

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE

TRANSITION PERIOD FROM TO

Commission File Number 001-39927

SEASTAR MEDICAL HOLDING CORPORATION

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of incorporation or organization)

3513 Brighton Blvd., Suite 410

Denver, CO

(Address of principal executive offices)

85-3681132

(I.R.S. Employer Identification No.)

80216

(Zip Code)

Registrant’s telephone number, including area code: (844) 427-8100

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value	ICU	The Nasdaq Stock Market LLC
Warrants, each whole warrant exercisable for one share of Common Stock for \$2,875 per share	ICUCW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Based on the closing sales price of the Registrant’s common stock on Nasdaq on June 30, 2025, the last business day of the Registrant’s second fiscal quarter, the aggregate market value of the voting stock held by non-affiliates of the Registrant was approximately \$7.3 million. All executive officers and directors of the Registrant, and all shareholders holding more than 10% of the Registrant’s outstanding voting stock (other than institutional investors, such as registered investment companies, eligible to file beneficial ownership reports on Schedule 13G), have been deemed, solely for the purpose of the foregoing calculation, to be “affiliates” of the Registrant.

The number of shares of Registrant’s Common Stock outstanding as of March 24, 2026, was 3,993,719

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant’s definitive proxy statement relating to its 2026 annual meeting of stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K. We anticipate that we will file the 2026 proxy statement on or before April 29, 2026.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Annual Report”) contains statements that are forward-looking and as such are not historical facts. These statements are based on the beliefs and assumptions of management. Although we believe that our plans, intentions, and expectations reflected in or suggested by these forward-looking statements are reasonable, we cannot assure you that we will achieve or realize these plans, intentions, or expectations. Forward-looking statements are inherently subject to risks, uncertainties, and assumptions. Generally, statements that are not historical facts, including statements concerning the possible or assumed future actions, business strategies, events, or results of operations, are forward-looking statements. In some instances, these statements may be preceded by, followed by or include the words “believes,” “estimates,” “expects,” “projects,” “forecasts,” “may,” “will,” “should,” “seeks,” “plans,” “scheduled,” “anticipates” or “intends” or the negatives of these terms or variations of them or similar terminology.

Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements which speak only as of the date hereof. You should understand that the following important factors, among others, could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- our expectations regarding ongoing clinical trials and our plans to conduct further clinical trials, including anticipated enrollment, clinical site activation, completion, results, and timing thereof;
- our plans and expected timeline related to our products, including timing of commercial launch, or developing new products, to address additional indications or to obtain regulatory approvals or clearances or otherwise;
- the expected use of our products by clinicians, including market awareness, acceptance and adoption of our products, and anticipated utilization of our products;
- our expectations regarding the number of procedures that will be performed with our products, the number of clinicians we expect to train, and the number of our sales territories;
- our ability to obtain, maintain, and expand regulatory clearances for our current products and any new products we create;
- the expected growth of our business and our organization;
- our expectations regarding pricing of our products, cost of sales, government and third-party payer coverage and reimbursement;
- our ability to retain and recruit key personnel;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers, most of whom are single-source suppliers;
- our ability to manufacture sufficient quantities of our products with sufficient quality and the sufficiency of our current manufacturing capabilities;
- our ability to obtain and maintain intellectual property protection for our products and our business;
- our ability to expand our business into new geographic markets and the anticipated timing thereof;
- our compliance with extensive Nasdaq and SEC requirements and government laws, rules and regulations both in the United States and internationally;
- our expectations regarding operating trends, future financial performance and expense management and our estimates of our future expenses, ongoing losses, future revenue, capital requirements and our need for, or ability to obtain, additional financing;
- our ability to identify and develop new and planned products and/or acquire new products;
- our experience with inflationary and price pressures and increased labor costs and labor and staffing shortages as a result of general macroeconomic factors;

- developments and projections relating to our market opportunity and penetration, competitors, or our industry;
- our intended use of net proceeds from our public offerings.
- our future capital requirements and sources and uses of cash;
- our ability to obtain funding or raise capital for its operations and future growth;
- any delays or challenges in obtaining FDA approval of our SCD product candidates;
- economic downturns and the possibility of rapid change in the highly competitive industry in which we operate;
- the ability to develop and commercialize our products or services following regulatory approval of our product candidates;
- the failure of third-party suppliers and manufacturers to fully and timely meet their obligations;
- product liability lawsuits, regulatory lawsuits proceedings relating to our products and services, or any other litigation matters;
- inability to secure or protect our intellectual property;
- dispute or deterioration of relationship with our major partners and collaborators;
- the ability to maintain the listing of our Common Stock on Nasdaq;
- delays associated with government and other grant funding;
- other risks and uncertainties indicated in this Annual Report, including those under “Risk Factors” herein, and other filings that have been made or will be made with the SEC.

