# SeaStar Medical Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Updates

March 25, 2026

*Added top-rated children's hospitals to QUELIMMUNE™ pediatric Acute Kidney Injury (AKI) customer base*

*Completed enrollment in FDA-mandated QUELIMMUNE SAVE Post-Marketing Registry*

*Exceeded 50% enrollment milestone in pivotal trial of SCD therapy in adult patients with AKI*

*Advanced pipeline indications with initiation of cardio-renal clinical trial*

*Webcast today at 4:30 pm Eastern Time*

DENVER, March 25, 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 and year ended December 31, 2025, and provided business updates on key initiatives.

"In 2025, we broadened our customer base of top-ranked children's hospitals, continued enrollment in the NEUTRALIZE-AKI pivotal clinical trial, and advanced our pipeline with the initiation of the cardio-renal clinical trial of our selective cytopheretic device (SCD) therapy," said Eric Schlorff, CEO of SeaStar Medical. "We move into 2026 with strong momentum and key value creating milestones that will not only impact our success but also advance our mission to bring a potential life-saving therapy to patients who would otherwise have little hope of survival."

Mr. Schlorff continued, "I want to acknowledge the dedication and tenacity of our team for surpassing the 50% enrollment milestone of the NEUTRALIZE-AKI trial. Every day that we activate a new clinical site, or enroll another subject, brings us closer to potentially helping as many patients in the ICU as possible defeat destructive hyperinflammation. To that end, we are already preparing portions of the Premarket Application (PMA) for modular submission to better facilitate the FDA review process for the adult AKI indication. The adult AKI patient population is approximately 50 times larger than the pediatric AKI market in the U.S. alone. It is the core market that we believe will drive significant revenue expansion for the company. Our success in building the QUELIMMUNE market now will provide critical support for that future revenue opportunity, as we anticipate continued strong adoption of QUELIMMUNE in 2026 and beyond."

**Key Business Highlights**

During 2025 and into the first three months of 2026, SeaStar Medical's achievements have included the following:

- Expanded the use of QUELIMMUNE therapy for ultra-rare pediatric AKI, adding 13 new customers from top-rated children's hospitals, bringing the total customer base to 16 and building increased depth in customer orders.
- 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 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 requiring renal replacement therapy (RRT). 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.
- Completed the required enrollment in the SAVE Registry, an FDA-mandated Post-Approval Study that is designed to confirm the safety of the QUELIMMUNE therapy as a treatment for children with AKI due to sepsis or a septic condition requiring RRT. 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.
- Advanced the SCD therapy as a potential treatment of adult patients with AKI in the ICU receiving continuous RRT, achieving a key milestone of over 50% enrollment in the trial, and now with 181 of 339 patients enrolled to date in the NEUTRALIZE-AKI pivotal trial.
- 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.

- Expanded the pipeline of potential SCD therapy indications with the initiation of the NEUTRALIZE-CRS clinical trial to treat patients with chronic heart failure (CHF) with cardiorenal syndrome (CRS) awaiting left ventricle 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.
- Improved the company's balance sheet substantially through the addition of approximately $23.9 million in capital during 2025 as well as a reduction of $3.1 million in operating liabilities.

**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 pivotal trial of the SCD therapy in patients with acute CHF with CRS awaiting LVAD 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 Three Months and Year Ended December 31, 2025**

***Comparison of the three months ended December 31, 2025, to the three months ended December 31, 2024***

For the three months ended December 31, 2025, net revenue was approximately $420 thousand, comprised of approximately $315 thousand from product sales of the QUELIMMUNE therapy and net revenue of approximately $105 thousand from the sale of the SCD to the AREVA Research Institute for its research of the SCD therapy to reduce hyperinflammation in combat soldiers after severe burns, inhalation injuries, and infections. This compares to net revenue of approximately $67 thousand for the three months ended December 31, 2024, from product sales of the QUELIMMUNE therapy. This increase reflects product sales to our expanding customer base of highly rated children's hospitals in the U.S.

