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

November 13, 2025

Business highlights include:

- *Three new top-rated children's hospitals adopt QUELIMMUNE therapy for ultra-rare pediatric Acute Kidney Injury (AKI)*
- *Commercial use of QUELIMMUNE therapy demonstrates positive survival results as reported from the QUELIMMUNE SAVE Surveillance Registry*
- *New clinical sites added to expand adult NEUTRALIZE-AKI pivotal trial enrollment*
- *Strengthened the balance sheet, raising $12.4 million to fund future operations*
- *Webcast call today at 4:30 p.m. Eastern Time*

DENVER, Nov. 13, 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 September 30, 2025, and provided business updates on key initiatives.

"In the third quarter, we made strong progress on multiple fronts which we believe position us well for our future growth," said Eric Schlorff, CEO of SeaStar Medical. "We added three top-ranked children's medical centers to our growing customer base and also reported very impressive survival results for the use of the QUELIMMUNE therapy in the treatment of 21 pediatric patients in a commercial setting. And we are gaining traction in the market. In the first half of the fourth quarter, we are extremely pleased to see very strong QUELIMMUNE sales, with orders to date already exceeding orders for the entire third quarter."

Mr. Schlorff continued, "In addition, we completed the interim analysis, enabling us to understand early safety data and trends toward efficacy for our NEUTRALIZE-AKI pivotal clinical trial of the selective cytopheretic device (SCD) therapy in adult patients with AKI. We also continued to add new clinical sites to ensure we meet our enrollment target by the end of 2026. In addition, we continued our disciplined effort to reduce costs while achieving strong operational results and we raised over $12 million to strengthen our balance sheet and extend our financial runway."

Key Business Highlights

Since the beginning of the third quarter, SeaStar Medical's key business updates include the following:

- Broadened the QUELIMMUNE customer base, securing three new customers from top-rated children's hospitals and building increased depth in the number of customers ordering QUELIMMUNE, with fourth quarter orders to date already exceeding third quarter orders.
- Presented at the 5th International Symposium on Acute Kidney Injury in Children real-world pediatric patient survival data from the commercial use of the QUELIMMUNE therapy based on early results from the SAVE Surveillance Registry of 21 critically ill pediatric patients with life-threatening AKI and sepsis or a septic condition in the commercial setting. The preliminary results showed no device related safety events with the QUELIMMUNE therapy with 76% of patients surviving through 60 days and 71% surviving through 90 days. These new data are on track to validate a 50% reduction in loss of life compared to historical data, as reported previously in Kidney Medicine.
- Announced a positive signal toward efficacy and zero device-related safety issues from the interim analysis of the NEUTRALIZE-AKI pivotal clinical trial by the independent Data Safety Monitoring Review Board (DSMB). Based on the analysis by the DSMB, the total enrollment for the trial has been adjusted from 200 to approximately 339 patients. The Company anticipates completing enrollment near the end of 2026, based on the current enrollment rate of clinical trial sites and the addition of several new sites in the NEUTRALIZE-AKI trial.
- Enrolled 21 additional patients in the NEUTRALIZE-AKI pivotal clinical trial, bringing total enrollment to 146 of an anticipated 339 total patients.
- Initiated its first clinical site for the NEUTRALIZE-CRS clinical trial of the SCD therapy to treat patients with acute chronic systolic heart failure (CHF) with cardiorenal syndrome (CRS) awaiting left ventricular assist device (LVAD) implantation. The trial is expected to enroll 20 patients in the ICU setting with CHF and CRS who are ineligible for LVAD or heart transplantation. If successful, this study could pave the way for a marketing application to the U.S. Food and Drug Administration (FDA).
- Raised $12.4 million through equity offerings priced at the market and through the exercise of 2.8 million warrants in the

third quarter. The additional infusion of capital strengthens the balance sheet and enables the company to focus its cash resources on the development of its SCD therapy for adult patients with AKI requiring CRRT, an annual U.S. market opportunity that is 50 times larger than the U.S. pediatric AKI market.