These and other factors that could cause actual results to differ from those implied by the forward-looking statements in this Annual Report are more fully described in the “*Risk Factors*” section. The risks described in “*Risk Factors*” are not exhaustive. New risk factors emerge from time to time, and it is not possible for us to predict all such risk factors, nor can we assess the impact of all such risk factors on our business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the foregoing cautionary statements. We undertake no obligations to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I

Item 1. Business.

Unless the context otherwise requires, all references in this section to “SeaStar Medical”, the “Company”, “we” “us” or “our” refer to SeaStar Medical Holding Corporation and our consolidated subsidiaries following the Business Combination (as defined herein), other than certain historical information that refers to the business of SeaStar Medical, Inc. (the “Predecessor”) prior to the consummation of the Business Combination.

Overview

We are a commercial-stage healthcare company focused on transformational treatments for critically ill patients facing organ failure and potential loss of life. Our Selective Cytopheretic Device (“SCD”) 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. It has broad potential applications for patients suffering from both acute and chronic kidney disease as well as cardiovascular and other serious inflammatory diseases.

We received Food and Drug Administration (“FDA”) approval on February 21, 2024, under a Humanitarian Device Exemption (“HDE”) for our pediatric SCD therapy. It is the only FDA approved product for use in pediatric patients with acute kidney injury (“AKI”) due to sepsis or a septic condition requiring kidney replacement therapy. We shipped our first commercial pediatric SCD (“QUELIMMUNE”) in July 2024. In addition, we are currently conducting a pivotal clinical trial, also referred to as “NEUTRALIZE-AKI” to assess the safety and efficacy of the SCD therapy in critically ill adult patients with AKI requiring continuous renal replacement therapy (“CRRT”). We are also conducting a feasibility study of the SCD therapy in adult patients with Cardiorenal Syndrome (“CRS”) awaiting left ventricular assist device (“LVAD”) implantation.

Our SCD therapy has been awarded six Breakthrough Device Designations (“BDD”) by the FDA. These BDDs cover multiple therapeutic indications for the use of our SCD therapy in adult patients with AKI, CRS awaiting LVAD implantation, hepatorenal syndrome, end stage renal disease (“ESRD”), and systemic inflammatory response while undergoing cardiac surgery. The BDD enables the potential for a speedier pathway to approval and the ability to have more frequent and flexible meetings with FDA.

The inflammatory response is essential to the healing process of critical organs; however, the overactivation of inflammatory cells, which can be triggered by many different bodily insults such as trauma, surgery or infection, can send the body into shock and cause severe damage to a variety of critical organs such as the heart, lungs and kidneys. Central to inflammation are the cells within blood and lymph circulatory systems, called white blood cells (primarily neutrophils and monocytes). In a normal inflammatory response, neutrophils are the first immune cells to arrive at the site and are key to the entire immune response that kills pathogens and promotes tissue repair. These inflammatory cells release chemicals (cytokines) that trigger the immune system to eliminate foreign pathogens or damaged tissue, enhancing the immune response.

If the inflammatory response becomes excessive and dysregulated (referred to as proinflammatory), the inflammatory cells will continue to produce cytokines and other damaging molecules, further enhancing the dysregulated immune response, and altering feedback mechanisms that regulate the immune system. This results in damaging hyperinflammation spreading uncontrollably to other parts of the body, often leading to acute and potentially chronic solid organ dysfunction or failure, including the heart, lung, kidney, liver, and even death. This hyperinflammatory response is also known as the “cytokine storm,” referring to the body’s reaction to the category of small-secreted proteins released by hyperinflammatory cells that affect communication between cells.

Currently, there are no therapeutic options that specifically neutralize the white blood cells that are primarily responsible for the destructive hyperinflammatory response. Clinicians typically address hyperinflammation with therapies that are either immunosuppressive or that target a specific cytokine, both of which are generally suboptimal in the treatment of hyperinflammation. We believe our technology has the potential to overcome limitations in existing anti-inflammatory treatments and address the challenge of selectively targeting activated neutrophils and monocytes.

