Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

January 13, 2026
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
101 N. Wacker Drive, Chicago, IL 60606

SeaStar Medical Holding Corp. (ICU-NASDAQ)

ICU: Critical Care Innovation for AKI Patients; Initiating Coverage of SeaStar Medical Holding Corp.

Based on our probability adjusted DCF model that takes into account potential future revenues for QUELIMMUNE in AKI and CRS, ICU is valued at $12.00/share. This model is highly dependent upon the continued clinical and commercial success of QUELIMMUNE and will be adjusted accordingly based upon future results.

Current Price (01/13/26)	$2.30
Valuation	**$12.00**

OUTLOOK

We are initiating coverage of SeaStar Medical Holding Corp. (ICU) with a valuation of $12.00. SeaStar is a commercial-stage healthcare company that is developing its first-in-class Selective Cytopheretic Device (SCD) as a means to combat organ failure stemming from a hyperinflammatory immune response and cytokine storm. It is applicable for patients suffering from both chronic and acute kidney injury (AKI) as well as other inflammatory diseases. The device was approved under a Humanitarian Device Exemption by the U.S. FDA for pediatric AKI patients in February 2024. Sales of the device have initiated and the company is currently focused on the top 50 hospitals that treat approximately 50% of all pediatric AKI patients. SeaStar is currently conducting the NEUTRALIZE-AKI trial to evaluate the SCD therapy in 339 adults with AKI in the ICU receiving continuous renal replacement therapy (CRRT). We anticipate enrollment in NEUTRALIZE-AKI completing near year-end 2026.

SUMMARY DATA

52-Week High	**$24.30**
52-Week Low	**$2.26**
One-Year Return (%)	**-88.21**
Beta	**-1.00**
Average Daily Volume (sh)	**108,968**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**1**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2026 Estimate	**N/A**
P/E using 2027 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	0.0 A	0.0 A	0.1 A	0.0 A	0.1 A
2025	0.3 A	0.3 A	0.2 A	0.2 E	1.0 E
2026					2.0 E
2027					3.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$1.89 A	-$10.26 A	-$10.96 A	-$9.05 A	-$66.32 A
2025	-$4.37 A	-$1.77 A	-$1.32 A	-$1.06 E	-$6.46 E
2026					-$2.29 E
2027					-$1.78 E

WHAT'S NEW

Initiating Coverage

Source: Seastar Medical Holding Corp.

We are initiating coverage of SeaStar Medical Holding Corp. (ICU) with a valuation of $12.00. SeaStar is a commercial-stage medical device company that is developing the Selective Cytopheretic Device (SCD) as a first-in-class, disease-modifying device that dampens the cytokine storm deriving from a hyperinflammatory response. Multiple bodily insults, including trauma, surgery, and infection, can trigger the overactivation of inflammatory cells and put the body into shock. The SCD is an extracorporeal synthetic membrane device that is designed to bind activated leukocytes. It is added to the standard continuous renal replacement therapy (CRRT) circuit that uses regional citrate anticoagulation and is placed immediately after the standard hemofilter cartridge. Activated neutrophils and monocytes bind the SCD biomimetic membrane, the bound and activated cells are deactivated by maintaining a specified ionized calcium level, and the proinflammatory cells are shifted to a lower inflammatory profile. The SCD therapy can be applied to treat multiple conditions, including both acute and chronic kidney disease along with cardiovascular disease and other inflammatory diseases. The company's first commercial product, QUELIMMUNE™, was approved to treat critically ill pediatric patients with life-threatening acute kidney injury (AKI) due to sepsis or a septic condition by the FDA in February 2024 under a Humanitarian Device Exemption (HDE). A pivotal trial in adults, NEUTRALIZE-AKI, is currently underway with enrollment expected to be completed near the end of 2026.

Commercial Stage Company – The company began commercializing the SCD (QUELIMMUNE®) following its approval for use in pediatric AKI patients with sepsis or septic conditions in 2024. The product is the only approved therapy of its kind and is currently being used by multiple children's hospitals, with expansion into additional children's hospitals ongoing. The approval has de-risked the regulatory pathway for additional FDA approvals in the future.

Positive Clinical Results with Supporting Case Studies – Following an initial serendipitous observation in an early pilot study, SeaStar has reported successful clinical results from multiple clinical trials involving hundreds of patients using the SCD that are further supported by successful case studies involving patients with life-threatening conditions.

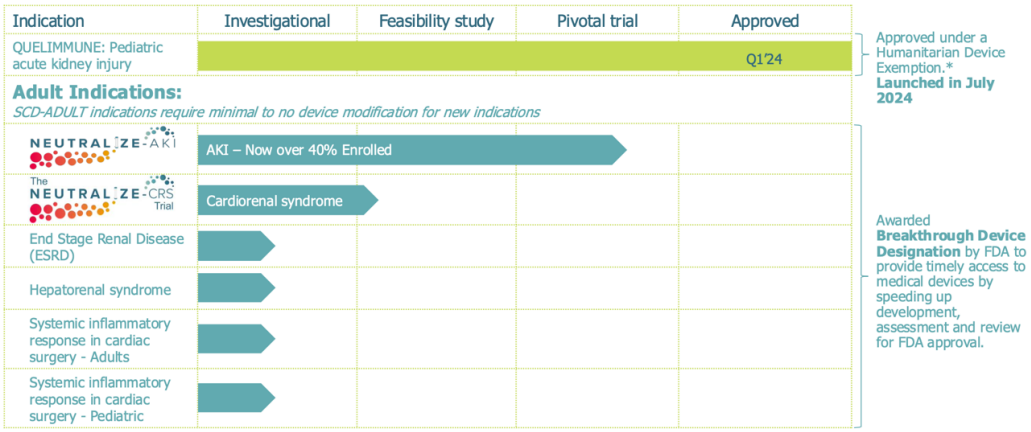
Pivotal Trial in Adult AKI Patients Ongoing – The NEUTRALIZE-AKI trial is currently being conducted in adult AKI patients requiring CRRT. Following a recent interim analysis by the independent Data Safety Monitoring Board (DSMB), a positive signal toward efficacy was noted with no device-related safety issues. The total enrollment for the trial was adjusted from 200 to approximately 339 and we currently anticipate enrollment completing near the end of 2026.

Favorable Economics Opens Up Multi-Billion Dollar Market – An analysis by SeaStar showed that the use of the SCD can save hospitals tens of thousands of dollars per patient based on a decreased length of stay and lower mortality. The total market for treating AKI in the U.S. is valued at approximately $4.5 billion, with the pediatric indication representing approximately $100 million of that total. Additional indications for the SCD therapy that could provide upside for the company include cardiorenal syndrome and hepatorenal syndrome.

INVESTMENT THESIS

SeaStar Medical Holding Corp. (ICU) is a commercial stage company that is developing its first-in-class Selective Cytopheretic Device (SCD) as a treatment for critically ill patients that are suffering from an uncontrolled hyperinflammatory response. The SCD therapy was approved by the FDA in February 2024 under a Humanitarian Device Exemption (HDE) for the treatment of pediatric acute kidney injury (AKI) patients due to sepsis or a septic condition. SeaStar reported 77% survival at Day 60 for pediatric patients (compared to a historical 50% mortality rate using the standard of care) along with no patients requiring dialysis. The company is currently conducting the NEUTRALIZE-AKI trial of up to 339 critically ill AKI patients requiring continuous renal replacement therapy (CRRT). The primary outcome of the study is a composite of all-cause mortality or dialysis dependency on Day 90. We anticipate enrollment concluding for the trial near the end of 2026. SeaStar has received Breakthrough Device Designation (BDD) for six different indications:

- the use of SCD as a treatment of immunomodulatory dysregulation in adults with AKI;
- the use of SCD in patients in the hospital ICU with acute or chronic systolic heart failure and worsening renal function due to cardiorenal syndrome or right ventricular dysfunction awaiting implantation of a left ventricular assist device;
- the use of SCD in patients in the hospital ICU with AKI and acute or chronic liver disease;
- the use of SCD to treat chronic systemic inflammation in end-stage renal disease (ESRD) patients who require chronic dialysis;
- the use of SCD to treat the systemic inflammatory response in adult patients undergoing cardiac surgery towards prevention of post-operative adverse complications and outcomes;
- the use of SCD to treat the systemic inflammatory response in pediatric patients undergoing cardiac surgery towards prevention of post-operative adverse complications and outcomes