Cost of goods sold for the three months ended December 31, 2025, was $12 thousand, demonstrating a margin greater than 90%, consistent with previous quarters in 2025. There was no cost of goods sold for QUELIMMUNE sales during the three months ended December 31, 2024, as the product units were expensed to research and development prior to approval and commercialization of QUELIMMUNE, consistent with U.S. GAAP.

Research and development expenses for the three months ended December 31, 2025, and 2024, were $2.2 million and $2.7 million, respectively. The decrease in research and development expenses was primarily driven by declines in consulting expenses, personnel costs and clinical research and development costs, partially offset by increases in device development costs and research supply costs.

General and administrative expenses for the three months ended December 31, 2025, and 2024, were approximately $1.2 million and $2.1 million, respectively. The decrease in general and administrative expenses was the result of reduced personnel costs and director, legal, accounting, and consulting-related fees, and licensing costs.

Other income, net, for the three months ended December 31, 2025, was approximately $0.1 million compared to other expense, net, of approximately $0.4 million for the three months ended December 31, 2024. The increase was primarily related to an increase in interest income and decline in interest expense.

Net loss for the three months ended December 31, 2025, was approximately $2.9 million, or $0.80 per share on approximately 3.6 million weighted-average shares outstanding. This compares with a net loss of approximately $4.4 million, or $8.98 per share, on approximately 0.5 million weighted-average shares outstanding for the three months ended December 31, 2024.

***Comparison of the year ended December 31, 2025, to the year ended December 31, 2024***

For the years ended December 31, 2025, and 2024, net revenue was approximately $1.2 million and $135 thousand, respectively.

The increase reflects our first full year of QUELIMMUNE product sales compared to only a half year in 2024.

Cost of goods sold for the year ended December 31, 2025, was $53 thousand. There was no cost of goods sold for QUELIMMUNE sales during the year ended December 31, 2024, as the product units were expensed to research and development prior to approval and commercialization of QUELIMMUNE, consistent with U.S. GAAP.

Research and development expenses for the years ended December 31, 2025, and 2024, were $7.5 million and $9.1 million, respectively. The decrease in research and development expenses was primarily driven by declines in personnel costs, consulting expenses, pre-clinical costs, and external clinical services costs. These decreases were partially offset by increased clinical trial site costs, supply costs for the clinical trial, and medical affairs expenditures.

General and administrative expenses for the years ended December 31, 2025, and 2024, were approximately $5.9 million and $8.9 million, respectively. The decrease in general and administrative expenses was the result of reduced personnel costs and director, legal, accounting, consulting related fees, licensing costs, and a one-time settlement cost with a former distributor in 2024. The decreases were partially offset by a one-time due diligence fee paid to a third-party financial institution.

Other income, net, for the year ended December 31, 2025, was approximately $28 thousand compared to other expense, net of approximately $7.0 million for the year ended December 31, 2024. The increase was primarily related to an increase in interest income, decline in interest expense, a decline in unfavorable non-cash changes in the fair value of financial instruments, offset by a one-time non-cash financing charge.

Net loss for the year ended December 31, 2025, was approximately $12.2 million, or $5.86 per share on approximately 2.1 million weighted-average shares outstanding. This compares with a net loss of approximately $24.8 million, or $66.33 per share, on approximately 0.4 million weighted-average shares outstanding for the year ended December 31, 2024.

Cash as of December 31, 2025, was $12.0 million, compared to $1.8 million as of December 31, 2024.

**SeaStar Medical Fourth Quarter and Year-End 2025 Financial Results Conference Call**

| | |
|---|---|
| Date/Time: | Wednesday, March 25, 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™ 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 Renal Replacement Therapy (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 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 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. 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 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.