Clinical and preclinical studies conducted over the last 15 years have demonstrated that our SCD therapy can modulate the degree of activity of proinflammatory cells to help reduce tissue damage and speed the repair and recovery of organ function. Data from our trials demonstrated that the use of our SCD therapy to reverse the cytokine storm in more than 150 pediatric and adult patients with acute kidney injury on CRRT reduced mortality rates by 50%, and of those patients who survived 60 days, none have required dialysis. We believe our SCD therapy has the potential to transform the treatment of acute organ failure in the intensive care unit (“ICU”) and to improve organ function in patients with chronic kidney disease, certain cardiovascular diseases, and other serious inflammatory diseases.

Preclinically, we evaluated our SCD therapy in various animal models representing multiple hyperinflammatory indications, including acute myocardial infarction, intracranial hemorrhage, chronic heart failure, sepsis, and acute respiratory distress syndrome. The animal models demonstrated the inflammatory response and how it was modified by our SCD therapy. We will continue to explore the application of our SCD therapy across a broad range of indications where proinflammatory activated neutrophils and monocytes contribute to disease progression or severity in both acute and chronic indications.

We are leveraging our patent protected and scalable SCD therapy platform to develop proprietary treatments that are organ agnostic and target both acute and chronic indications. The SCD therapy is delivered via an extracorporeal synthetic membrane device that easily integrates into existing CRRT systems that are commonly employed for patients with acute organ injury in hospitals, including in ICUs throughout the United States. It also has the potential to be integrated into kidney dialysis systems for chronic kidney disease patients receiving renal replacement therapy at centers throughout the United States. We believe that the ease of use and broad applicability of the therapy across multiple disease states should enable us to capture a sizable market for our SCD therapy with increasingly favorable economics.

Our senior management team and Board have extensive experience in the healthcare industry, including expertise in regulatory and medical affairs, commercialization and distribution in our initial therapeutic priority areas. We also have assembled a team of well-respected scientific advisors who are experts in the development of our technology and products.

There is a substantial clinical need for safe and effective control of hyperinflammation and we believe that our first-in-class SCD therapy can address the large potential market of over one million patients each year that face life-threatening hyperinflammatory conditions, including organ failure and potential loss of life.

SCD Therapy for Pediatric Patients

We are currently commercializing our first product, QUELIMMUNE, under an HDE that was approved by the FDA on February 21, 2024. QUELIMMUNE is currently the only FDA-approved product for critically ill pediatric patients with life-threatening acute kidney injury (AKI) due to sepsis or a septic condition.

We commenced our first product shipment of QUELIMMUNE in July 2024 and continue to target top-tier pediatric medical facilities for adoption of the QUELIMMUNE therapy. As a condition of the approval, the FDA stipulated that we would need to institute a post approval patient surveillance registry to track certain safety and performance metrics (the "SAVE Surveillance Registry"). This typically requires an Institutional Review Board ("IRB") review and approval to use QUELIMMUNE therapy at the medical facility, which can lengthen the QUELIMMUNE adoption process. As of December 31, 2025, we had 10 active commercial hospital customers that have completed the process for the SAVE Surveillance Registry and have purchased QUELIMMUNE therapy. Additional customer activations are planned for 2026.

A benefit of the SAVE Surveillance Registry is the opportunity to collect real-world data from the commercial use of QUELIMMUNE therapy. Early results from the first 21 critically ill pediatric patients with life-threatening AKI and sepsis or a septic condition in the commercial setting in the SAVE Surveillance Registry showed no device related safety events with the QUELIMMUNE therapy with 76% of patients surviving through 60 days and 71% surviving through 90 days. We believe these data are on track to validate a 50% reduction in loss of life compared to historical data. Additionally, in December of 2025, based on the safety data from this set of patients, the FDA approved a reduction in the mandatory enrollment size of the SAVE Surveillance Registry from the originally-required 300 patients to only 50 patients. We enrolled the 50th patient of the SAVE Surveillance Registry on March 4, 2026.

We are also evaluating additional clinical development opportunities in children based on unmet medical needs. One such indication is for the use of our SCD therapy for the treatment of systemic inflammatory response in pediatric patients undergoing cardiac surgery, aimed at preventing post-operative complications and adverse outcomes, for which FDA awarded BDD on March 27, 2025.