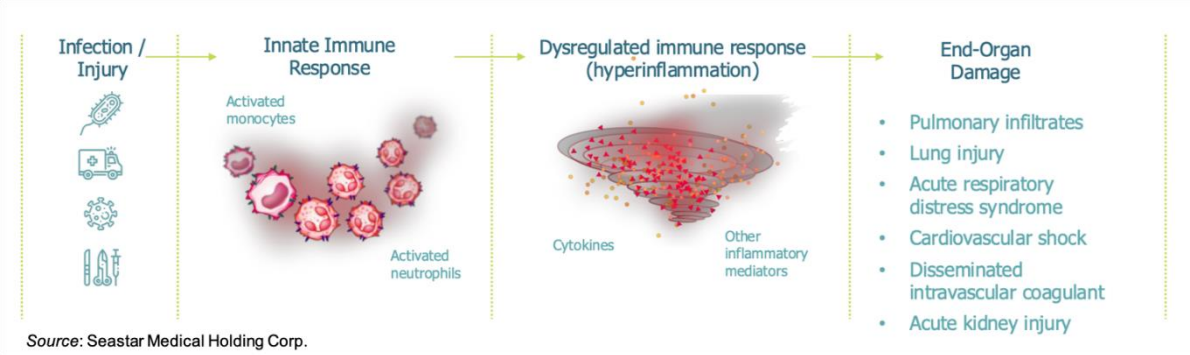
*QUELIMMUNE is approved by the FDA as a Humanitarian Use Device (HUD) to treat pediatric patients with acute kidney injury and sepsis or septic condition weighing 10 kilograms and requiring kidney replacement therapy

Source: Seastar Medical Holding Corp.

Hyperinflammatory Response

Systemic Inflammatory Response Syndrome (SIRS) results in an exaggerated immune response as the result of a harmful stressor that ultimately results in severe inflammation throughout the body. Objectively, it is defined by the presence of any two of the following: Body temperature >100.4ºF or < 96.8ºF; heart rate > 90 bpm; respiratory rate > 20 breaths/minute or $PaCO_2$ < 32 mm Hg; leukocyte count > 12,000/μL or <4,000/μL It can be caused by a number of different conditions, including infection, surgery, and ischemia.

At the molecular level, SIRS involves a complex interplay of the humoral and cellular immune response, cytokines, and the complement pathway. Interleukin (IL)-1 and tumor necrosis factor alpha (TNF-α) are key early mediators of the condition that in turn allow nuclear factor-κB (NF-κB) to initiate the release of additional proinflammatory cytokines (e.g., IL-6, IL-8, and interferon-gamma) (Baddam *et al.*, 2025). Changes in the coagulation pathway are also initiated by IL-1 and TNF-α and lead to microvascular thrombosis, heightened capillary permeability, increased vascular fragility, and compromised tissue perfusion. These all contribute to an increased risk of organ dysfunction that can affect multiple systems, including the central nervous system, respiratory system, cardiovascular system, and renal system, which can cause acute kidney injury (AKI).



Source: Seastar Medical Holding Corp.

Acute Kidney Injury

Acute Kidney Injury (AKI) refers to the kidneys no longer being able to properly filter waste products from the blood, which can lead to a buildup of waste and chemical imbalances. It does not have one cause, but instead is multifactorial in its origin. A universal definition and staging for AKI were proposed by the Kidney Disease: Improving Global Outcomes (KDIGO), which utilizes three stages for AKI based on serum creatinine level and urine output (KDIGO). Stage 3 AKI requiring CRRT is associated with mortality rates between 44% and 52% (ARFTN *et al.*, 2008; RENAL RTSI *et al.*, 2009). In addition, there is an increased risk of developing chronic kidney disease following AKI (Chawla *et al.*, 2014) along with an increased risk of cardiovascular mortality, acute myocardial infarction, and heart failure (Coca *et al.*, 2009; Odutayo *et al.*, 2017). In addition to the above risks to the patient, AKI is also associated with increased length of hospital stay and overall healthcare costs (Chertow *et al.*, 2005).

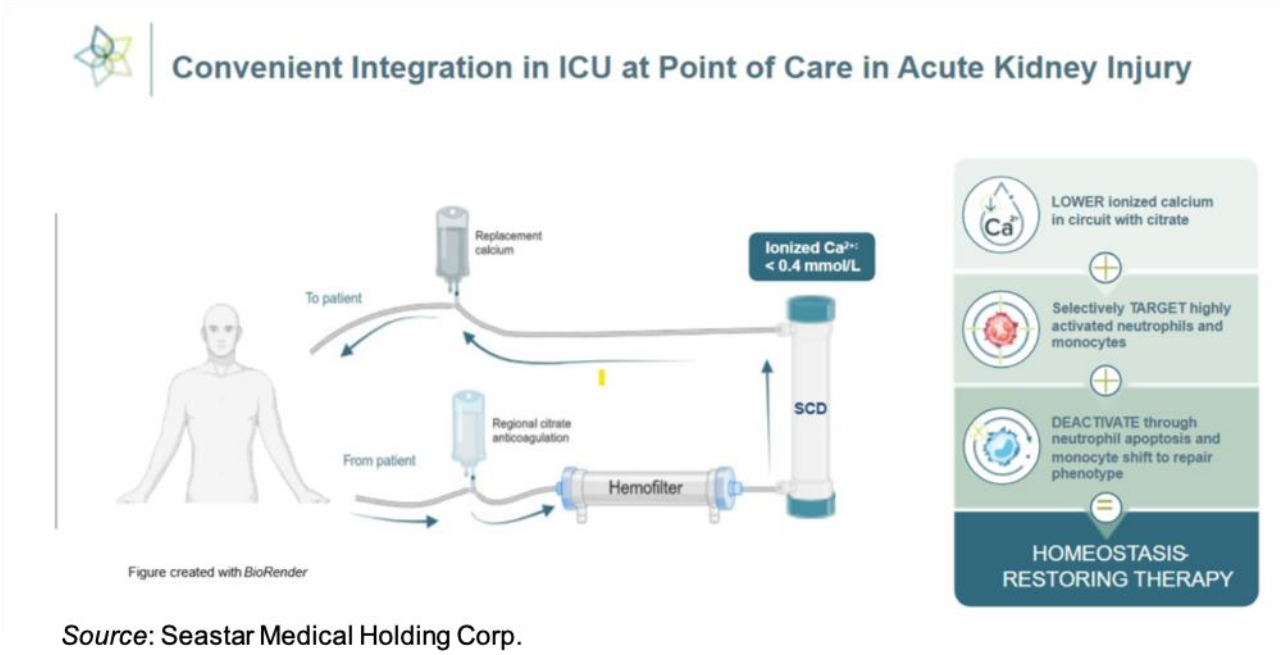
The causes of AKI can be categorized into three groups: prerenal AKI, which accounts for approximately 60% of cases and is the result of hypoperfusion of normal kidneys; intrinsic renal AKI, which results from structural damage to any component of the kidneys and accounts for up to 40% of cases; and the much less common postrenal AKI, which results from urinary tract obstruction (Ostermann *et al.*, 2017). In essence, the majority of AKI cases are not actually renal-specific, but are instead caused by septic shock, post major surgery, cardiogenic shock, and hypovolemia (Uchino *et al.*, 2005).

Care for AKI patients is mostly supportive, with hemodynamic stabilization being of critical importance since regulation mechanisms are impaired with AKI (Ostermann *et al.*, 2019). Optimized fluid balance, vasopressor drugs, diuretics (if fluid overload and electrolyte imbalances are an issue), and minimization of prescription drugs (to avoid additional nephrotoxicity) are used to stabilize the patient. CRRT is the most common form of renal support as it helps to maintain volume, electrolyte, acid-base, and uremic solute homeostasis.