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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)

| | As of December 31, 2025 | As of December 31, 2024 |
|---|---|---|
| ASSETS | | |
| Current assets | | |
| Cash | $ 11,980 | $ 1,819 |
| Accounts receivable, net of allowance for credit losses of $35 and $0, respectively | 237 | 112 |
| Inventory | 66 | — |
| Prepaid expenses | 1,297 | 1,835 |
| Total current assets | 13,580 | 3,766 |
| Other assets | 578 | 892 |
| Total assets | $ 14,158 | $ 4,658 |
| LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT) | | |
| Current liabilities | | |
| Accounts payable | $ 948 | $ 3,046 |
| Accrued expenses | 2,268 | 3,188 |
| Notes payable, net of deferred financing costs | 525 | 574 |
| Liability classified warrants | 1 | 33 |
| Total current liabilities | 3,742 | 6,841 |
| Total liabilities | 3,742 | 6,841 |
| Commitments and contingencies (Note 10) | | |
| Stockholders' equity/(deficit) | | |
| Preferred stock – $0.0001 par value, 10,000,000 shares authorized at December 31, 2025 and December 31, 2024; no shares issued and outstanding at December 31, 2025 and December 31, 2024 | — | — |
| Common stock – $0.0001 par value per share; 450,000,000 and 500,000,000 shares authorized at December 31, 2025 and December 31, 2024, respectively; 34,096,420 and 5,977,246 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively | 4 | 2 |
| Additional paid-in capital | 162,126 | 137,379 |
| Accumulated deficit | (151,714) | (139,564) |
| Total stockholders' equity/(deficit) | 10,416 | (2,183) |
| Total liabilities and stockholders' equity/(deficit) | $ 14,158 | $ 4,658 |

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

| | Three Months Ended December 31, *(unaudited)* | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| Net revenue | $ 420 | $ 67 | $ 1,234 | $ 135 |

| | | | | |
|---|---|---|---|---|
| Cost of goods sold | 12 | — | 53 | — |
| Gross profit | 408 | 67 | 1,181 | 135 |
| Operating expenses | | | | |
| Research and development | 2,200 | 2,738 | 7,518 | 9,105 |
| General and administrative | 1,224 | 2,096 | 5,838 | 8,872 |
| Total operating expenses | 3,424 | 4,834 | 13,356 | 17,977 |
| Loss from operations | (3,016) | (4,767) | (12,175) | (17,842) |
| Total other income (expense), net | 112 | 348 | 28 | (6,985) |
| Loss before provision for income taxes | (2,904) | (4,419) | (12,147) | (24,827) |
| Provision for income taxes | — | — | 3 | 3 |
| Net loss | $ (2,904) | $ (4,419) | $ (12,150) | $ (24,830) |
| Net loss per share of common stock, basic and diluted | $ (0.80) | $ (8.98) | $ (5.86) | $ (66.33) |
| Weighted-average shares outstanding, basic and diluted | 3,621,696 | 492,016 | 2,073,087 | 374,356 |

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

| | Year Ended December 31, | |
|---|---|---|
| | **2025** | **2024** |
| Cash flows from operating activities | | |
| Net loss | $ (12,150) | $ (24,830) |
| 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) | 697 |
| Shares issued for the standby equity purchase agreement commitment fee | 298 | — |
| Stock-based compensation | 624 | 887 |
| Change in operating assets and liabilities | | |
| Accounts receivables, net | (125) | (112) |
| Inventory | (66) | — |
| Prepaid expenses | 538 | 297 |
| Other assets | 314 | 313 |
| Accounts payable | (2,098) | (1,281) |
| Accrued expenses | (920) | 1,875 |
| Other liabilities | — | (100) |
| Net cash used in operating activities | (13,599) | (16,007) |
| 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 | 16,126 | 17,441 |
| Proceeds from exercise of warrants | 1,815 | 853 |
| Proceeds of pre-funded warrants | 5,886 | 3,766 |
| Proceeds from issuance of notes payable | 767 | 713 |
| Payment of notes payable | (834) | (5,402) |
| Net cash provided by financing activities | 23,760 | 17,650 |
| Net increase in cash | 10,161 | 1,643 |
| Cash, beginning of period | 1,819 | 176 |
| Cash, end of period | $ 11,980 | $ 1,819 |

**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 |