SCD Therapy for Adult Patients

We are currently conducting a pivotal trial, NEUTRALIZE-AKI, to evaluate the safety and efficacy of our SCD therapy in 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 SCD therapy in addition to CRRT as the standard of care, compared with the control group receiving only CRRT standard of care. The trial protocol includes an interim analysis by an independent Data Safety Monitoring Board ("DSMB") at the trial's 90-day primary endpoint with the first 100 subjects. This pivotal trial is expected to enroll a total of 339 patients and as of March 13, 2026, we had enrolled 178 patients. We anticipate reporting topline clinical trial results and, assuming a successful trial outcome, submission of a Pre-market Approval ("PMA") application in 2027.

We are also evaluating additional clinical development of the SCD therapy in adults based on unmet clinical needs and market opportunity. Our BDD awards by the FDA in multiple therapeutic areas are expected to expedite the clinical development and regulatory review of the SCD therapy for use in the designated patient populations and are the primary focus of our future clinical development decisions. We received our first BDD awards in 2022 with the following additional BDDs in adult patient indications thereafter:

- On April 29, 2022, we received a BDD for the use of our SCD in the treatment of immunomodulatory dysregulation in adult patients (18 and older) with AKI, which is expected to accelerate the regulatory approval process for our ongoing pivotal trial.
- On September 28, 2023, we received BDD for our SCD for use 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.
- On October 18, 2023, we received BDD designation for our SCD for use with patients in the hospital ICU with AKI and acute on chronic liver failure.
- On November 6, 2024, we received BDD for our SCD to treat chronic systemic inflammation in end-stage renal disease (ESRD) patients who require chronic hemodialysis, also known as chronic dialysis. This is our first BDD in a chronic disease setting.
- On March 27, 2025, the FDA awarded a BDD for our SCD therapy for the treatment of systemic inflammatory response in adult patients undergoing cardiac surgery, aimed at preventing post-operative complications and adverse outcomes.

We believe that our SCD therapy is readily applicable for use in other indications as well, which will increase the addressable market for our SCD therapy, but will also require additional clinical studies and FDA approval.

We have pursued patent protection for our SCD therapy as well as other technologies. Our patent portfolio consists of 46 patents and 1 pending patent applications in the U.S. and certain foreign jurisdictions. Of these patents and patent applications, 21 patents and 1 patent applications are owned exclusively by us, and 25 patents are co-owned with the University of Michigan (“UOM”). The UOM has granted us an exclusive worldwide, royalty-bearing license to the UOM’s interest in all of the co-owned patents and applications. This license permits us to commercialize our SCD therapy in all human therapeutic indications. For more information, see “Intellectual Property” below.

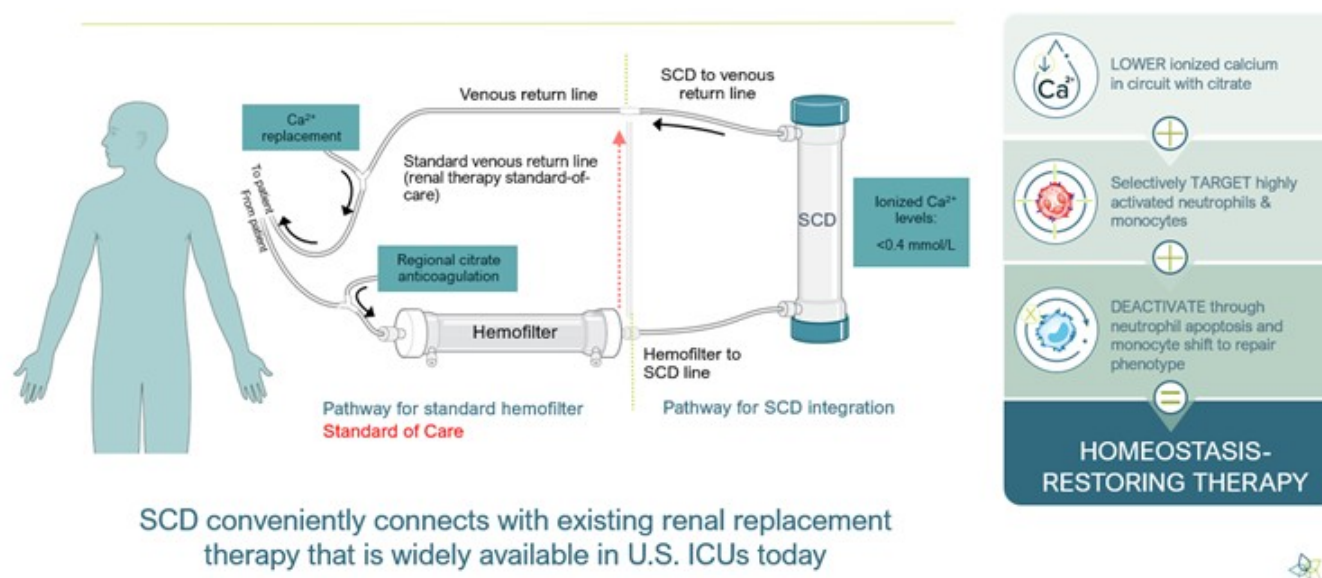
Our Approach - The SCD Therapeutic Device

