SeaStar Medical Reports Second Quarter 2026 Financial Results and Provides Business Updates

August 12, 2026

Added 3 top-rated children's hospitals to QUELIMMUNE ® pediatric acute kidney injury (AKI) customer base, increasing net revenue 82% versus second quarter 2025

Advanced enrollment in the NEUTRALIZE-AKI pivotal clinical trial in adult patients with AKI

Obtained ICD-10-PCS codes to enable standardized inpatient hospital billing for its selective cytopheretic device (SCD) therapy, including QUELIMMUNE

Webcast today at 4:30 pm Eastern Time

DENVER, Aug. 12, 2026 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company focused on transformational treatments for critically ill patients facing organ failure and potential loss of life, announced today financial results for the three months ended June 30, 2026, and provided business updates on key initiatives.

"The enthusiasm for the use of our QUELIMMUNE therapy is resonating broadly throughout the pediatric critical care community," said Eric Schlorff, CEO of SeaStar Medical. "We believe our continued QUELIMMUNE revenue growth bodes well for our future potential opportunity in the adult AKI market that is 50 times larger than the current pediatric market in the U.S."

Mr. Schlorff continued, "We are keenly focused on achieving our enrollment target of 339 adult AKI patients in the NEUTRALIZE-AKI trial, and we are working with the FDA on our modular Premarket Approval (PMA) application for our SCD therapy as an organ-sparing and life-saving treatment for the adult patient population. With strong gross margins for QUELIMMUNE and universal ICD-10-PCS codes already established for our SCD therapies, we believe this first-in-class therapy for the treatment of adult patients with AKI has clear potential to both save lives and create significant shareholder value, should we obtain FDA approval."

Key Business Highlights

SeaStar Medical's achievements since the beginning of the second quarter of 2026 include the following:

- Expanded the use of QUELIMMUNE (SCD-PED) therapy for ultra-rare pediatric AKI, adding 3 new customers from top-rated children's hospitals, bringing the total customer base to 20 and building increased depth in customer orders. This led to second quarter 2026 net revenue of $0.6 million for QUELIMMUNE product sales, an increase of 82% versus the second quarter of 2025.

- Advanced enrollment in the NEUTRALIZE-AKI pivotal clinical trial evaluating the SCD therapy as a potential treatment of adult patients with AKI in the ICU receiving continuous renal replacement therapy. The trial has enrolled 223 of 339 patients to date. Completion of enrollment is anticipated around year end or into the first quarter of 2027, which would enable a PMA application to the FDA near the end of 2027, pending a positive outcome of the trial.

- Received from the Centers for Medicare & Medicaid Services (CMS) dedicated International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) codes. These codes enable administrative, billing, and statistical reporting for the use of SeaStar Medical's SCD therapy in patients with AKI requiring renal replacement therapy in the inpatient hospital setting. The new ICD-10-PCS codes are expected to take effect on October 1, 2026.

- Sponsored and participated in the KidneyBee Summit 2026. The Summit, which occurs annually, is a highly specialized, interdisciplinary conference that brings together nurses, advanced practice providers, and physicians from across the country. Its core importance stems from tackling the exact systemic failures that leave pediatric kidney failure under-recognized.

- Assembled leading experts in the treatment of pediatric AKI to speak at the SeaStar Medical educational webinar, "Rethinking Pediatric Sepsis-Associated AKI," that brought together practicing pediatric nephrologists, critical care physicians, advanced practice providers, nurses, and critical care teams to learn more about pediatric sepsis-associated AKI and the use of the QUELIMMUNE therapy.

Financial Results for the Second Quarter 2026

Net revenue for the three months ended June 30, 2026, was approximately $0.6 million reflecting increased demand for the QUELIMMUNE therapy. This compared to net revenue of approximately $0.3 million for the three months ended June 30, 2025.

Cost of goods sold for the three months ended June 30, 2026, and 2025, was $54 thousand and $27 thousand reflecting gross margins of 91% and 92% for the three months ended June 30, 2026, and 2025, respectively.

Research and development expenses for the three months ended June 30, 2026, and 2025, were $2.5 million and $1.0 million, respectively. The increase in research and development expenses was primarily driven by increased clinical trial expenses and personnel costs.

General and administrative expenses for the three months ended June 30, 2026, and 2025, were approximately $1.8 million and $1.0 million, respectively. The increase in general and administrative expenses was the result of an increase in compensation costs, legal and professional fees, and certain Securities and Exchange Commission (SEC) related expenses.

Other income (net) was $0.1 million for the three months ended June 30, 2026, compared to other expense (net) of $0.2 million for the three months ended June 30, 2025. The change was primarily related to a reduction in financing fees and increased interest income.

Net loss for the three months ended June 30, 2026, was approximately $3.7 million, or $0.91 per share on approximately 4.1 million weighted-average shares outstanding. This compares with a net loss of approximately $2.0 million, or $1.77 per share, on approximately 1.1 million weighted-average shares outstanding for the three months ended June 30, 2025.

Cash at June 30, 2026, was $7.0 million, compared to $12.0 million at December 31, 2025.

SeaStar Medical Second Quarter Financial Results Conference Call

Date/Time:	Wednesday, August 12, 2026, 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 being commercialized for children with AKI and sepsis or septic condition weighing 10 kilograms or more who are on antibiotics and being treated in the ICU with RRT. It was approved in February 2024 under a Humanitarian Device Exemption application.