While the above strategies are currently used to treat AKI patients, there are still no established therapies for AKI. Mortality rates continue to be high for this patient population and AKI survivors are at an increased risk of developing chronic kidney disease (CKD), which is defined as the persistence of kidney disease for a period of more than 90 days. Thus, there exists a significant need for more effective treatment options for AKI.

Selective Cytopheretic Device Therapy

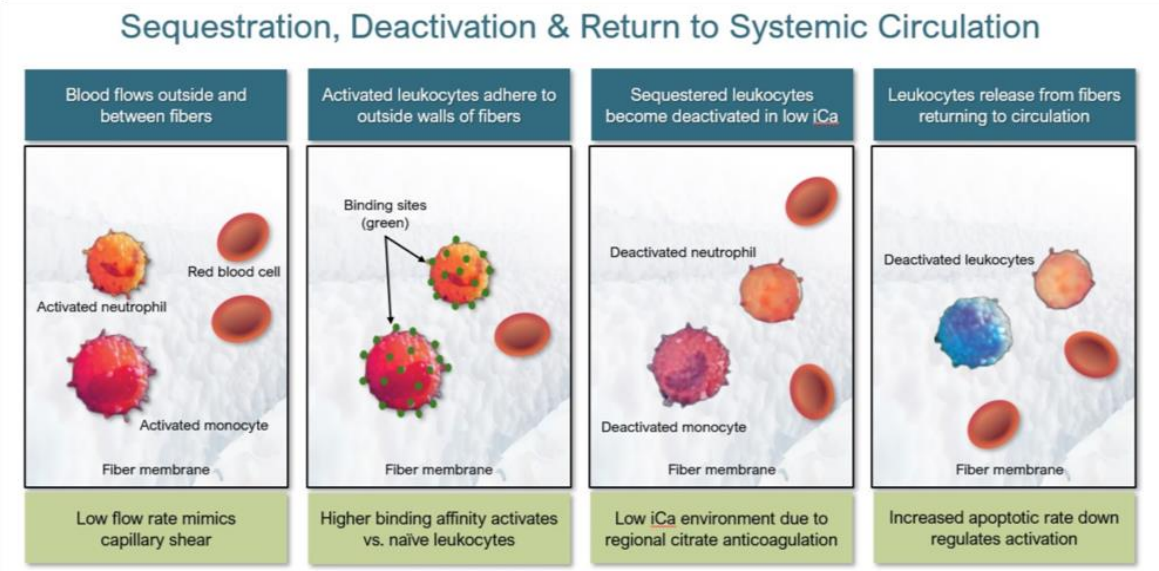
A large number of scientific advances have been the results of serendipitous discoveries, with some of the most notable examples being Alexander Fleming's discovery of penicillin, Barnett Rosenberg's identification of cisplatin, and Akira Endo's work that led to the development of statin drugs. A serendipitous observation by Dr. David Humes during development of a renal tubule assist device (RAD) containing adult human renal tubule cells (Tumlin *et al*., 2008) led to the creation of the Selective Cytopheretic Device (SCD). He noticed that AKI patients treated with a RAD lacking renal tubule cells showed improvement in their condition, which led to follow-up studies and evaluation. The SCD consists of a polycarbonate cylindrical housing that contains a biocompatible polysulfone hollow fiber membrane. The device is attached in-line with CRRT and utilizes a low-shear stress blood flow path around the bundled fibers, which promotes binding of activated neutrophils and monocytes. The activated cells are immunomodulated when they are exposed to a low ionized calcium (iCa) environment (<0.4 mM Ca^{2+}) and then released back to the systemic circulation. An overview of the SCD setup is given below.



Source: Seastar Medical Holding Corp.

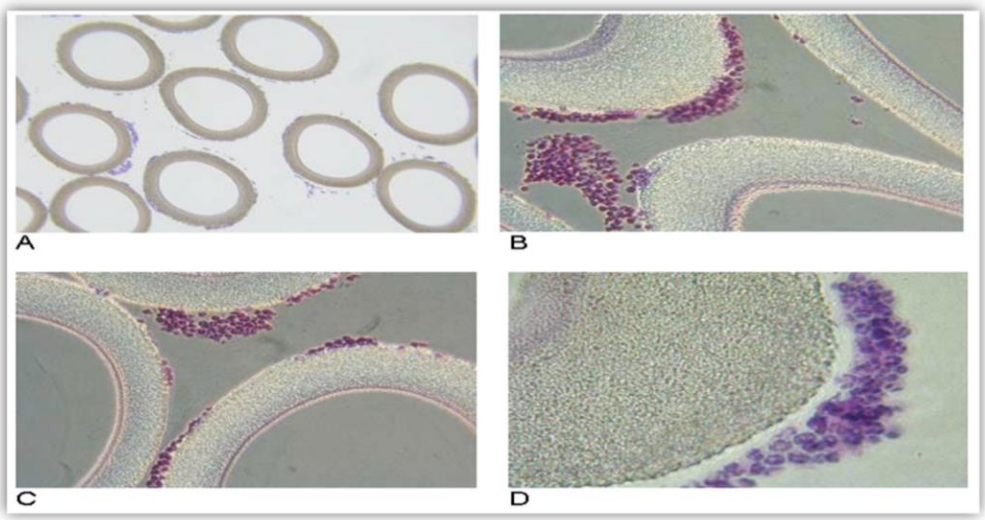
Mechanism of Action

A number of studies have been performed to better understand how the SCD exerts its anti-inflammatory effects. While the exact mechanism is still being evaluated, there appear to be three elements to the SCD therapy: a) binding of activated neutrophils and monocytes on the SCD biomimetic membrane; b) deactivating the activated neutrophils by maintaining a specified iCa level within the SCD; and c) shifting proinflammatory monocytes to a lower inflammatory profile. The SCD is used with a clinically validated regional citrate anticoagulation protocol to lower the iCa level. This serves two purposes: to prevent clotting within the circuit and to immuno-modulate the activated neutrophils and monocytes before they are eluted from the SCD and returned to the patient. An overview of the process is given below.



Source: Seastar Medical Holding Corp.

Neutrophils and monocytes, but not lymphocytes, are the cell types that preferentially bind to the SCD membrane (Tumlin *et al.*, 2011). The following figure shows microscopy images of an SCD after being used for patient treatment with the cells stained with Hematoxylin and Eosin (H&E). Panel A is a low-power image (160x), panels B and C are higher-power images (400x) and panel D is a high-power image showing neutrophils and monocytes in adherent cell clusters (1600x). Flow cytometry of the cells in the image confirmed most of the cells were activated neutrophils and monocytes.



Source: Seastar Medical Holding Corp.

A detailed molecular analysis of the SCD mechanism of action was recently published (Westover *et al.*, 2024). The researchers set up *in vitro* blood circuits to analyze the effects of iCa concentration on neutrophil and monocyte characteristics both before and after adhering to the SCD. The results of the study showed:

- The iCa level within the blood perfusion circuit directly affected how many cells bound to the SCD. As the iCa level was decreased, there was a subsequent decrease in the total number of bound cells, however the cells that did bind were more activated than cells that were in the recirculating blood perfusate.

- The binding of neutrophils to the SCD was accompanied by a significant decline in CD62L (L-selectin), which is a cell surface ligand on neutrophils and is shed upon neutrophil binding to surfaces (Walcheck *et al.*, 1996). In addition, after binding the neutrophils degranulated with release of lactoferrin, elastase, and MMP-9 and increased expression of the cell surface marker CD66b (CECAM8), which prior studies have shown moves to the cell surface upon degranulation (Zhao *et al.*, 2004).

- The bound and degranulated neutrophils in the SCD show a high degree of apoptosis, which is surprising given that the release of constituents of exocytotic vesicles (e.g., lactoferrin, elastase, and MMP-9) typically confers an extended life span to neutrophils (Silvestre-Roig *et al.*, 2016). The enhanced neutrophil apoptosis upon binding to the SCD is likely due to the low iCa level as declines in calcium entry promotes apoptosis (Whyte *et al.*, 1993).

- For monocytes, the data showed that it is the pro-inflammatory subset and not the anti-inflammatory subset of monocytes that bind to the SCD. The monocytes that were bound and eluted off the SCD showed much higher rates of pro-inflammatory cytokines (e.g., TNF-α and IL-6) compared to circulating monocytes.

