SeaStar Medical Announces 2026 Milestones

January 7, 2026

Drive adoption of QUELIMMUNE for ultra-rare pediatric AKI, expanding revenue and doubling the customer base

Advance SeaStar Medical's first-in-class SCD therapy for the adult AKI indication – a potential $4.5 billion market – through completion of enrollment of the NEUTRALIZE-AKI pivotal trial and initiation of the PMA process

Progress the clinical development of the SCD therapy in patients with severe heart failure

Leverage rapid pathways to commercialization of the SCD therapy through additional FDA Humanitarian Use and Breakthrough Device Designations

DENVER, Jan. 07, 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 its key milestones for 2026.

"Our first full year as a commercial company provided a clear demonstration that the Selective Cytopheretic Device (SCD) therapy can save lives and spare organ function, with major pediatric medical institutions, such as Cincinnati Children's Hospital, Stanford Medical Center, UCSF Benioff Children's Hospitals, and University of Michigan, adopting the therapy and reporting their findings," said Eric Schlorff, CEO of SeaStar Medical. "Beyond the pediatric acute kidney injury (AKI) patient population, there are hundreds of thousands of patients that experience the life-threatening consequences of uncontrolled destructive hyperinflammation with no viable treatment options today. We are already evaluating the potential broad applicability of our SCD therapy in adult patients with AKI and also in patients with chronic heart failure (CHF) awaiting a left ventricular assist device (LVAD) implantation. These indications represent a potential multi-billion-dollar market opportunity in the U.S. alone. The ability to expand the SCD therapy to additional indications and therapeutic areas could extend this opportunity even further."

Mr. Schlorff continued, "We believe 2026 will be a major pivot point for the company. With continued adoption of the QUELIMMUNE therapy, we believe we can save more children's lives and spare damage to their organs. We also plan to accelerate enrollment in our NEUTRALIZE-AKI pivotal trial to complete enrollment near the end of 2026. Provided a successful outcome of the trial, we will submit our Premarket Approval application (PMA) in 2027 in hopes of a rapid approval and strong early adoption, given our established commercial infrastructure."

Key 2026 milestones for SeaStar Medical include the following:

- Broaden QUELIMMUNE adoption to include 15 additional top-ranked children's medical centers, more than doubling the total number of sites and building increased depth in customer orders. SeaStar Medical 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 near the end of 2026 and initiation of a modular PMA process. SeaStar Medical has been granted Breakthrough Device Designation by the FDA for this indication, which is designed to expedite the PMA approval process for novel devices that will save lives and treat debilitating diseases. The modular PMA process may also speed the 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 cardiorenal syndrome (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.

SeaStar Medical's 2026 milestones are built on the foundation of achievements from 2025 including:

- Expanded the QUELIMMUNE customer base to 10 customers from top-rated children's hospitals, building increased depth

in the number of customers ordering QUELIMMUNE. This ultra-rare pediatric AKI market represents SeaStar Medical's first approved product that employs its SCD technology. Product line extensions represent significantly larger market opportunities.

- Presented real-world pediatric patient survival data from the commercial use of the QUELIMMUNE therapy that 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 new data from the SAVE Surveillance Registry of 21 critically ill pediatric patients with life-threatening AKI and sepsis or a septic condition were presented at the 5th International Symposium on Acute Kidney Injury in Children. 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.

- Announced a successful interim analysis of the NEUTRALIZE-AKI trial by the independent Data Safety Monitoring Review Board (DSMB), providing a positive signal toward efficacy and zero device-related safety issues. This pivotal clinical trial is designed to evaluate the safety and efficacy of the SCD therapy in 339 adults with AKI in the ICU receiving continuous renal replacement therapy (CRRT).

- Initiated the NEUTRALIZE-CRS clinical trial to treat patients with acute CHF with cardiorenal syndrome (CRS) awaiting 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.

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 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 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 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 (CRRT), a life-threatening condition with no effective treatment options that impacts over 200,000 adults in the U.S. annually.

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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 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; the timeline for commercialization of new SCD applications; the ability of SeaStar Medical to meet the expected regulatory and commercial timelines; and the ability to expand the SCD therapy to additional indications and to obtain Humanitarian Use and Breakthrough Device Designations. 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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