Our SCD therapy is designed as a disease-modifying device that neutralizes overactive 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. In many serious acute illnesses, a hyperinflammatory response occurs as a well-defined coordinated sequential response. Neutrophils are the first responders followed by monocytes. The monocytes, as they egress into tissue also follow another sequence of differentiation into tissue macrophages. The first are proinflammatory macrophages, followed by patrolling, reparative macrophages.

This complex highly coordinated process is critical for host defense and tissue repair but needs to be tightly regulated by the body’s inflammatory signaling and cellular apoptosis. If it is not tightly regulated and begins to spiral out of control, further tissue destruction may occur when uncontrolled hyperinflammation leads to degradative processes with worsening tissue or organ function. If this excessive systemic inflammation is severe and prolonged, multi-organ failure, including cardiovascular, respiratory, renal, hepatic and neurologic dysfunction may occur, resulting in poor clinical outcomes. Prior therapeutic approaches to block soluble mediator targets, such as cytokines or free radicals have not proven successful. We believe that our SCD approach, which targets only highly activated cells, is a potentially transformative, if not disruptive, therapeutic approach to a range of acute and chronic inflammatory disorders.

Our SCD therapy is an extracorporeal synthetic membrane device designed to bind activated leukocytes (neutrophils and monocytes) when integrated into an existing CRRT circuit in conjunction with the use of regional citrate anticoagulation (“RCA”). The SCD is simply added to the standard CRRT circuit that uses RCA and is placed immediately following the standard hemofilter cartridge. Highly inflamed blood from the patient passes through the CRRT system and hemofilter, and into the SCD. In the low calcium environment mediated by RCA, the inflamed cells in the blood are modulated towards a less inflammatory state. Upon exiting our SCD, calcium is replaced and the blood is returned to the patient’s body.

Unique mechanism of action restores reparative physiology



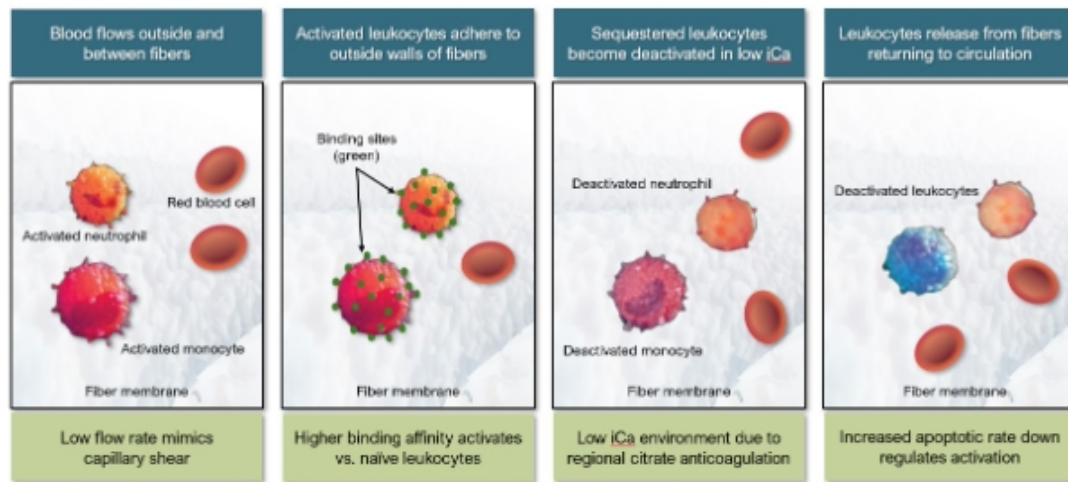
SCD conveniently connects with existing renal replacement therapy that is widely available in U.S. ICUs today