Financial Results for the Third Quarter 2025

Net revenue for the three months ended September 30, 2025, and 2024, was approximately $0.2 million and $0.1 million, respectively, 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.

Cost of goods sold for the three months ended September 30, 2025, and 2024, was $14 thousand and $0 respectively. QUELIMMUNE units sold during the three months ended September 30, 2024, were expensed to research and development, consistent with U.S. GAAP, as they were acquired prior to commercialization of QUELIMMUNE.

Research and development expenses for the three months ended September 30, 2025, and 2024, were $1.9 million and $2.3 million, respectively. The decrease in research and development expenses was primarily driven by a decline in consulting expenses and personnel costs, partially offset by increased clinical research and development costs.

General and administrative expenses for the three months ended September 30, 2025, and 2024, were approximately $1.9 million and $2.2 million, respectively. The decrease in general and administrative expenses was the result of lower franchise tax expense, and a decline in legal and consulting related fees, partially offset by higher audit fees.

Other income (net) for the three months ended September 30, 2025, was approximately $0.1 million compared to other expense of approximately $0.1 million for the three months ended September 30, 2024. The increase was primarily related to an increase in interest income and decline in interest expense.

Net loss for the three months ended September 30, 2025, was approximately $3.5 million, or $0.13 per share on approximately 26.4 million weighted-average shares outstanding. This compares with a net loss of approximately $4.5 million, or $1.10 per share, on approximately 4.1 million weighted-average shares outstanding for the three months ended September 30, 2024.

Cash at September 30, 2025, was $13.8 million, compared to $1.8 million at December 31, 2024.

SeaStar Medical Third Quarter Financial Results Conference Call

Date/Time:	Thursday, November 13, 2025, at 4:30 p.m. ET / 2:30 p.m. MT
Webcast:	The live webcast and replay can be found here.
Register for the call:	Preregistration is required to attend the live call and can be accessed here. A pin code and dial in number will be provided with registration.

A replay of the call will be available after 7:30 p.m. ET and can be accessed here.

About QUELIMMUNE

The QUELIMMUNE (SCD-PED) therapy is SeaStar Medical's first commercial product based on its patented Selective Cytopheretic Device (SCD) technology. The QUELIMMUNE™ therapy is being commercialized for children (age 22 or younger) with AKI and sepsis or a septic condition weighing 10 kilograms or more who are on antibiotics and being treated in the ICU with Renal Replacement Therapy (RRT). It was approved in February 2024 under a Humanitarian Device Exemption application that requires medical institutions to also participate in the SAVE Surveillance Registry and complete Institutional Review Board approvals prior to adoption and use of the QUELIMMUNE therapy. This prolongs the adoption timeline by medical institutions, but provides important data on the use of QUELIMMUNE in the "real-world" setting.

Data from two clinical studies of the QUELIMMUNE therapy, published in Kidney Medicine, showed a 77% survival rate in patient treated with QUELIMMUNE versus standard of care, representing an approximate 50% reduction in loss of life compared to historical data in this patient population. No dialysis was required for survivors and 87.5% of survivors had normal kidney function at Day 60 after ICU discharge.

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 339 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 (SCD) Therapy

The 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 is designed for broad applications in multiple acute and chronic kidney and cardiovascular diseases, representing 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 CRRT, 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. The QUELIMMUNE (SCD-PED) therapy is SeaStar Medical's first commercial product based on its patented Selective Cytopheretic Device (SCD) technology. The QUELIMMUNE (SCD-PED) therapy 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 Medical'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 (CRRT), 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)