Data from two clinical trials 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 February 2026, data published in the prestigious, peer-reviewed journal, *Pediatric Nephrology*, highlighted the early experience from the QUELIMMUNE SAVE Registry, a post-approval surveillance registry, evaluating the role of the QUELIMMUNE therapy in the treatment of critically ill pediatric patients with life-threatening Acute Kidney Injury (AKI) and sepsis requiring renal replacement therapy. Observations from the first 21 pediatric patients with AKI and sepsis requiring renal replacement therapy showed no device-related adverse events or infections and no reports of immunosuppressive effects by the device. In addition, preliminary outcomes analyses show a 76% survival rate at Day 28 and Day 60, and a 71% survival rate at Day 90. These new data are on track to validate a 50% reduction in patient mortality at 60 days compared to historical data, similar to what was observed in the registration study reported in *Kidney Medicine*.

The patented technology behind QUELIMMUNE is known as the Selective Cytopheretic Device (SCD) therapy and has broad applications for treating the destructive hyperinflammation that shuts down organ function and causes loss of life.

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 RRT 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 continuous RRT, including dialysis, and prevent loss of life.

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 continuous RRT. 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 continuous RRT as the standard of care, compared with the control group receiving only continuous RRT 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 severe infections or other septic conditions, severe trauma, surgery, and organ failures. 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 SeaStar Medical

SeaStar Medical is a commercial-stage healthcare company focused on transformational treatments for critically ill patients facing organ failure and potential loss of life. SeaStar Medical'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 requiring renal replacement therapy (RRT) 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 the NEUTRALIZE-AKI pivotal clinical 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 our future potential opportunity in the adult AKI market; the size of the adult AKI market compared to the pediatric market; commercial acceptance of QUELIMMUNE; the ability of SCD to treat patients with AKI and other diseases; ; the anticipated timing of regulatory submissions; the ability to meet our enrollment targets; the ability to create shareholder value; 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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SeaStar Medical Holding Corporation
Condensed Consolidated Balance Sheets
(in thousands, except for share and per-share amounts)

	June 30, 2026	December 31, 2025
	(unaudited)	
ASSETS		
Current assets		
Cash	$ 6,959	$ 11,980
Accounts receivable, net of allowance for credit losses of $2 and $3, respectively	208	237
Inventory	77	66
Prepaid expenses	984	1,297
Total current assets	8,228	13,580
Other assets	421	578
Total assets	$ 8,649	$ 14,158
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities		
Accounts payable	$ 750	948
Accrued expenses	3,468	2,268
Notes payable, net of deferred financing costs	134	525
Liability classified warrants	1	1
Total current liabilities	4,353	3,742
Total liabilities	4,353	3,742
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock - $0.0001 par value, 10,000,000 shares authorized at June 30, 2026 and December 31, 2025; no shares issued and outstanding at June 30, 2026 and December 31, 2025	—	—
Common stock - $0.0001 par value per share; 425,000,000 and 450,000,000 shares authorized at June 30, 2026 and December 31, 2025, respectively; 4,259,842 and 3,844,613 shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	4	4
Additional paid-in capital	163,257	162,126
Accumulated deficit	(158,965)	(151,714)
Total stockholders' equity	4,296	10,416
Total liabilities and stockholders' equity	$ 8,649	$ 14,158

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,	
	2026	2025	2026	2025
Net revenue	$ 615	$ 338	$ 1,110	$ 631
Cost of goods sold	54	27	100	27
Gross profit	561	311	1,010	604
Operating expenses				
Research and development	2,520	1,037	4,864	3,468
General and administrative	1,832	1,030	3,540	2,716
Total operating expenses	4,352	2,067	8,404	6,184
Loss from operations	(3,791)	(1,756)	(7,394)	(5,580)
Other income (expense)				

Interest income	69	45	160	93
Interest expense	(8)	(9)	(14)	(18)
Other financing costs	—	(298)	—	(298)
Change in fair value of warrants liability	—	16	—	32
Total other income (expense), net	61	(246)	146	(191)
Loss before provision for income taxes	(3,730)	(2,002)	(7,248)	(5,771)
Provision for income taxes	—	—	3	3
Net loss	$ (3,730)	$ (2,002)	$ (7,251)	$ (5,774)
Net loss per share of common stock, basic and diluted	$ (0.91)	$ (1.77)	$ (1.81)	$ (5.78)
Weighted-average shares outstanding, basic and diluted	4,084,283	1,132,952	4,001,770	998,122

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

	Six Months Ended June 30,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (7,251)	$ (5,774)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of deferred financing costs	14	18
Change in fair value of liability classified warrants	—	(32)
Shares issued for the standby equity purchase agreement commitment fee	—	298
Stock-based compensation	(8)	264
Change in operating assets and liabilities		
Accounts receivables	29	(105)
Inventory	(11)	(77)
Prepaid expenses	313	784
Other assets	157	156
Accounts payable	(198)	112
Accrued expenses	1,200	(1,305)
Net cash used in operating activities	(5,755)	(5,661)
Cash flows from financing activities		
Proceeds from issuance of shares, net of offering costs	1,139	5,154
Proceeds from exercise warrants	—	2
Proceeds of pre-funded warrants	—	5,580
Payment of notes payable	(405)	(592)
Net cash provided by financing activities	734	10,144
Net increase (decrease) in cash	(5,021)	4,483
Cash, beginning of period	11,980	1,819
Cash, end of period	$ 6,959	$ 6,302