SeaStar Medical Reports First Quarter Financial Results and Provides Business Updates

May 13, 2026

Added 7 top-rated children's hospitals to QUELIMMUNE ® pediatric acute kidney injury (AKI) customer base, increasing first quarter revenue 69% versus first quarter 2025 revenue

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

Initiated efforts for the submission of a modular post-marketing application (PMA)

Webcast today at 4:30 pm Eastern Time

DENVER, May 13, 2026 (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, 2026, and provided business updates on key initiatives.

"Our QUELIMMUNE customer base continues to grow with a groundswell of enthusiasm among key experts that is driving our penetration into new accounts," said Eric Schlorff, CEO of SeaStar Medical. "We saw a significant jump in revenue of 69% this quarter versus the first quarter of last year. The trajectory is very encouraging as we consider the next opportunity in the adult market, which is approximately 50 times larger than the pediatric AKI market."

Mr. Schlorff continued, "We are working diligently to enroll adult patients with AKI in the NEUTRALIZE-AKI pivotal trial. We have activated multiple new clinical sites in the last six months and believe that a successful outcome of this trial would position us to file a PMA with the FDA for the adult AKI indication in 2027. Our success in building the QUELIMMUNE market now will provide critical support for this potential future opportunity."

Key Business Highlights

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

- Expanded the use of QUELIMMUNE (SCD-PED) therapy for ultra-rare pediatric AKI, adding 7 new customers from top-rated children's hospitals, bringing the total customer base to 17 and building increased depth in customer orders. This led to first quarter 2026 net revenue of $0.5 million for QUELIMMUNE product sales, an increase of 69% versus the first quarter of 2025.
- Advanced enrollment in the NEUTRALIZE-AKI pivotal trial that is evaluating the Selective Cytopheretic Device (SCD) therapy as a potential treatment of adult patients with AKI in the ICU receiving continuous renal replacement therapy (RRT). The trial has enrolled 198 of 339 patients to date.
- Completed the required enrollment in the 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 AKI and sepsis or a septic condition. The registry has successfully enrolled 50 patients, and the company will be reporting the 28-day safety results from the SAVE Registry to the FDA upon completion of its analysis of the data.
- Announced the publication of early post-approval, real-world experience from the use of the QUELIMMUNE therapy in the prestigious, peer-reviewed journal Pediatric Nephrology. The publication, co-authored by leading experts in pediatric critical care management, highlights early experience from the first 21 pediatric patients in the SAVE Registry. The published data from the commercial use of the QUELIMMUNE therapy 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 results are on track to validate a nearly 50% reduction in loss of life compared to historical data, as reported previously in Kidney Medicine.
- Presented new data at the 31st International Conference on Advances in Critical Care Nephrology, also known as AKI & CRRT 2026, highlighting patient experience from the first 32 pediatric patients in the SAVE Registry. The clinical experience from the updated cohort demonstrated trends consistent with those previously reported from the initial cohort of 21 patients and the QUELIMMUNE registrational studies, and continue to support the QUELIMMUNE therapy safety and potential benefit in this critically-ill patient population.
- Assembled leading experts in the treatment of pediatric AKI to speak at the SeaStar Medical educational symposium at the AKI & CRRT 2026 meeting to discuss the complex pathophysiology of pediatric AKI with sepsis, the SAVE Registry, the immunomodulatory effects of the QUELIMMUNE therapy which may ameliorate dysregulated hyperinflammatory disease states, and other topics of interest to the nephrology community.
- Initiated efforts for the submission of a modular PMA to potentially speed the FDA review and approval process for the SCD therapy as a potential treatment for adult patients with AKI in the ICU receiving continuous RRT. SeaStar Medical has

also been granted Breakthrough Device Designation by the FDA for this indication, which may expedite the PMA approval process for novel devices that will save lives and treat debilitating diseases.

Anticipated 2026 Milestones

- Broaden QUELIMMUNE adoption to include 15 additional top-ranked children's medical centers, more than doubling the total number of sites from the beginning of the year and building increased depth in customer orders. SeaStar Medical also anticipates achieving approximately $2 million in net product revenue in 2026.
- Advance the SCD therapy for the adult AKI indication through completion of enrollment in the NEUTRALIZE-AKI pivotal trial around the end of 2026 and begin submission of relevant PMA modules to the FDA to facilitate the PMA review and approval process.
- Evaluate broader applicability of the SCD therapy through the conduct of a clinical trial of the SCD therapy in patients with chronic heart failure with cardiorenal syndrome awaiting left ventricular assist device implantation. SeaStar Medical has also been granted Breakthrough Device Designation by the FDA for this indication given the severity of the disease and lack of current effective treatments.
- Explore rapid regulatory pathways to commercialization of the SCD therapy as a first-in-class therapy, designed to save lives and spare organ function in numerous destructive hyperinflammatory conditions. SeaStar Medical will seek additional Humanitarian Use and Breakthrough Device Designations to potentially provide lifesaving support to these patients as rapidly as possible.