An additional analysis was recently published that examined how the SCD affects the neutrophil to lymphocyte ratio (NLR), a key marker of inflammation (Iyer *et al.*, 2025). For AKI and sepsis, multiple studies have shown a significant positive correlation between a high NLR and worse disease severity, progression, and clinical outcomes (Fan *et al.*, 2019; Chen *et al.*, 2022). The study by Iyer *et al*. analyzed hematological data for 76 adult patients with AKI requiring CRRT that were also treated with the SCD compared to 32 CRRT-only patients. The results showed that while both groups began with similar NLRs, SCD-treated patients demonstrated a statistically significant reduction in NLR compared to control patients at day 6 (P=0.011) and that the reductions were driven by decreases in neutrophils and increases in lymphocytes.

Clinical Results

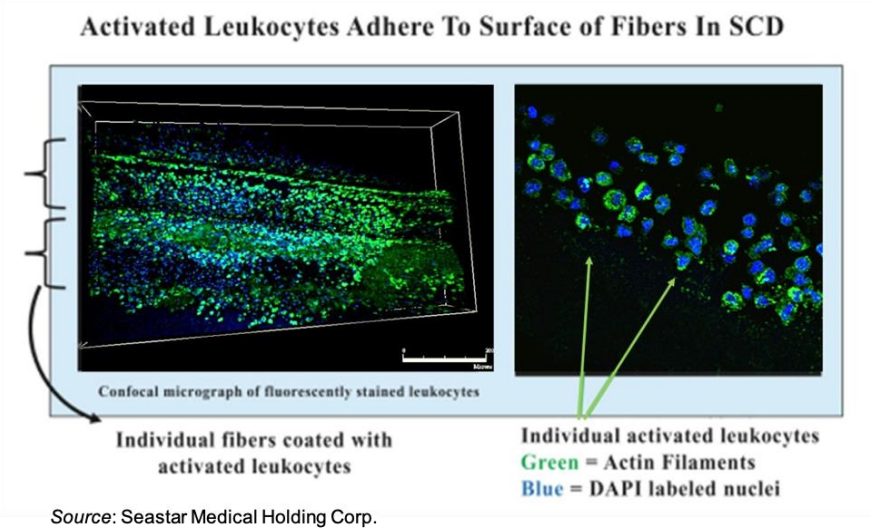
The SCD therapy has been evaluated in a number of clinical trials in both adult and pediatric populations. The table below gives an overview of the trials, with additional information for each trial provided after the table.

Study Name	Objective	Primary Endpoint	Study Population	Total Enrolled	Device-Related SAEs	Key Outcomes
China Study	AKI Safety, Mortality and Device Integrity Study	Safety and in-hospital mortality	AKI	N=9	None	The mortality for the case-matched controls was 77% (7/9), vs 22% (2/9) in the SCD treatment group (P=0.027) (Ding F, et al. *ASAIO J*. 2011;57(5):426-432).
ARF-002	AKI Safety, Mortality and Device Integrity Study	Safety and 60-day survival	AKI	N=35	None	Death from any cause at day 60 was 31.4% (11/35). Renal recovery, defined as dialysis independence, was observed in all of the surviving subjects at day 60. (Standard of care therapy is associated with a >50% 60-day mortality (Tumlin JA, et al. *Semin Dial*. 2013;26(5):616-623).
SCD-003	To determine the difference between SCD therapy and CKRT alone in survival	Day 60 survival	AKI	N=134	None	This was a Phase 3A randomized controlled trial. Due to a nationwide calcium shortage during the study, most patients received ineffective therapy as regional ionized calcium (iCa) levels couldn't be maintained at the target range. This resulted in no differences in outcomes in the intent-to-treat patient population. However, the subset of patients who achieved the target iCa ranges showed a significant clinical benefit in a per-protocol (PP) analysis. In this group, the 60-day mortality rate was 16% in the SCD-treated group compared to 41% in the control group. Furthermore, the composite endpoint of mortality and/or dialysis dependency at day 60 was lower in the PP SCD-treated group compared to the control group (16% vs. 58%, respectively, p = 0.01) (Tumlin JA, et al. *PLoS One*. 2015;10(8):e0132482). See additional details below on the SCD-003 study
SCD-PED-01	To determine safety and efficacy of SCD therapy + CKRT in pediatric patients	Day 60 survival and 60-day dialysis dependency	AKI	N=16	None	75% of patients (12/16) survived to hospital discharge. 100% of surviving patients (12/12) were dialysis independent by day 60 (Goldstein SL, et al. *Kidney Int Rep*. 2020;6(3):775-784; Goldstein SL, et al. *Kidney Medicine*.2024, doi: https://doi.org/10.1016/j.xkme.2024.100). See additional details below on the SCD-PED studies.
SCD-PED-02	To assess the safety of SCD in children with AKI weighing ≥10 kg and ≤20 kg	Safety	AKI	N=6	None	5/6 (83%) patients survived to ICU discharge and all surviving patients were dialysis-independent by day 60 (Goldstein SL, et al. *Kidney Medicine*. 2024, doi: https://doi.org/10.1016/j.xkme.2024.100). See additional details below on the SCD-PED studies.
SCD-005	To assess the safety and efficacy of SCD in AKI or ARDS patients associated with COVID-19 infections	Mortality at day 60; dialysis dependency at day 60; ventilation at day 28	AKI or ARDS after COVID-19	N=22	None	SCD-treated patients had a reduction in 60-day mortality of 50% (11/22), vs 81% (13/16) in a contemporary control group from a concurrent prospective CKRT registry (P=0.102). The subjects who received >96 hours of SCD treatment, per protocol, had a further reduction in mortality to 31% (5/16) (P<0.012) (Yessayan LT, et al. *Crit Care Explor*. 2022;4(5):e0694).

Source: Seastar Medical Holding Corp.

Humes *et al.*, 2010: This study presented a subset analysis of a Phase 2b study evaluating a renal assist device (RAD) containing adult human renal tubule cells (Humes *et al.*, 2004; Tumlin *et al.*, 2008), and served as the basis for development of the SCD. Patients in that study were treated with systemic heparin or regional citrate anticoagulation and received either a sham non-cell (SCD) or a cell-containing

cartridge. A total of 24 patients were assigned to the non-cell cartridge group, with half receiving heparin and half receiving citrate. At 28 days, the mortality rate in the heparin patient group was 50% compared to just 25% in the citrate group. At 90 days, the mortality rate in the heparin group was 75% compared to just 33% in the citrate group. There was only one discontinuation, which was due to a low platelet count. Intriguingly, even though thrombocytopenia is a recognized complication of ICU patients, aside from the one patient that discontinued, there were no substantive change from baseline values in total white blood cell count, neutrophil, and platelet counts. The researchers also performed immunofluorescent staining of a few of the SCD cartridges after patient treatment, which is shown below. When the cells were eluted off the membrane, it was determined that >90% of the cells were neutrophils.



Source: Seastar Medical Holding Corp.

Ding *et al.*, 2011: This was a prospective, proof-of-concept trial that evaluated the SCD therapy in AKI patients requiring CRRT in the ICU (China study). A total of nine patients were treated with the SCD and their results were compared to a case-matched historical control group. The results showed the mortality rate for the SCD was 22.22% compared to 77.78% for the historical control group (*P*=0.027). Multiple regression analysis identified the SCD as the only significant variable that affected mortality among age, SOFA score, average change in urine output over the first 7 days during or after treatment, and treatment modality (*P*=0.0222). There were no reports of neutropenia, no bleeding events (average platelet counts remained >50,000 throughout treatment), and no serious adverse events attributable to SCD

Tumlin *et al.*, 2013: This was a second pilot study (ARF-002) designed to test the SCD therapy in adult AKI patients requiring CRRT in the ICU. The prospective, nonrandomized, multicenter study enrolled a total of 35 patients, with the majority (88.6%) being on assisted ventilation. Day 60 mortality from any cause for this patient population was 31.4%. All surviving subjects achieved renal recovery, defined as dialysis independence, at Day 60. A total of 199 adverse events were reported, with no SAEs deemed definitely related to therapy by the principal investigator. The investigators also evaluated the change in biomarkers and found that IL-10 levels were significantly lower in survivors compared to non-survivors at baseline, day 3, and day 5 while IL-6 levels were lower in survivors versus non-survivors only on day 3. In addition, the CD11b MFI (Mean Fluorescence Intensity) level of circulating neutrophils declined significantly from baseline to day 3, which is important as CD11b is a marker of neutrophil activation and inflammation.