	September 30, 2025	December 31, 2024
	(unaudited)	
ASSETS		
Current assets		
Cash	$ 13,763	$ 1,819
Accounts receivable, net of allowance for credit losses of $35 and $0, respectively	221	112
Inventory	83	—
Prepaid expenses	807	1,835
Total current assets	14,874	3,766
Other assets	656	892
Total assets	$ 15,530	$ 4,658
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities		
Accounts payable	$ 2,018	$ 3,046
Accrued expenses	2,047	3,188
Notes payable, net of deferred financing costs	—	574
Liability classified warrants	1	33
Total current liabilities	4,066	6,841
Total liabilities	4,066	6,841
Commitments and contingencies (Note 10)		
Stockholders' equity/(deficit)		
Preferred stock - $0.0001 par value, 10,000,000 shares authorized at September 30, 2025 and December 31, 2024; no shares issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock - $0.0001 par value per share; 450,000,000 and 500,000,000 shares authorized at September 30, 2025 and December 31, 2024, respectively; 34,096,420 and 5,977,246 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	3	2
Additional paid-in capital	160,271	137,379
Accumulated deficit	(148,810)	(139,564)
Total stockholders' equity/(deficit)	11,464	(2,183)
Total liabilities and stockholders' equity/(deficit)	$ 15,530	$ 4,658

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net revenue	$ 183	$ 68	$ 814	$ 68
Cost of goods sold	14	—	41	—
Gross profit	169	68	773	68
Operating expenses				
Research and development	1,850	2,336	5,318	6,367
General and administrative	1,898	2,188	4,614	6,776

Total operating expenses	3,748	4,524	9,932	13,143
Loss from operations	(3,579)	(4,456)	(9,159)	(13,075)
Other income (expense)				
Interest income	107	58	200	82
Interest expense	—	(272)	(18)	(497)
Other financing costs	—	—	(298)	—
Change in fair value of convertible notes	—	—	—	(6,145)
Change in fair value of warrants liability	—	192	32	(773)
Total other income (expense), net	107	(22)	(84)	(7,333)
Loss before provision for income taxes	(3,472)	(4,478)	(9,243)	(20,408)
Provision for income taxes	—	—	3	3
Net loss	$ (3,472)	$ (4,478)	$ (9,246)	$ (20,411)
Net loss per share of common stock, basic and diluted	$ (0.13)	$ (1.10)	$ (0.60)	$ (6.10)
Weighted-average shares outstanding, basic and diluted	26,393,400	4,086,871	15,512,119	3,348,490

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

	Nine Months Ended September 30,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (9,246)	$ (20,411)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of deferred financing costs	18	102
Change in fair value of convertible notes (issued, converted and outstanding)	—	6,145
Change in fair value of liability classified warrants (exercised and outstanding)	(32)	773
Shares issued for the standby equity purchase agreement commitment fee	298	—
Stock-based compensation	554	675
Change in operating assets and liabilities		
Accounts receivables, net	(109)	(68)
Inventory	(83)	—
Prepaid expenses	1,028	666
Other assets	236	235
Accounts payable	(1,028)	(858)
Accrued expenses	(1,141)	932
Other liabilities	—	495
Net cash used in operating activities	(9,505)	(11,314)
Cash flows from financing activities		
Proceeds from issuance of convertible notes	—	979
Payment of convertible notes	—	(700)
Proceeds from issuance of shares, net of offering costs	14,337	13,582
Proceeds from exercise of convertible note warrants	1,818	853
Proceeds of pre-funded warrants	5,886	3,766
Proceeds from exercise of warrants		—
Payment of notes payable	(592)	(5,260)
Net cash provided by financing activities	21,449	13,220
Net increase in cash	11,944	1,906
Cash, beginning of period	1,819	176
Cash, end of period	$ 13,763	$ 2,082
Supplemental disclosure of cash flow information		

Cash paid for interest	$	—	$	523
Exercise of liability classified warrants	$	—	$	3,106
Shares issued from conversion of convertible notes	$	—	$	10,210
Board compensation settled in shares of common stock in-lieu of cash	$	—	$	210
Issuance of convertible note warrants	$	—	$	586