Financial Results for the First Quarter 2026

For the three months ended March 31, 2026, net revenue was approximately $0.5 million, reflecting sales of the QUELIMMUNE pediatric SCD therapy. This compared to net revenue of approximately $0.3 million for the three months ended March 31, 2025.

Research and development expenses for the three months ended March 31, 2026, and 2025, were $2.3 million and $2.4 million, respectively. The decrease in research and development expenses was primarily driven by a decrease in clinical trial costs related to the NEUTRALIZE-AKI pivotal trial, offset by increases in personnel costs and costs for external services.

General and administrative expenses for the three months ended March 31, 2026, and 2025, were approximately $1.7 million and $1.7 million, respectively. General and administrative expenses for the three months ended March 31, 2026, reflected an increase in legal and accounting related expenses, offset by declines in personnel costs and SEC related costs.

Other income (net) increased approximately $30 thousand for the three months ended March 31, 2026, compared to the three months ended March 31, 2025. The increase was primarily driven by increased interest income.

Net loss for the three months ended March 31, 2026, was approximately $3.5 million, or $0.90 per share on approximately 3.9 million weighted-average shares outstanding. This compared with a net loss of approximately $3.8 million, or $4.38 per share, on approximately 0.9 million weighted-average shares outstanding for the three months ended March 31, 2025.

The Company reported cash of $9.3 million as of March 31, 2026, compared to $12.0 million as of December 31, 2025.

SeaStar Medical First Quarter Financial Results Conference Call

Date/Time:	Wednesday, May 13, 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 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.

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 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 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 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 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 to product revenue in 2026; anticipated patient enrollment and the expansion of the clinical trial sites; the total addressable market for the SCD applications; the ability of SeaStar Medical to gain market share and generate sales with respect to anticipated revenue in 2026; broadening QUELIMMUNE adoption by the addition of top-ranked children's medical centers; the amount and timing of future QUELIMMUNE commercial sales; commercial acceptance of QUELIMMUNE; 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.

Contact:
IR@SEASTARMED.COM

— Financial Tables to Follow —

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

	March 31, 2026 (unaudited)	December 31, 2025
ASSETS		
Current assets		
Cash	$ 9,348	$ 11,980
Accounts receivable, net of allowance for credit losses of $8 and $0, respectively	179	237
Inventory	57	66
Prepaid expenses	1,180	1,297
Total current assets	10,765	13,580
Other assets	499	578
Total assets	$ 11,263	$ 14,158
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities		
Accounts payable	$ 719	948
Accrued expenses	2,897	2,268
Notes payable, net of deferred financing costs	331	525
Liability classified warrants	1	1
Total current liabilities	3,948	3,742
Total liabilities	3,948	3,742
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.0001 par value, 10,000,000 shares authorized at March 31, 2026 and December 31, 2025; no shares issued and outstanding at March 31, 2026 and December 31, 2025	—	—
Common stock - $0.0001 par value per share; 425,000,000 and 450,000,000 shares authorized at March 31, 2026 and December 31, 2025, respectively; 3,993,719 and 3,884,613 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	4	4
Additional paid-in capital	162,546	162,126
Accumulated deficit	(155,235)	(151,714)

Total stockholders' equity	7,315	10,416
Total liabilities and stockholders' equity	$ 11,263	$ 14,158

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

	Three Months Ended March 31,	
	2026	**2025**
Net revenue	$ 495	$ 293
Cost of goods sold	46	—
Gross profit	449	293
Operating expenses		
Research and development	2,344	2,431
General and administrative	1,708	1,684
Total operating expenses	4,052	4,115
Loss from operations	(3,603)	(3,822)
Other income (expense)		
Interest income	91	48
Interest expense	(6)	(11)
Change in fair value of warrants liability	—	16
Total other income (expense), net	85	53
Loss before provision for income taxes	(3,518)	(3,769)
Provision for income taxes	3	3
Net loss	$ (3,521)	$ (3,772)
Net loss per share of common stock, basic and diluted	$ (0.90)	$ (4.38)
Weighted-average shares outstanding, basic and diluted	3,918,339	861,794

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

	Three Months Ended March 31,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (3,521)	$ (3,772)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of deferred financing costs	6	11
Change in fair value of liability classified warrants (exercised and outstanding)	—	(16)
Stock-based compensation	91	167
Change in operating assets and liabilities		
Accounts receivables, net	58	2
Inventory	9	(44)
Prepaid expenses	117	501
Other assets	79	79

Accounts payable	(229)	351
Accrued expenses	629	67
Net cash used in operating activities	(2,761)	(2,654)
Cash flows from financing activities		
Proceeds from issuance of shares, net of offering costs	329	1,566
Proceeds from exercise warrants	—	2
Proceeds of pre-funded warrants	—	4,785
Payment of notes payable	(200)	(222)
Net cash provided by financing activities	129	6,131
Net increase in cash	(2,632)	3,477
Cash, beginning of period	11,980	1,819
Cash, end of period	$ 9,348	$ 5,296