Tumlin *et al.*, 2015: This was a randomized, placebo controlled trial (SCD-003) of 134 ICU patients with AKI in which 65 patients received CRRT alone and 69 received CRRT therapy with the SCD. The study was initiated in September 2011. In the second quarter of the enrollment period there was a national calcium shortage in the U.S. The shortage of calcium infusion solution resulted in a tendency to minimize citrate infusion rates. Thus, the iCa level within the blood circuit tended to be above the recommended range of 0.25-0.4 mM. Since the SCD therapy requires a narrow intra-circuit iCa range to function effectively, and the concern that patients were not getting effective therapy, the interim analysis was

performed early after enrollment of only 134 patients. The interim analysis showed no significant difference in mortality, with a 60-day mortality of 39% in the SCD group compared to 36% for the control group (*P*=0.23). Of the 134 subjects enrolled in the study, 19 SCD subjects and 31 control subjects were maintained in the recommended iCa range (< 0.4 mM) for ≥90% of the therapy time. Mortality at day 60 in this subset of patients was 16% in the SCD group compared to 41% in the control group (*P*=0.11), which was not significant due to the small patient numbers. Ultimately, 9 of the 21 clinical trial sites were unable to enroll subjects due to the low inventories of injectable calcium, thus the study was terminated early. However, the results of the study pointed to the importance of keeping a calcium concentration < 0.4 mM for maximum efficacy of the SCD. To further explore this point, a post hoc analysis examined the difference between control patients with calcium levels < 0.4 mM and control patients with calcium levels > 0.4 mM. No difference in mortality was noted between these two groups, suggesting that calcium level alone is insufficient to confer a survival advantage. Conversely, this same analysis performed in patients treated with the SCD showed a significant survival benefit between those with calcium levels < 0.4 mM and those with calcium levels > 0.4 mM. This further supports the hypothesis that low iCa level in conjunction with the SCD is necessary for optimizing survival outcomes.

Goldstein *et al*., 2020: This was the first study of the SCD therapy in a pediatric population (SCD-PED-01). A total of 16 pediatric patients with AKI and multiorgan dysfunction receiving CRRT were enrolled. The circuit iCa level was maintained at < 0.4 mM for 90.2% of the SCD therapy time. Fifteen of the 16 subjects survived to the end of SCD therapy, with the one subject who did not survive dying after seven hours of therapy following development of irreversible ventricular tachycardia from severe myocardial inflammation. Twelve of the 16 subjects survived to hospital discharge; two of the subjects died on ECMO and one other hospital death occurred on day 16 due to cardiopulmonary failure requiring ECMO. Of the 12 survivors, all were dialysis independent with normal serum creatinine at day 60. There were 12 SAEs, however none of them were device related and none were related to the study. These data supported the safe use of the SCD in a pediatric population.

Goldstein *et al*., 2024: This is a summary of the results from two prospective studies (SCD-PED-01 and SCD-PED-02) in pediatric patients with AKI and multiorgan dysfunction requiring CRRT. It discussed the 16 patients from SCD-PED-01 along with 6 additional patients from SCD-PED-02. Five of the six patients from SCD-PED-02 survived to 60 days and no device-related SAEs reported in SCD-PED-02. The researchers also reported a comparison of the combined SCD-PED population to a size matched cohort and showed 77% of the SCD-PED population survived to the time of ICU discharge or 60 days compared to 55% from the size matched cohort (*P*=0.04). While no definitive claims of efficacy can me made given the small sample size, the 77% survival rate compares favorably with published reports showing an approximate 50% survival rate for critically ill children in CRRT studies.

Yessayan *et al*., 2022: This was a prospective proof-of-concept study (SCD-005) to evaluate the SCD therapy in COVID-19 ICU patients with multiple organ failure. A total of 22 patients with acute respiratory distress syndrome (ARDS) who required mechanical ventilation were enrolled into the study. All patients except one had AKI that required CRRT. Sixteen patients that met the enrollment criteria were selected as contemporaneous controls from a concurrent prospective registry CRRT trial. The results showed that SCD therapy was safe with no device-related serious adverse events. There were significant reductions reported in the levels of eight plasma biomarkers, including IL-6, IL-15, IL-10, and soluble ST2 in those treated with the SCD. The SCD-treated cohort had a reduction in 60-day mortality to 50% compared with 81% in the control cohort. In addition, patients who received ≥ 96 hours of SCD treatment, per protocol, had a further reduction in mortality to 31% (*P*<0.012).

In addition to the above clinical trials, there have been a number of case reports published in which the SCD was used to treat patients with different life-threatening conditions:

Hambrick *et al*., 2023: This report described a twelve-year-old (Patient 1) and two 2-year old twins (Patients 2 and 3) with shiga-toxin associated-hemolytic uremic syndrome (STEC-HUS) requiring CRRT. Patient 1 was suffering from AKI with multisystem organ failure. After receiving seven days of SCD therapy and CRRT, the patient gradually recovered and had normal kidney and hematologic parameters

at 60-day follow up. Patients 2 and 3 were both suffering from AKI that required CRRT and each received 24 hours of SCD therapy. Patient 2 had normalization and Patient 3 had near-normalization of kidney function at 60-day follow up. Importantly, SCD treatment was associated with recovery from multisystem organ dysfunction while being well tolerated with no device-related adverse events.

Yessayan *et al*., 2024: This report described two patients with acute on chronic liver failure (ACLF), which is an acute clinical deterioration in patients with a pre-existing chronic liver disease. Patients with ACLF that is accompanied by AKI have mortality rates of 85% at 90 days (Allegretti *et al*., 2022). Severe ACLF with ≥ 4 organ failures have a reported 100% mortality at 28 days (Gustot *et al*., 2015).

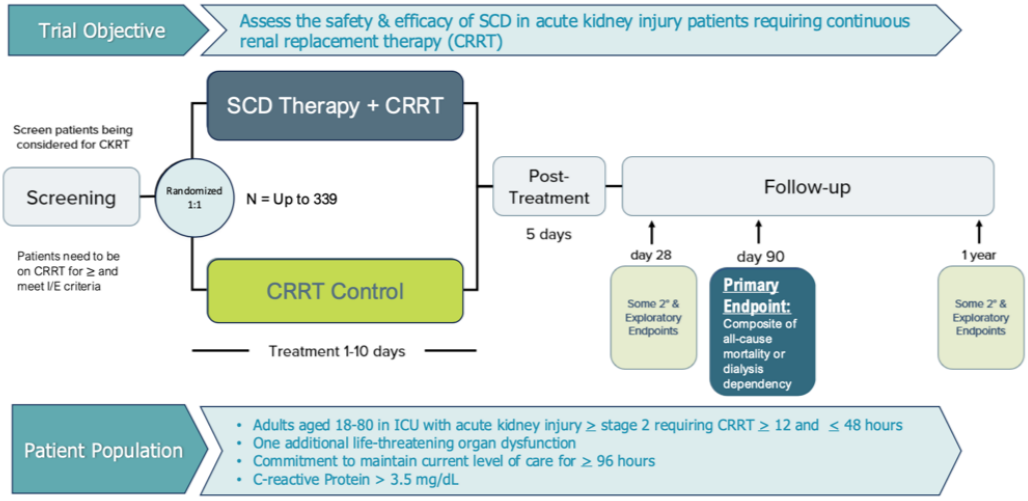
Patient 1 had acute alcohol associated hepatitis who was diagnosed with hepatorenal syndrome and started on CRRT. He met the criteria for ACLS with ≥ 4 organ failures. The patient received SCD therapy for 7 consecutive days. Following initiation of SCD treatment, the patient stabilized and showed improvement of his multiorgan dysfunctions. His liver enzymes declined along with reductions in plasma IL-6 and IL-8 levels. He was discharged from the ICU 7 days after initiation of SCD treatment and he was alive at day 90 while being evaluated for a liver transplant.

