accounting-related costs, as well as legal-related and consulting expenses, partially offset by an increase in SEC-related expenses.

Other expenses (net) decreased approximately $8.8 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024. The decrease was primarily related to the retirement of outstanding debt obligations and the elimination of convertible notes and related warrants since March 31, 2024.

Net loss for the three months ended March 31, 2025, SeaStar Medical was approximately $3.8 million, or $0.44 per share on approximately 8.6 million weighted-average shares outstanding. This compared with a net loss of approximately $12.7 million, or $4.73 per share, on approximately 2.7 million weighted-average shares outstanding for the three months ended March 31, 2024.

The Company reported cash, cash equivalents and long-term investments of $5.3 million as of March 31, 2025, compared to $1.8 million as of December 31, 2024. In January 2025 the Company announced an approximately $6.0 million registered direct offering priced at-the-market.

SeaStar Medical First Quarter Financial Results Conference Call

Date/Time:	Wednesday, May 14, 2025, at 4:30 p.m. ET / 2:30 p.m. MT
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 May 20, 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 Renal Replacement Therapy (RRT). The QUELIMMUNE therapy was approved in February 2024 under a Humanitarian Device Exemption 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. SeaStar Medical commenced its commercial launch of the QUELIMMUNE therapy in July 2025. In January 2025, SeaStar Medical was awarded the 2025 Corporate Innovator Award by the National Kidney Foundation for 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 the SCD therapy 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 the 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 sepsis, severe trauma, surgery and COVID-19. AKI can cause destructive hyperinflammation, which is the overproduction or overactivity of inflammatory effector cells and other molecules that can be toxic. Damage resulting from this destructive 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 (ESRD) 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) therapy is designed as a disease-modifying device that neutralizes over-active immune cells and stops the cytokine storm that yields destructive hyperinflammation and creates a cascade of events that wreak havoc in the patient's body. The SCD therapy has broad applications in multiple acute and chronic kidney and cardiovascular diseases, representing nearly a million patients who today have no FDA-approved options for treating their disease. Unlike pathogen removal and other blood-purification tools, the SCD therapy is integrated with an existing continuous renal replacement therapy (CRRT) hemofiltration system 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, eliminate the need for future RRT, including dialysis, and prevent loss of life.

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 six 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 1955. 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 total addressable market for adult SCD applications; the ability of SeaStar Medical to gain market share and generate sales with respect to the total addressable market for adult SCD applications; 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.

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— Financial Tables to Follow —

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

	March 31, 2025	December 31, 2024
	(unaudited)	
ASSETS		
Current assets		
Cash	$ 5,296	$ 1,819
Accounts receivable, net	110	112
Inventory	44	—
Prepaid expenses	1,334	1,835
Total current assets	6,784	3,766
Other assets	813	892
Total assets	$ 7,597	$ 4,658
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities		
Accounts payable	$ 3,397	$ 3,046
Accrued expenses	3,255	3,188
Notes payable, net of deferred financing costs	363	574
Liability classified warrants	17	33
Total current liabilities	7,032	6,841
Total liabilities	7,032	6,841
Commitments and contingencies (Note 10)		
Stockholders' equity/(deficit)		
Preferred stock - $0.0001 par value, 10,000,000 shares authorized at March 31, 2025 and December 31, 2024; no shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock - $0.0001 par value per share; 450,000,000 and 500,000,000 shares authorized at March 31, 2025 and December 31, 2024, respectively; 9,257,763 and 5,977,246 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	2	2
Additional paid-in capital	143,899	137,379
Accumulated deficit	(143,336)	(139,564)
Total stockholders' equity/(deficit)	565	(2,183)
Total liabilities and stockholders' equity/(deficit)	$ 7,597	$ 4,658

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

	Three Months Ended March 31,	
	2025	2024
Net revenue	$ 293	$ —
Cost of goods sold	—	—
Gross profit	293	—
Operating expenses		
Research and development	2,431	1,697
General and administrative	1,684	2,253
Total operating expenses	4,115	3,950
Loss from operations	(3,822)	(3,950)
Other income (expense)		

Interest expense	(11)	(143)
Interest income	48	—
Change in fair value of convertible notes	—	(5,758)
Change in fair value of liability classified warrants	16	(2,846)
Total other income (expense), net	53	(8,747)
Loss before provision for income taxes	(3,769)	(12,697)
Provision for income taxes	3	—
Net loss	$ (3,772)	$ (12,697)
Net loss per share of common stock, basic and diluted	$ (0.44)	$ (4.73)
Weighted-average shares outstanding, basic and diluted	8,617,932	2,684,243

SeaStar Medical Holding Corporation
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (3,772)	$ (12,697)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of deferred financing costs	11	27
Change in fair value of convertible notes (issued, converted and outstanding)	—	5,758
Change in fair value of liability classified warrants (exercised and outstanding)	(16)	2,846
Stock-based compensation	167	434
Change in operating assets and liabilities		
Accounts receivables, net	2	—
Inventory	(44)	—
Prepaid expenses	501	614
Other assets	79	2
Accounts payable	351	(493)
Accrued expenses	67	21
Net cash used in operating activities	(2,654)	(3,488)
Cash flows from financing activities		
Proceeds from issuance of convertible notes	—	979
Proceeds from issuance of shares, net of issuance costs	1,566	4,543
Proceeds from sale of pre-funded warrants	4,785	3,769
Proceeds from exercise of warrants	2	853
Payment of notes payable	(222)	(1,813)
Net cash provided by financing activities	6,131	8,331
Net increase in cash	3,477	4,843
Cash, beginning of period	1,819	176
Cash, end of period	$ 5,296	$ 5,019

Supplemental disclosure of cash flow information	Three Months Ended March 31,	
	2025	**2024**
Cash paid for interest	$ —	$ —
Exercise of pre-funded warrants	$ —	$ 3,106
Shares issued as payment of convertible notes	$ —	$ 9,387

Issuance of convertible note warrants	$	—	$	586

Source: SeaStar Medical