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SeaStar Medical Holding Corp. (ICU-NASDAQ)

ICU: QUELIMMUNE® Commercial Adoption Continues; Adult AKI Study Progresses Toward 2027 Completion

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 (11/16/26)	$0.84
Valuation	**$12.00**

OUTLOOK

On November 11, 2026, SeaStar Medical Holding Corp. (ICU) announced financial results for the third quarter of 2026 and provided a business update. Revenue increased 247% YoY to $635K, with QUELIMMUNE now being used in 20 hospitals across the U.S. The pivotal NEUTRALIZE-AKI trial of SCD therapy in adults with acute kidney injury (AKI) requiring continuous renal replacement therapy (CRRT) has enrolled 251 of its planned 339 patients, with enrollment now expected to conclude by mid-2027. The company has submitted the first PMA module, with the final clinical module to be submitted approximately nine months after enrollment completion, assuming a successful trial outcome.

SUMMARY DATA

52-Week High	**$5.08**
52-Week Low	**$0.84**
One-Year Return (%)	**-77.94**
Beta	**-1.07**
Average Daily Volume (sh)	**284,899**
Shares Outstanding (mil)	**5**
Market Capitalization ($mil)	**$4**
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-Growth**
Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	0.3 A	0.3 A	0.2 A	0.4 A	1.2 A
2026	0.5 A	0.6 A	0.6 A	0.5 E	2.2 E
2027					3.0 E
2028					10.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	-$4.37 A	-$1.77 A	-$1.32 A	-$0.79 A	-$5.86 A
2026	-$0.90 A	-$0.91 A	-$1.03 A	-$0.78 E	-$3.60 E
2027					-$2.08 E
2028					-$1.58 E

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WHAT'S NEW

Business Update

SeaStar Medical Holding Corp. (ICU) recently reported third-quarter 2026 financial results and provided a business update. Revenue from the sale of QUELIMMUNE increased 247% year over year to $635K due to continued adoption of QUELIMMUNE for pediatric acute kidney injury (AKI). During the earnings call, management indicated that all 20 current hospital customers are using the product, with the vast majority representing repeat customers. The company also believes it will exceed its previously established $2 million revenue guidance for 2026. Importantly, the FDA has confirmed that SeaStar has fulfilled the post-approval requirements for the SAVE registry, removing a potentially meaningful administrative barrier to hospital adoption.

The pivotal NEUTRALIZE-AKI trial evaluating selective cytopheretic device (SCD) therapy in adults with AKI requiring CRRT has enrolled 251 of its planned 339 patients, with enrollment now expected to be completed in mid-2027. The company has submitted the first module of the adult premarket approval (PMA) application and anticipates submitting the final clinical module approximately nine months after enrollment completion, assuming a successful outcome to the trial. SeaStar recently received its seventh Breakthrough Device Designation, this time for adult sepsis-associated hyperinflammation, an indication that could potentially benefit from data generated in NEUTRALIZE-AKI.

Commercial Progress and Updated Outlook

SeaStar generated third quarter 2026 revenue of $635K, representing a 247% increase compared with $183K in the prior-year period. Gross margin remained above 90%, consistent with previous quarters, reflecting the attractive economics of QUELLIMUNE. Revenue for the first nine months of 2026 was $1.745 million, more than double the $814K generated during the comparable period in 2025. Although revenue was relatively unchanged sequentially compared with approximately $600K in 2Q26, management emphasized that QUELIMMUNE addresses an ultra-rare pediatric population, making quarterly sales inherently dependent on the number of patients needing treatment. All 20 current hospital customers are using QUELIMMUNE, with the majority of them having placed repeat orders, thus the relatively flat QoQ revenue should not be viewed as a lack of customer engagement or declining utilization, but instead is derived from the variable incidence of eligible patients.

Management indicated that its commercial strategy continues to focus on the 50 largest pediatric medical centers in the U.S., 20 of which are new customers. The company has added 10 new customers during 2026 and intends to continue expanding its hospital network while increasing utilization within existing accounts. The company did not disclose the number of individual patients treated during the quarter, but its comments suggest that the current commercial base is becoming increasingly established, with repeated usage beginning to drive growth.