Patient 2 had chronic liver disease stemming from non-alcoholic steatohepatitis (NASH) and was admitted to the hospital for hypotension and decompensated cirrhosis. He was diagnosed with hepatorenal syndrome and started on CRRT. Three days after initiating CRRT he was started on SCD treatment, at which point the patient stabilized. He received SCD therapy for 6 days, however after stopping SCD therapy his condition rapidly deteriorated and he was able to successfully complete a liver transplant 6 days after SCD therapy ended. He was discharged from the hospital 42 days after SCD therapy ended with normal liver function.

Amerson *et al*., 2024: This case report involved a 28-year old women diagnosed with streptococcal toxic shock syndrome five days after cesarean section. Conventional therapy did not improve her condition and she was placed on venoarterial extracorporeal membrane oxygenation (ECMO) followed by pathogen hemoperfusion with the Seraph 100 blood filter and then SCD therapy. The patient's condition gradually improved with ECMO decannulation after six days and extubation from mechanical ventilation after 14 days. She discontinued all kidney replacement therapy three weeks later. There were no device-related adverse events reported.

Neutralize-AKI Study

Based on the positive results from the initial studies, the NEUTRALIZE-AKI pivotal study was designed to assess the safety and efficacy of the SCD (NCT05758077). It is a two-arm, randomized, open label, controlled, multi-center trial that will enroll up to 339 adult patients in the ICU with AKI requiring CRRT and at least one additional organ failure across 30 clinical centers. SCD therapy will be administered for up to 10 days with a primary outcome of all-cause mortality or dialysis dependency at day 90. An overview of the trial is given below.



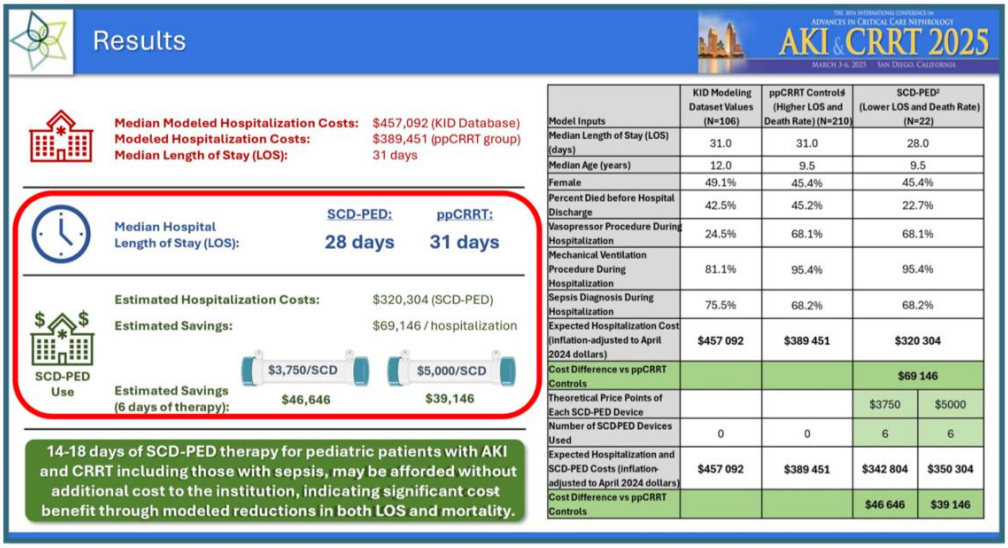
Source: Seastar Medical Holding Corp.

In September 2025, SeaStar announced that the independent data safety monitoring board (DSMB) recommended the continuation of the trial as there were no device-related safety concerns along with a signal of potential clinical benefit in the treatment group across key study outcome measures. The DSMB also recommended increasing the total enrollment of the trial from the originally planned 200 to 339. Medicare/Medicaid patients that enter the trial receive reimbursement from CMS, which can help to reduce overall trial costs, increase site activations, and to accelerate enrollment. Thus far, the trial has enrolled 150 patients (as of last public disclosure in 2025) and we estimate patient enrollment will complete near the end of 2026.

AKI Market

The SCD will be sold to hospitals to use on AKI patients in the ICU requiring CRRT. There are approximately 5.7 million ICU admissions in the U.S. every year (Viglianti *et al.*, 2011). AKI incidence among critically ill ICU patients is high, with multiple cohort studies reporting AKI in approximately 50-60% of ICU admissions. Among ICU patients who develop AKI, approximately 10-15% receive acute renal replacement therapy, either CRRT (75%) or intermittent renal replacement therapy (Rewa *et al.*, 2023). This equates to approximately 280,000 patients per year. The pediatric AKI population is estimated to be approximately 1/50th of that size, or about 4,000 patients per year.

The SCD addresses one of the highest-cost populations in the hospital: ICU patients with dialysis-requiring AKI. These patients routinely incur six-figure admission costs, and hospitals already absorb the expense of CRRT and other advance supportive technologies. Thus, the SCD can be thought of as a cost-offset ICU device rather than a standalone reimbursed therapy, with adoption driven by reductions in ICU length of stay, dialysis utilization, and complication rates. The SAVE Surveillance Registry is assessing the use of the SCD in critically ill pediatric patients with AKI requiring RRT. Data from the first 21 pediatric patients shows no device related safety events and a 76% survival at Day 60 and a 71% survival at Day 90, which could ultimately show a 50% reduction in loss of life compared to historical data. From a cost-benefit perspective, a recent publication highlighted a cost regression model for pediatric hospitalizations with AKI requiring CRRT, with an estimated savings of $69,146 with the use of the SCD (Humes *et al.*, 2025). This is summarized in the following figure.



Model Inputs	KID Modeling Dataset Values (N=106)	ppCRRT Controls (Higher LOS and Death Rate) (N=210)	SCD-PED (Lower LOS and Death Rate) (N=22)	
Median Length of Stay (LOS) (days)	31.0	31.0	28.0	
Median Age (years)	12.0	9.5	9.5	
Female	49.1%	45.4%	45.4%	
Percent Died before Hospital Discharge	42.5%	45.2%	22.7%	
Vasopressor Procedure During Hospitalization	24.5%	68.1%	68.1%	
Mechanical Ventilation Procedure During Hospitalization	81.1%	95.4%	95.4%	
Sepsis Diagnosis During Hospitalization	75.5%	68.2%	68.2%	
Expected Hospitalization Cost (inflation-adjusted to April 2024 dollars)	$457 092	$389 451	$320 304	
Cost Difference vs ppCRRT Controls			$69 146	
Theoretical Price Points of Each SCD-PED Device			$3750	$5000
Number of SCDPED Devices Used	0	0	6	6
Expected Hospitalization and SCD-PED Costs (inflation-adjusted to April 2024 dollars)	$457 092	$389 451	$342 804	$350 304
Cost Difference vs ppCRRT Controls			$46 646	$39 146

Source: Seastar Medical Holding Corp.

Initial uptake is expected to occur at high-acuity centers with established CRRT programs, thus supporting a focused commercial strategy and a $600 million U.S. opportunity without requiring changes to existing reimbursement frameworks. In support of this, for the pediatric market the company is focusing on top academic sites first in an effort to create brand recognition and treatment experience. Approximately 50 hospitals treat 50% of pediatric AKI patients and will serve as the focus of the company's commercial strategy. Approximately 20% of these 50 hospitals have prior experience with the SCD and will serve as the initial target population. SeaStar is planning to manage all aspects of the sales and distribution process to reduce middleman fees and ensure prompt delivery of product.

Additional Indications

While the company is currently focused on the use of the SCD therapy in AKI, there are a number of other indications that could be amenable to SCD therapy, including cardiorenal syndrome and hepatorenal syndrome.