Our SCD therapy delivers its therapeutic benefit by attenuating the excessive inflammatory response of activated neutrophils and monocytes. Uninterrupted, the excessive inflammatory response progresses to multi-organ failure, with documented increases in both morbidity and mortality in critically ill patients. Our initial approved product, QUELIMMUNE, is focused on critically ill pediatric AKI patients on CRRT. Our SCD therapy leverages the existing footprint of CRRT pump systems in ICUs today, as well as the growing use and adoption of RCA. Citrate is used to bind the free ionized calcium within the extracorporeal circuit which is needed to impact the neutrophils and monocytes. A study in the Journal of the American Medical Association in 2020 demonstrated that while the use of RCA has the same mortality profile as heparin, RCA has been shown to be more effective in preserving filter life and is used to create the low calcium environment for our SCD therapy, which impacts the white blood cells interaction with the SCD membrane leading to the reduction in inflammation.

Mechanism of Action

The mechanism of action of our SCD therapy consists of three elements: (i) selectively binding activated neutrophils and monocytes on our SCD biomimetic membrane (ii) deactivating the activated neutrophils by maintaining a specified ionized calcium level within our SCD, and (iii) shifting proinflammatory monocytes to a lower inflammatory profile. Our SCD utilizes clinically validated RCA protocols to lower the ionized calcium level, which not only prevents clotting within the circuit but also immuno-modulates the activated neutrophils and monocytes, which are then returned to the patient. Calcium is then infused into the blood line returning to the patient from the SCD, thereby maintaining normal calcium levels in the patient throughout the process.

Sequestration, Deactivation & Return to Systemic Circulation



Our SCD and Neutrophils

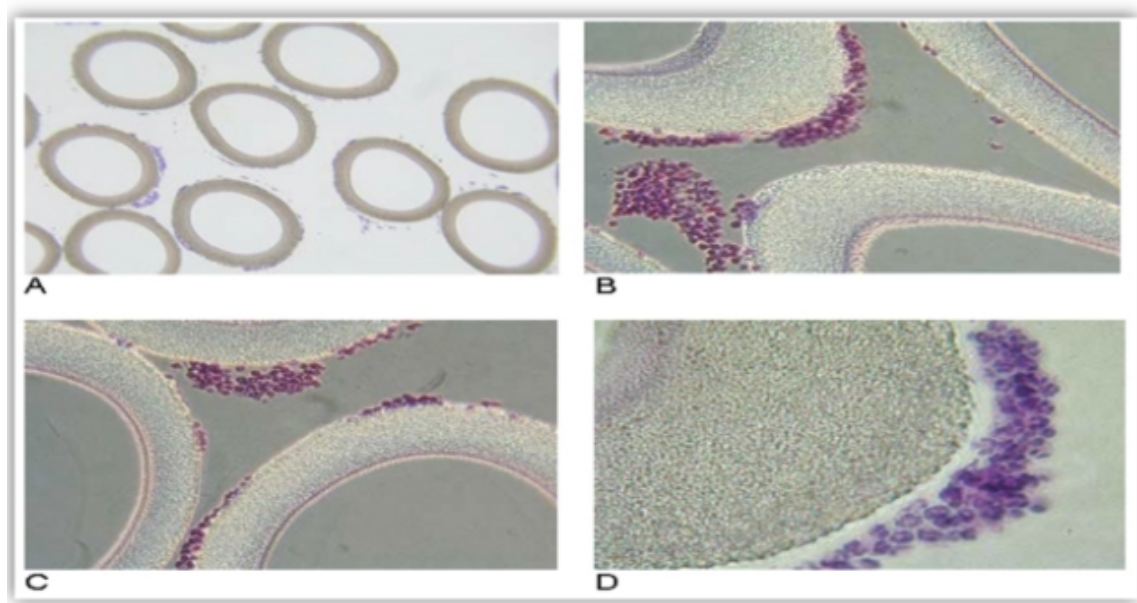
Calcium plays a critical role in many biological processes. In the case of neutrophils, calcium can have a profound effect on their activity. It has been shown that lowering calcium to critical levels in the regional circuit can lead to higher levels of neutrophil apoptosis (deactivation). Our SCD is designed to selectively bind the most highly activated neutrophils, associated with hyperinflammation, and in a low ionized calcium ("iCa") environment, the activated neutrophils are deactivated, which has the downstream effect of reducing hyperinflammation. These deactivated cells are then released back into circulation, resulting in no downstream immunosuppression, immunodepletion, leukopenia or neutropenia. When neutrophils are in homeostasis, the normal half-life is six to eight hours, but in a hyperinflammatory state, neutrophil apoptosis is delayed, leading to increased numbers of activated neutrophils in circulation. Through clinical and preclinical studies, our SCD has been shown to selectively sequester and deactivate the most highly activated neutrophils, allowing the body to restore neutrophil homeostasis.