An important development during the quarter was the FDA's confirmation that SeaStar had fulfilled the post-approval study requirements associated with the SAVE registry. Previously, participation in the registry required additional institutional resources and administrative work, which can slow the hospital onboarding process. During the earnings call, management indicated that it had already received positive feedback from prospective customers that had been waiting for this requirement to be fulfilled. Although the commercial impact remains to be quantified, removing this requirement should make QUELIMMUNE more accessible to additional hospitals. In addition, dedicated ICD-10-PCS procedure codes assigned by CMS became effective October 1, 2026, providing hospitals with a mechanism to track and bill procedures involving QUELIMMUNE. Together, these developments should facilitate broader adoption by reducing administrative burdens and improving the infrastructure supporting hospital utilization.

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Management reiterated its confidence that 2026 QUELIMMUNE revenue will exceed the previously given $2 million guidance for the year, although it declined to provide a revised target. The company expects to provide 2027 revenue guidance early next year. Given the ultra-rare nature of the indication, quarterly revenue will likely remain somewhat variable, but the combination of additional hospital customers, repeat utilization, improved clinical awareness, and removal of the SAVE Registry requirement provides a solid foundation for continued commercial growth.

SAVE Registry Results Strengthen Clinical Positioning

The commercial outlook is further supported by positive clinical data recently presented at the American Society of Nephrology (ASN) Kidney Week 2026. The results showed a statistically significant improvement in survival among QUELIMMUNE-treated pediatric patients compared with a clinically aligned historical cohort from the Kids' Inpatient Database. The analysis demonstrated 90-day survival of approximately 65% among treated patients compared with 47% in the comparator population (*P*=0.043). Survival was also statistically higher at 60 days and hospital discharge. Additionally, 83% of treated patients who did not receive renal replacement therapy at baseline were independent of renal replacement therapy at 90 days. No device-related adverse events were reported among the 50 treated patients.

Management emphasized that these patients represented an extremely sick population, with approximately 1/3rd requiring ECMO and nearly all requiring mechanical ventilation and vasopressors. The observed survival benefit is therefore encouraging, particularly given the historical mortality associated with this condition. Although the comparison with an external historical control does introduce some limitations, the findings provide additional clinical support for QUELIMMUNE and should help strengthen physician awareness and hospital adoption efforts.

Update on NEUTRALIZE-AKI

SeaStar is continuing to enroll patients in the NEUTRALIZE-AKI pivotal trial evaluating SCD therapy in 339 adult patients with AKI requiring CRRT. The study has enrolled 251 patients, approximately 74% of the planned total. Management did revise its enrollment completion guidance to mid-2027, extending the timeline from the previous expectation of year-end 2026 or the first quarter of 2027. The relatively steady enrollment pace is partially due to restrictive inclusion and exclusion criteria, which is designed to identify patients with potentially modifiable disease. Four additional clinical sites were recently onboarded, with more sites to become active by year-end. Management indicated that the current enrollment rate supports the mid-2027 target, although further site activation and improved recruitment could potentially accelerate completion.

SeaStar anticipates submitting the final clinical module of its PMA application approximately nine months after completing enrollment. This suggests a potential final submission around the first quarter of 2028, assuming enrollment concludes by mid-2027. The company has already submitted its first PMA module and expects to submit additional modules over the coming months. The modular approach allows the FDA to review portions of the application before completion of the trial, potentially reducing the time required for final regulatory review. In addition, the Breakthrough Device Designation should provide access to priority review following submission of the completed application, assuming positive clinical results.

The primary endpoint of NEUTRALIZE-AKI is a composite of 90-day mortality or dialysis dependency. Secondary endpoints include 28-day mortality, ICU-free days, major adverse kidney events at Day 90, and dialysis dependency at one year. While the enrollment delay is disappointing, the addition of clinical sites, the emphasis on enrolling the correct patient population, and ongoing PMA preparation represent positive progress toward approval into the substantially larger adult AKI market.

Additional Development Opportunity in Adult Sepsis

SeaStar also received its seventh FDA Breakthrough Device Designation for SCD therapy, specifically for the treatment of hyperinflammation in adults with sepsis or a septic condition. This is particularly interesting because management indicated that the existing NEUTRALIZE-AKI protocol includes prespecified statistical analyses of patients with sepsis and acute respiratory distress syndrome (ARDS). Management expects that more than 70% of the enrolled population will have sepsis or a septic condition, potentially providing a meaningful dataset to evaluate the therapy in this subgroup.

