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

November 11, 2026

Continued adoption of the QUELIMMUNE® therapy yielded 247% increase in net revenue compared to the third quarter of 2025

Achieved nearly 75% enrollment in the NEUTRALIZE-AKI pivotal clinical trial in adult patients with acute kidney injury (AKI) receiving CRRT

Reported statistically significant higher survival for QUELIMMUNE-treated patients versus comparator cohort at ASN Kidney Week 2026 late-breaking presentation

Fulfilled FDA post-approval requirements for SAVE Registry study

Webcast today at 4:30 p.m. Eastern Time

DENVER, Nov. 11, 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 September 30, 2026, and provided business updates on key initiatives.

“The strength of the QUELIMMUNE therapy adoption in this ultra-rare pediatric AKI market provides great promise for our pipeline indications,” said Eric Schlorff, CEO of SeaStar Medical. “And we continue to build momentum in educating the critical care pediatric health care community. In addition to several medical meeting presentations by Dr. Kevin Chung, our CMO, we have already begun sharing with critical care professionals the statistically significant higher survival in QUELIMMUNE-treated patients that was presented at the late-breaking presentation at ASN Kidney Week 2026.”

Mr. Schlorff continued, “The NEUTRALIZE-AKI pivotal clinical trial has enrolled nearly 75% of its intended 339 patients, and we have already submitted the first module of the premarket approval application to the FDA in hopes that our modular submission will speed this potential approval. Our Breakthrough Device Designation for this indication will also enable a priority review once we submit the final module with the NEUTRALIZE-AKI pivotal trial results, provided a positive outcome in the trial.”

Key Business Highlights

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

- Expanded the use of the QUELIMMUNE (SCD-PED) therapy as a treatment for ultra-rare sepsis-associated AKI in pediatric patients receiving renal replacement therapy (RRT), increasing net revenue 247% to $635 thousand compared to the third quarter of 2025. Gross profit margins remained at greater than 90%.
- Presented at ASN Kidney Week 2026 real-world pediatric patient survival data from the commercial use of the QUELIMMUNE therapy based on results from the SAVE Registry of 50 critically ill pediatric patients with life-threatening sepsis-associated AKI. The QUELIMMUNE (SCD-PED) therapy group showed statistically significant higher survival in the primary analysis at Day 60, Day 90, and at hospital discharge versus comparator cohorts. No device-related adverse events occurred in patients treated with the QUELIMMUNE (SCD-PED) therapy.
- Fulfilled FDA post-approval requirements for the SAVE Registry study for QUELIMMUNE for the treatment of sepsis-associated AKI in pediatric patients. FDA’s decision now enables hospitals to employ the QUELIMMUNE therapy without the research infrastructure that the SAVE Registry demanded, which may increase availability for these critically ill pediatric patients.
- Advanced enrollment in the NEUTRALIZE-AKI pivotal clinical trial evaluating the SCD therapy as a potential treatment for adult patients with AKI in the ICU receiving continuous renal replacement therapy (CRRT). The trial is nearly 75% enrolled, with 251 of 339 patients enrolled to date. The NEUTRALIZE-AKI pivotal clinical trial is expected to complete enrollment by mid-year 2027.
- Completed and submitted to the FDA the first module of a modular premarket approval (PMA) application for the potential approval of the SCD therapy as a treatment for adult patients with AKI in the ICU receiving CRRT.
- Granted Breakthrough Device Designation from the FDA for the SCD therapy for the treatment of hyperinflammation in adult patients with sepsis or a septic condition. The Breakthrough Device Designation is a regulatory pathway designed to

provide for accelerated development, assessment, and review for FDA approval of medical devices and potentially more effective treatments of life-threatening or irreversibly debilitating diseases or conditions. This marks the seventh Breakthrough Device Designation for the SCD therapy thus far across a range of indications.

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

Financial Results for the Third Quarter 2026

Net revenue for the three months ended September 30, 2026, and 2025, was approximately $0.6 million and $0.2 million, respectively, reflecting increased sales of QUELIMMUNE.

Cost of goods sold for the three months ended September 30, 2026, and 2025, was $48 thousand and $14 thousand respectively.

Research and development expenses for the three months ended September 30, 2026, and 2025, were $3.6 million and $1.9 million, respectively. The increase in research and development expenses was primarily driven by increased clinical research activities for the NEUTRALIZE-AKI pivotal clinical trial, SCD development costs, personnel, and payroll costs.

General and administrative expenses for the three months ended September 30, 2026, and 2025, were approximately $1.6 million and $1.9 million, respectively. The decrease in general and administrative expenses was the result of a decline in personnel, legal, audit, and SEC-related costs, partially offset by increased professional services, director fees, and franchise taxes.

Other income (net) for the three months ended September 30, 2026, was approximately $0.1 million compared to other expense of approximately $0.1 million for the three months ended September 30, 2025.