- Cardiorenal Syndrome (CRS): CRS is a clinical disorder where therapy designed to relieve the congestive symptoms of chronic heart failure is limited by a decline in renal function. There are an estimated one million hospital admissions annually in the U.S. due to CRS. Patients are typically treated with diuretics to relieve persistent congestion; however, this typically results in worsening renal function, progression of heart failure, and ultimately death. A CRS trial is currently being conducted at the UOM to test whether SCD treatment will improve cardiac and renal functions. Cardiac function is being measured by the rate of ejection fraction while renal function is measured by serum creatinine and blood urine nitrogen levels.

- Hepatorenal Syndrome (HRS): HRS is a sudden loss of kidney function in patients with advanced liver cirrhosis. It is driven by a hyperinflammatory process and is associated with a very high mortality. An investigator-initiated pilot study (NCT04898010) will evaluate the SCD in treating up to 10 ICU patients with AKI and HRS Type 1. Two patients have been treated successfully thus far and their results were summarized above in Yessayan *et al.*, 2024.

Intellectual Property

SeaStar currently has 16 issued U.S. patents along with four pending U.S. patent applications. The company also has 18 issued foreign patents and three pending foreign patent applications. The patents and patent applications belong to four patent families. The patents and applications in Patent Family 1 are co-owned by SeaStar and the University of Michigan (UOM). The patents and applications in Patent Families 2-4 are solely owned by SeaStar.

Patent Family 1 consists of nine U.S. patents and one pending U.S. patent application. The patents will expire from 2028-2031, while the pending application, if granted, will expire in 2028. International patents are co-owned with the UOM in Canada, Japan, and New Zealand with patent applications pending in Europe and Hong Kong. The international patents, and pending applications, will expire in 2028. The license agreement with the UOM grants a worldwide, royalty bearing, exclusive license to the university's interest in the co-owned patents and applications in Patent Family 1. In exchange, SeaStar will pay the UOM a 1% royalty fee on net sales and has paid a one-time milestone payment of $0.1 million upon FDA approval of the first license product under the license. The agreement was amended in October 2024 to extend the 1% royalty on net sales until the later of a) the last patent to expire or b) the ten-year anniversary of the first commercial sale.

Patent Family 2 includes two U.S. patents and one pending U.S. patent application directed to a second generation of the SCD cartridge and methods of use for using the SCD to process leukocytes. The patents will expire in 2032 and the application, if granted, will expire in 2031. International patents have been granted in Australia, Canada, Europe, and Japan.

Patent Family 3 includes one U.S. patent directed to methods of treating chronic heart failure using the SCD, which will expire in 2032. An international patent has been granted in Japan that will expire in 2032. Patent Family 4 includes two U.S. patents directed at treating chronic heart failure and acute decompensated heart failure using the SCD. The patents will expire in 2032. International patents have been granted in Australia and Canada, with a pending application in Europe. Those patents will also expire in 2032.

The company also owns patents and patent applications in four additional patent families (Patent Families 5-8). Patent Family 5 consists of one pending U.S. application directed to devices and methods for reducing rejection of a transplanted organ in a recipient, which if granted will expire in 2040. Patent Family 6 consists of a pending international patent application directed to devices and methods for treating cytokine release syndrome and tumor lysis syndrome, which if granted will expire in 2041. Patent Family 7 consists of a U.S. patent direct to an extracorporeal cell-based therapeutic device and delivery system for renal cells, which expires in 2027. Patent Family 8 consists of a U.S. patent directed to methods for enhanced prorogation of renal cells, which expires in 2031.

Financials and Capital Structure

On January 5, 2011, the company enacted a 1-for-10 reverse split. All share values are given post-split. On November 13, 2025, SeaStar reported financial results for the third quarter of 2025. The company reported revenue of $183,000 for the third quarter of 2025 compared to $68,000 for the third quarter of 2024. The company first received HDE from the FDA in February 2024 and shipped its first product in July 2024. There are currently ten customer sites for QUELIMMUNE. Cost of goods sold during the third quarter of 2025 was less than $0.1 million. No cost of goods sold were recorded during the third quarter of 2024 as the inventory was assigned no value under U.S. GAAP since it was expensed to research and development expense upon purchase prior to obtaining final regulatory clearance to sell QUELIMMUNE commercially. R&D expenses in the third quarter of 2025 were $1.9 million compared to $2.3 million in the third quarter of 2024. The decrease was primarily due to lower clinical trial expenses and reduced preclinical consulting services partially offset by increased costs associated with the NEUTRALIZE-AKI study. G&A expenses for the third quarter of 2025 were $1.9 million compared to $2.2 million for the third quarter of 2024. The decrease was primarily due to lower legal fees, lower franchise tax expense, and decreased SEC-related costs partially offset by increased compensation costs and audit fees.

As of September 30, 2025, SeaStar had approximately $13.8 million in cash and cash equivalents. During the third quarter of 2025 the company raised approximately $12.4 million through equity offerings priced at the market and through the exercise of approximately 0.3 million warrants. As of January 5, 2026, SeaStar had approximately 3.8 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 6.5 million.

Risks to Consider

In addition to the risks listed below, investors are encouraged to read the company's latest 10-K filing that discusses additional risk factors.

Development Risk: The SCD is currently in a pivotal Phase 3 trial in adult AKI patients. While the device has been successful thus far, and the DSMB has indicated there is sign of potential benefit in the treatment group, there is no guarantee that the trial will be successful. The device has received HDE for the pediatric AKI population, however if the NEUTRALIZE-AKI trial is unsuccessful, the device is unlikely to be fully approved by the FDA. In addition, if the NEUTRALIZE-AKI trial is unsuccessful then a new trial will likely need to be conducted, which could add considerable time until the SCD is fully approved. Even if the device is approved for use in AKI patients, there is no guarantee that the device will be successful in other patient populations, which could limit the devices total market opportunity.

Commercial Risk: The company received HDE approval from the FDA for the use of the SCD in pediatric patients in February 2024 and shipped the first commercial QUELIMMUNE units in July 2024. Thus, the company has a limited commercial operating history, which makes it difficult to accurately forecast future results. Even if the company were to receive full approval to market the SCD in adult patient populations, there is no guarantee that there would be sufficient demand for the product.

Intellectual Property Risk: SeaStar co-owns, and licenses from, the UOM patents related to the SCD technology. If the UOM were to terminate the license, the company would no longer have exclusive rights to those patents and the UOM would be free to license their interest in the co-owned patents to a competitor. Even with patent protection, there is no guarantee that a competitor would not be able to develop a similar product that circumvents the company's intellectual property protection.

Financial Risk: As of September 30, 2025, SeaStar had approximately $13.8 million in cash and cash equivalents. The company will need to obtain additional capital in order to support its operations and complete its planned regulatory approval process. There is no guarantee that the company will be able to obtain additional financing or, if funding is obtained, it may not be on acceptable terms. Raising additional capital could cause dilution of current shareholders. In addition, the company has approximately 26 million warrants outstanding, which if exercised could lead to significant dilution for existing shareholders.

MANAGEMENT PROFILES

Eric Schlorff – Chief Executive Officer

Eric Schlorff has served as the Chief Executive Officer of SeaStar Medical since 2019, responsible for the management, strategy, and operations of the company. He has extensive experience in financial planning and managing large, complex organizations. In addition, he has deep knowledge of SeaStar Medical's business operations, including the scientific basis, regulatory requirements and sales and marketing channels. Prior to joining SeaStar Medical in 2016, Mr. Schlorff spent more than 20 years at Dow Chemical Company, serving in served in multiple role, including Global Director of Alternative Investments for the Dow Chemical Pension Plan, Global Finance Leader for Crop Protection & Seeds at Dow AgroSciences, Global Market Intelligence Leader at Dow AgroSciences, Global Financial Manager of Royalties at Dow Agrosciences, Senior Investment Manager of Alternative Investments at Dow Chemical Company, New Business Development of Pharmaceuticals at Dow Chemical Company, Global Financial Analyst within the New Businesses division at Dow Chemical Company, and Global Financial Analyst within Dow AgroSciences at Dow Chemical Company. Mr. Schlorff has a bachelor's degree in chemistry and biology from Mac Murray College, an M.S. in pharmacology from Southern Illinois University School of Medicine and a master's in business administration from University of Illinois Urbana-Champaign.