The company intends to engage with the FDA regarding the sepsis indication while NEUTRALIZE-AKI enrollment continues, rather than waiting until the study is completed. If the overall trial is successful and the prespecified subgroup analysis is supportive, management believes the resulting data could provide a basis for advancing SCD therapy in adult sepsis. The Breakthrough Device Designation facilitates earlier regulatory discussions but does not independently establish a separate approval pathway or eliminate the need for adequate clinical evidence. Nevertheless, this opportunity adds another potential application for the SCD platform without necessarily requiring an entirely separate initial clinical development program.

Financial Update

On November 11, 2026, SeaStar announced financial results for the third quarter of 2026. The company reported net revenue of approximately $0.6 million, compared to approximately $0.2 million in the third quarter of 2025. The increase was due to increased sales of QUELIMMUNE. R&D expenses for the third quarter 2026 were $3.6 million compared to $1.9 million in the third quarter of 2025. The increase in R&D expenses was primarily due to increased clinical research activities, SCD development costs, personnel costs, and payroll costs. G&A expenses in the third quarter of 2026 were $1.6 million compared to $1.9 million for the third quarter of 2025. The decrease in the current quarter was primarily due to a decline in personnel, legal, audit, and SEC-related costs, partially offset by increased professional services, director fees, and franchise taxes.

SeaStar exited the third quarter of 2026 with $4.0 million in cash and cash equivalents. Subsequent to the end of the quarter, the company raised approximately $3.3 million of gross proceeds from warrant exercises that occurred in October 2026. As of November 1, 2026, the company had approximately 5.3 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 9.0 million.

Conclusion

SeaStar made important progress during the third quarter, particularly with the expansion of QUELIMMUNE commercialization, the completion of the SAVE Registry requirements, and the submission of the first module of its adult AKI PMA application. The SAVE Registry findings provide encouraging clinical support for the pediatric product, while the elimination of the mandatory registry requirement and introduction of dedicated procedure codes should help facilitate additional hospital adoption. Lastly, the existing customer base is becoming more established, with repeat usage across nearly all accounts. While the revised mid-2027 enrollment timeline does push out the anticipated regulatory milestone further into the future, we don’t view it as a major setback, particularly given that it is due to maintaining a strict adherence to identifying the proper patient population. With no changes to our model, our valuation remains at $12 per share.

PROJECTED FINANCIALS

SeaStar Medical Holding Corp.	2025 A	Q1 A	Q2 A	Q3 A	Q4 E	2026 E	2027 E	2028 E
Quelimmune	$1.2	$0.5	$0.6	$0.6	$0.5	$2.2	$3.0	$10.0
License and other revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$1.2**	**$0.5**	**$0.6**	**$0.6**	**$0.5**	**$2.2**	**$3.0**	**$10.0**
Cost of revenues	$0.1	$0.0	$0.1	$0.0	$0.1	$0.2	$0.2	$0.8
Research & development	$7.5	$2.3	$2.5	$3.6	$2.5	$10.9	$12.0	$14.0
General & administrative	$5.8	$1.7	$1.8	$1.6	$1.9	$7.0	$7.5	$10.0
Operating Income	($12.2)	($3.6)	($3.8)	($4.6)	($4.0)	($15.9)	($16.7)	($14.8)
Non-Operating Expenses (Net)	$0.0	$0.1	$0.1	$0.1	$0.1	$0.3	$0.0	$0.0
Pre-Tax Income	($12.1)	($3.5)	($3.7)	($4.5)	($3.9)	($15.7)	($16.7)	($14.8)
Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1.0
Net Income	**($12.2)**	**($3.5)**	**($3.7)**	**($4.5)**	**($3.9)**	**($15.7)**	**($16.7)**	**($15.8)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($5.86)**	**($0.90)**	**($0.91)**	**($1.03)**	**($0.78)**	**($3.60)**	**($2.08)**	**($1.58)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	2.1	3.9	4.1	4.4	5.0	4.3	8.0	10.0

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

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