



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

August 13, 2025

Business highlights include:

- *Adult NEUTRALIZE-AKI trial enrolls 31 new patients, now over 60% enrolled*
- *Three new top-rated children's hospitals adopt QUELIMMUNE therapy for ultra-rare pediatric Acute Kidney Injury (AKI)*
- *Positive survival results reported from QUELIMMUNE SAVE Surveillance Registry*
- *Webcast call today at 4:30 p.m. Eastern Time*

DENVER, Aug. 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 June 30, 2025, and provided business updates on key initiatives.

"Since the beginning of the second quarter, we have made great progress on several fronts," said Eric Schlorff, CEO of SeaStar Medical. "We enrolled 31 additional patients in the NEUTRALIZE-AKI trial, reported three new QUELIMMUNE customers from top-rated U.S.-based children's hospitals, announced positive survival results for the first 20 pediatric patients treated in a commercial setting with QUELIMMUNE from the SAVE Surveillance Registry, and raised additional capital to shore up our balance sheet."

Mr. Schlorff continued, "We are now focused on several important upcoming, value-creating milestones. These include the interim results for the first 100 patients in the NEUTRALIZE-AKI trial, presentation of additional data from the SAVE Surveillance Registry, and the onboarding of other notable children's hospitals to our customer list. Also, assuming a successful outcome from our NEUTRALIZE-AKI trial, in 2026 we plan to file our Pre-Marketing Approval (PMA) application for our Selective Cytopheretic Device (SCD) therapy as an organ-sparing and life-saving treatment for adult patients with Acute Kidney Injury (AKI) requiring continuous renal replacement therapy (CRRT)."

Key Business Highlights

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

- Achieved the 50% patient enrollment milestone (100 patients) in the NEUTRALIZE-AKI pivotal clinical trial, triggering the interim analysis, and subsequently increased total enrollment to 125 of 200 total anticipated patients. Recommendations from the per protocol prespecified interim analysis by the trial's independent Data Safety Monitoring Review Board (DSMB) are expected to be provided to the Company in the third quarter of 2025.
- Broadened the QUELIMMUNE customer base, securing three new customers from top-rated children's hospitals.
- Reported positive survival data from the SAVE Surveillance Registry, evaluating the QUELIMMUNE therapy in the first 20 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 and 75% of patients survived through 28 days. These new data are on track to validate or potentially exceed a 50% reduction in loss of life compared to historical data, as reported previously in [Kidney Medicine](#).
- Received agreement from the U.S. Centers for Medicare & Medicaid Services (CMS) to pay for certain expenses incurred by medical centers treating patients covered by Medicare or Medicaid who are enrolled in the NEUTRALIZE-CRS investigational clinical trial – a rare award with less than 100 clinical trials covered annually.
- Announced that a \$2 million United States Department of Defense (DoD) grant was awarded to The Autonomous Reanimation and Evacuation (AREVA) Research Institute to support a three-year research study that will explore the application of SeaStar Medical's SCD therapy to reduce hyperinflammation in warfighters after severe burns, inhalation injury, and infection. The grant is one of four selected out of 160 total submissions by the 2024 Military Burn Research Program and represents cutting-edge research for extracorporeal immunomodulation to reduce inflammation after severe burns, inhalation injury, and septicemia.
- Implemented additional cost-saving measures to increase the company's financial runway and 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.
- Raised \$12.4 million in gross proceeds, before deducting offering-related expenses, through a public offering in June 2025

and two registered direct offerings in July and August 2025. These offerings were priced at-the-market and proceeds will support the company's ongoing operations into 2026.

Financial Results for the Second Quarter 2025

Net revenue for the three months ended June 30, 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 June 30, 2025, and 2024, were \$1.0 million and \$2.3 million, respectively. The decrease in research and development expenses was primarily driven by a decline in preclinical and clinical trial expenses, consulting expenses, and personnel costs.

General and administrative expenses for the three months ended June 30, 2025, and 2024, were approximately \$1.0 million and \$2.3 million, respectively. The decrease in general and administrative expenses was the result of a decline in audit and accounting related fees, Directors' compensation, certain Securities and Exchange Commission (SEC) fees, personnel costs, and consultant expenditures.

Other expenses (net) increased approximately \$1.7 million for the three months ended June 30, 2025, compared to the three months ended June 30, 2024. The increase was primarily related the decline in favorable gains from the change in fair value of liability classified warrants, a one-time financing fee, offset by the retirement of outstanding debt obligations since March 31, 2024.