Kevin Chung, MD, FCCM, FACP – Chief Medical Officer

Dr. Kevin Chung, a renowned expert in burns, multi-organ support, and extracorporeal therapies, is Chief Medical Officer of SeaStar Medical where he is responsible for the strategy, direction, and execution of the company's clinical development plans as the company develops and commercializes extracorporeal therapies. Prior to joining SeaStar Medical, Dr. Chung served as professor and Chair of the Department of Medicine, and professor of Surgery, at the F. Edward Hebert School of Medicine at the Uniformed Services University of the Health Sciences, Bethesda, Maryland. Earlier in his career, he served as Chief of the Department of Medicine at Brooke Army Medical Center in San Antonio. Dr. Chung deployed as the Chief, Intensive Care Unit, for the 86th Combat Support Hospital in Baghdad, Iraq 2008, and as Director, Joint Combat Casualty Research Team in Bagram, Afghanistan 2012. He is a 1995 graduate of the United States Military Academy at West Point and a 1999 graduate of Georgetown University School of Medicine. Dr. Chung has authored over 300 peer reviewed manuscripts, reviews, editorials, and book chapters, and has been an invited speaker for over 150 lectures internationally.

Michael Messinger – Chief Financial Officer

Mr. Messinger has more than two decades of experience and leadership in financing and accounting for drug discovery and development organizations. He currently serves as a member of the board of directors of Filament Health Corp. and a strategic consultant to various biotechnology companies. Mr. Messinger most recently served as Chief Financial Officer of ContraFect Corporation, where he led the company through its Nasdaq IPO in 2014, multiple financing rounds, including investments from Pfizer Inc., and a $90 million contract with BARDA (Biomedical Advanced Research and Development Authority). Prior to joining ContraFect, Mr. Messinger held senior financial roles at Lexicon Pharmaceuticals, Inc. and Coelacanth Corporation. He started his career as an auditor at Ernst & Young LLP. Mr. Messinger received his B.B.A. degree in accounting from the University of Michigan.

VALUATION

We are initiating coverage of SeaStar Medical Holding Corp. (ICU) with a valuation of $12.00. SeaStar is a commercial stage company that is developing its first-in-class Selective Cytopheretic Device (SCD) as a treatment for critically ill patients that are suffering from an uncontrolled hyperinflammatory response. The SCD therapy was approved by the FDA in February 2024 under a Humanitarian Device Exemption (HDE) for the treatment of pediatric acute kidney injury (AKI) patients due to sepsis or a septic condition. SeaStar reported 77% survival at Day 60 for pediatric patients (compared to a historical 50% mortality rate using the standard of care) along with no patients requiring dialysis. The company is currently conducting the NEUTRALIZE-AKI trial of up to 339 critically ill AKI patients requiring continuous renal replacement therapy (CRRT). The primary outcome of the study is a composite of all-cause mortality or dialysis dependency on Day 90. We anticipate enrollment concluding for the trial near the end of 2026.

Selective Cytopheretic Device Therapy

A serendipitous observation by Dr. David Humes during development of a renal tubule assist device (RAD) containing adult human renal tubule cells (Tumlin *et al.*, 2008) led to the creation of the Selective Cytopheretic Device (SCD). He noticed that AKI patients treated with a RAD lacking renal tubule cells showed improvement in their condition, which led to follow-up studies and evaluation. The SCD consists of a polycarbonate cylindrical housing that contains a biocompatible polysulfone hollow fiber membrane. The device is attached in-line with CRRT and utilizes a low-shear stress blood flow path around the bundled fibers, which promotes binding of activated neutrophils and monocytes. The activated cells are immunomodulated when they are exposed to a low ionized calcium (iCa) environment (<0.4 mM Ca^{2+}) and then released back to the systemic circulation.

A number of studies have been performed to better understand how the SCD exerts its anti-inflammatory effects. While the exact mechanism is still being evaluated, there appear to be three elements to the SCD therapy: a) binding of activated neutrophils and monocytes on the SCD biomimetic membrane; b) deactivating the activated neutrophils by maintaining a specified iCa level within the SCD; and c) shifting proinflammatory monocytes to a lower inflammatory profile. The SCD is used with a clinically validated regional citrate anticoagulation protocol to lower the iCa level. This serves two purposes: to prevent clotting within the circuit and to immuno-modulate the activated neutrophils and monocytes before they are eluted from the SCD and returned to the patient.

The company is currently conducting the Phase 3 NEUTRALIZE-AKI pivotal study to assess the safety and efficacy of the SCD (NCT05758077). It is a two-arm, randomized, open label, controlled, multi-center trial that will enroll up to 339 adult patients in the ICU with AKI requiring CRRT and at least one additional organ failure across 30 clinical centers. SCD therapy will be administered for up to 10 days with a primary outcome of all-cause mortality or dialysis dependency at day 90. In September 2025, SeaStar announced that the independent data safety monitoring board (DSMB) recommended the continuation of the trial as there were no device-related safety concerns along with a signal of potential clinical benefit in the treatment group across key study outcome measures. Thus far, the trial has enrolled 150 patients (as of last public disclosure in 2025) and we estimate patient enrollment will complete near the end of 2026.

Valuation

We value SeaStar using a probability-adjusted discounted cash flow model that takes into account revenues from the sale of the SCD in both the pediatric and adult AKI market. While not currently a part of the model, we note that the company is planning to pursue the use of the SCD therapy for additional indications, including cardiorenal syndrome and hepatorenal syndrome, both of which represent potential upside to our valuation. Our model utilizes a discount rate of 15%.

The device is already approved for sale in the pediatric indication, and the company has reported $814,000 for the first nine months of 2025. We model for approximately $1 million in total revenues for 2025. For future years, we model for approximately $1 million more in sales per year for the next few years for the SCD in the pediatric indication with peak sales of $12 million in 2036.

For the adult AKI population, we estimate for the NEUTRALIZE-AKI trial to complete enrollment before the end of 2026, which would lead to a Premarket Approval application in 2027 and sales to begin in 2028. We model for peak revenues in the adult AKI population of $600 million to occur in 2037. We estimate gross margins of 90%, R&D expenses of 20% and G&A expenses of 27% of net revenues, and a tax rate of 21%. Combining the revenues for the pediatric and adult population and using a 90% probability of approval leads to an NPV for the AKI indication of $155 million.

Combining the net present value for the SCD in AKI with the current cash position ($13 million) and the potential cash from warrant exercises (approximately $33 million) leads to a net present value for SeaStar of $200 million. Dividing by the diluted share count (approximately 6.5 million) plus an additional 10 million shares to account for additional financings leads to a valuation of $12 per share.

PROJECTED FINANCIALS

SeaStar Medical Holding Corp.	2024 A	Q1 A	Q2 A	Q3 A	Q4 E	2025 E	2026 E	2027 E
Quelimmune	$0.1	$0.5	$0.5	$0.5	$0.5	$2.0	$3.0	$4.0
License and other revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.1**	**$0.5**	**$0.5**	**$0.5**	**$0.5**	**$2.0**	**$3.0**	**$4.0**
Cost of revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1
Research & development	$9.1	$2.4	$1.0	$1.9	$2.0	$7.3	$8.0	$8.5
General & administrative	$8.9	$1.7	$1.0	$1.9	$1.7	$6.3	$6.5	$6.8
Operating Income	($17.8)	($3.6)	($1.6)	($3.3)	($3.2)	($11.7)	($11.6)	($11.4)
Non-Operating Expenses (Net)	($7.0)	$0.1	($0.2)	$0.1	$0.1	$0.0	$0.0	$0.0
Pre-Tax Income	($24.8)	($3.6)	($1.8)	($3.2)	($3.1)	($11.7)	($11.6)	($11.4)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	**($24.8)**	**($3.6)**	**($1.8)**	**($3.2)**	**($3.1)**	**($11.7)**	**($11.6)**	**($11.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($66.32)**	**($4.13)**	**($1.62)**	**($1.20)**	**($0.97)**	**($5.95)**	**($2.11)**	**($1.63)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	0.4	0.9	1.1	2.6	3.2	2.0	5.5	7.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE

© 2026 barchart.com

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.