Net loss for the three months ended September 30, 2026, was approximately $4.5 million, or $1.03 per share on approximately 4.4 million weighted-average shares outstanding. This compares with a net loss of approximately $3.5 million, or $1.30 per share, on approximately 2.7 million weighted-average shares outstanding for the three months ended September 30, 2025.

Cash at September 30, 2026, was $4.0 million, which does not include the $3.3 million of gross proceeds from warrant exercises that occurred in October 2026. This compares to cash of $12.0 million at December 31, 2025.

SeaStar Medical Third Quarter Financial Results Conference Call

Date/Time:	Wednesday, November 11, 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 a septic condition weighing 10 kilograms or more and aged ≤22 years 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.

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

QUELIMMUNE was approved by FDA under a Humanitarian Device Exemption based on safety and probable benefit. The effectiveness of this device for this use has not been demonstrated. Adverse reactions observed in clinical studies include hypotension, hypothermia, tachycardia, hyperglycemia, and thrombocytopenia. Additional risks may include blood loss or extracorporeal circuit complications. QUELIMMUNE must be used with citrate anticoagulation.

For complete risk information, please see: https://seastarmedical.com/quelimmune

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 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 NEUTRALIZE-AKI Pivotal Trial

The NEUTRALIZE-AKI (NEUTRophil and monocyte deActivation via SeLective Cytopheretic Device – a randomIZEd clinical trial in AKI) 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 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 seven 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 (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 expanded access to critically ill pediatric patients as a result of the fulfillment of the SAVE Registry requirements, the potential benefit from the SCD-PED therapy with a favorable observed safety profile; anticipated improved survival in real-world critical care practice; anticipated adoption our products; 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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QUELIMMUNE is a registered trademark of SeaStar Medical Holding Corporation.

— Financial Tables to Follow —

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

	September 30, 2026 (unaudited)	December 31, 2025
ASSETS		
Current assets		
Cash	$ 3,989	$ 11,980
Accounts receivable, net of allowance for credit losses of $2 and $3, respectively	178	237
Inventory	45	66
Prepaid expenses	755	1,297
Total current assets	4,967	13,580
Other assets	343	578
Total assets	$ 5,310	$ 14,158
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities		
Accounts payable	$ 1,467	948
Accrued expenses	3,373	2,268
Notes payable, net of deferred financing costs	—	525
Liability classified warrants	1	1
Total current liabilities	4,841	3,742
Total liabilities	4,841	3,742
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.0001 par value per share, 10,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock - $0.0001 par value per share; 425,000,000 and 450,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; 4,461,965 and 3,844,613 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	4	4
Additional paid-in capital	163,959	162,126
Accumulated deficit	(163,494)	(151,714)
Total stockholders' equity	469	10,416
Total liabilities and stockholders' equity	$ 5,310	$ 14,158

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,	
	2026	2025	2026	2025
Net revenue	$ 635	$ 183	$ 1,745	$ 814
Cost of goods sold	48	14	148	41
Gross profit	587	169	1,597	773
Operating expenses				
Research and development	3,574	1,850	8,438	5,318
General and administrative	1,594	1,898	5,134	4,614
Total operating expenses	5,168	3,748	13,572	9,932
Loss from operations	(4,581)	(3,579)	(11,975)	(9,159)
Other income (expense)				
Interest income	54	107	214	200
Interest expense	(2)	—	(16)	(18)
Other financing costs	—	—	—	(298)
Change in fair value of warrants liability	—	—	—	32
Total other income (expense), net	52	107	198	(84)
Loss before provision for income taxes	(4,529)	(3,472)	(11,777)	(9,243)
Provision for income taxes	—	—	3	3
Net loss	$ (4,529)	$ (3,472)	$ (11,780)	$ (9,246)
Net loss per share of common stock, basic and diluted	$ (1.03)	$ (1.30)	$ (2.85)	$ (5.96)
Weighted-average shares outstanding, basic and diluted	4,390,541	2,669,340	4,132,784	1,551,212

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

	Nine Months Ended September 30,	
	2026	2025
Cash flows from operating activities		
Net loss	$ (11,780)	(9,246)
Adjustments to reconcile net loss to net cash used in operating activities	—	—
Amortization of deferred financing costs	16	18
Change in fair value of liability classified warrants	—	(32)
Shares issued for the standby equity purchase agreement commitment fee	—	298
Stock-based compensation	155	554
Change in operating assets and liabilities		
Accounts receivables, net	59	(109)
Inventory	21	(83)
Prepaid expenses	542	1,028
Other assets	235	236
Accounts payable	519	(1,028)
Accrued expenses	1,105	(1,141)
Net cash used in operating activities	(9,128)	(9,505)
Cash flows from financing activities		

Proceeds from issuance of shares	1,678	14,337
Proceeds from exercise of warrants	—	1,818
Proceeds from issuance of pre-funded warrants	—	5,886
Payment of notes payable	(541)	(592)
Net cash provided by financing activities	1,137	21,449
Net increase in cash	(7,991)	11,944
Cash, beginning of period	11,980	1,819
Cash, end of period	$ 3,989	$ 13,763