Net loss for the three months ended June 30, 2025, was approximately \$2.0 million, or \$0.18 per share on approximately 11.3 million weighted-average shares outstanding. This compares with a net loss of approximately \$3.2 million, or \$1.03 per share, on approximately 3.2 million weighted-average shares outstanding for the three months ended June 30, 2024.

Cash at June 30, 2025 was \$6.3 million, compared to \$1.8 million at December 31, 2024. In July and August 2025 the Company raised an additional \$8.4 million in two registered direct offerings.

SeaStar Medical Second Quarter Financial Results Conference Call

Date/Time: Wednesday, August 13, 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 p.m. 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 August 20, 2025.

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 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 (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'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 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 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)

	June 30, 2025	December 31, 2024
	(unaudited)	
ASSETS		
Current assets		
Cash	\$ 6,302	\$ 1,819
Accounts receivable, net of allowance for credit losses of \$8 and \$0, respectively	217	112
Inventory	77	—
Prepaid expenses	1,051	1,835
Total current assets	7,647	3,766
Other assets	736	892
Total assets	\$ 8,383	\$ 4,658
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities		
Accounts payable	\$ 3,158	\$ 3,046
Accrued expenses	1,883	3,188
Notes payable, net of deferred financing costs	—	574
Liability classified warrants	1	33
Total current liabilities	5,042	6,841
Total liabilities	5,042	6,841
Commitments and contingencies (Note 10)		
Stockholders' equity/(deficit)		
Preferred stock - \$0.0001 par value, 10,000,000 shares authorized at June 30, 2025 and December 31, 2024; no shares issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock - \$0.0001 par value per share; 450,000,000 and 500,000,000 shares authorized at June 30, 2025 and December 31, 2024, respectively; 17,343,269 and 5,977,246 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	2	2
Additional paid-in capital	148,677	137,379
Accumulated deficit	(145,338)	(139,564)
Total stockholders' equity/(deficit)	3,341	(2,183)
Total liabilities and stockholders' equity/(deficit)	\$ 8,383	\$ 4,658

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

Three Months Ended June 30,		Six Months Ended June 30,	
2025	2024	2025	2024

Net revenue	\$ 338	\$ —	\$ 631	\$ —
Cost of goods sold	27	—	27	—
Gross profit	311	—	604	—
Operating expenses				
Research and development	1,037	2,334	3,468	4,031
General and administrative	1,030	2,335	2,716	4,588
Total operating expenses	2,067	4,669	6,184	8,619
Loss from operations	(1,756)	(4,669)	(5,580)	(8,619)
Other income (expense)				
Interest income	45	25	93	25
Interest expense	(9)	(82)	(18)	(225)
Other financing costs	(298)	—	(298)	—
Change in fair value of convertible notes	—	(387)	—	(6,145)
Change in fair value of warrants liability	16	1,880	32	(966)
Total other income (expense), net	(246)	1,436	(191)	(7,311)
Loss before provision for income taxes	(2,002)	(3,233)	(5,771)	(15,930)
Provision for income taxes	—	3	3	3
Net loss	\$ (2,002)	\$ (3,236)	\$ (5,774)	\$ (15,933)
Net loss per share of common stock, basic and diluted	\$ (0.18)	\$ (1.03)	\$ (0.58)	\$ (5.36)
Weighted-average shares outstanding, basic and diluted	11,329,517	3,154,782	9,981,215	2,975,248

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

	Six Months Ended June 30,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (5,774)	\$ (15,933)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of deferred financing costs	18	57
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)	966
Shares issued for the standby equity purchase agreement commitment fee	298	—
Stock-based compensation	264	475
Change in operating assets and liabilities		
Accounts receivables, net	(105)	—
Inventory	(77)	—
Prepaid expenses	784	897
Other assets	156	152
Accounts payable	112	(255)
Accrued expenses	(1,305)	689
Other liabilities	—	495
Net cash used in operating activities	<u>(5,661)</u>	<u>(6,312)</u>
Cash flows from financing activities		
Proceeds from issuance of convertible notes	—	979
Payment of convertible notes	—	(700)
Proceeds from issuance of shares	5,154	4,492
Proceeds of pre-funded warrants	5,580	3,766

Proceeds from exercise of warrants	2	853
Payment of notes payable	(592)	(2,075)
Net cash provided by financing activities	10,144	7,315
Net increase in cash	4,483	1,003
Cash, beginning of period	1,819	176
Cash, end of period	\$ 6,302	\$ 1,179

Supplemental disclosure of cash flow information

Cash paid for interest	\$ —	\$ 439
Exercise of liability classified warrants	\$ —	\$ 3,106
Shares issued from conversion of convertible notes	\$ —	\$ 10,210
Issuance of convertible note warrants	\$ —	\$ 586



Source: SeaStar Medical