Our SCD and Monocytes

We believe the role of circulating monocytes in systemic inflammation and organ-specific injury is becoming more appreciated by healthcare professionals. Similar to calcium's effect on neutrophils, calcium also has an important influence on monocyte activity. A high percentage of the circulating monocyte-derived macrophage subtypes (M1 proinflammatory versus M2 patrolling, reparative) have been shown to influence the degree of acute organ injury and chronic organ dysfunction. In *in-vitro* testing, we have shown that, in a low iCa environment, our SCD membrane binds the proinflammatory monocytes within the blood more selectively and lowers their inflammatory activity. This selective binding and immunomodulation has also been shown in human clinical trials and results in fewer proinflammatory circulating monocytes. It is important to note that our SCD does not sequester 100% of these monocytes as they are important to maintaining immune homeostasis. Similar to neutrophils above, immunomodulated monocytes are also released back into circulation following treatment, resulting in no downstream immunosuppression, immunodepletion, leukopenia or neutropenia. We call the SCD mechanistic process of binding these cells, deactivating them, and releasing them back into circulation, a "catch-and-release" system.

Histological evaluation of our SCD

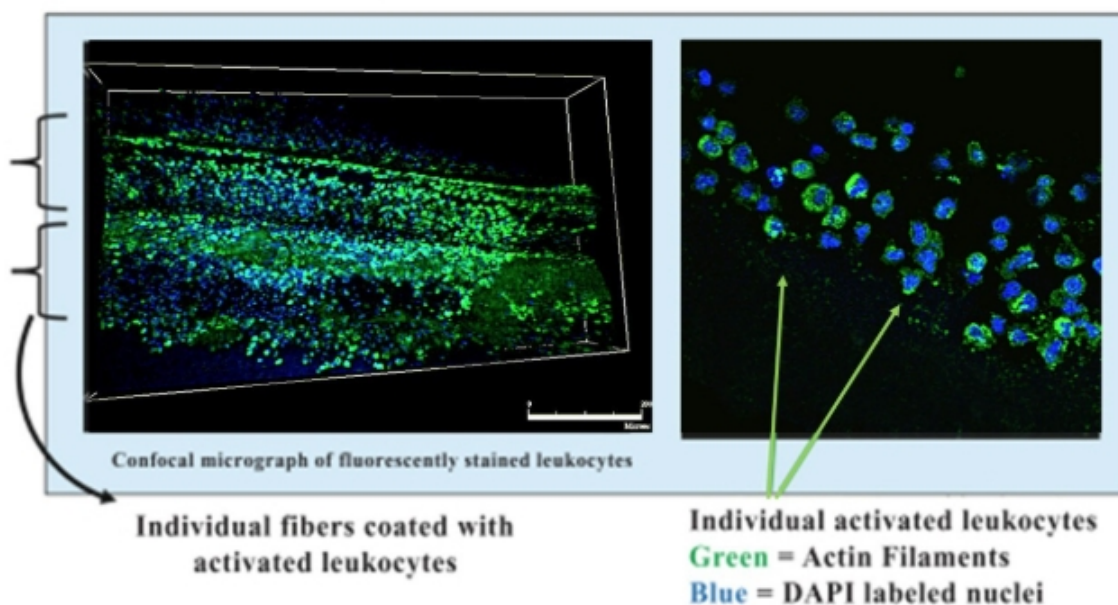
Microscopy of our SCD after being used for patient treatment demonstrated the binding of leukocytes on the outer surface of the hollow fiber membranes of the cartridge along the blood flow path within the extracorporeal circuit. Flow cytometry confirmed that they were the most activated neutrophils and monocytes (see below)



Above image: Activated leukocytes adherence to the membranes. Light micrograph stained with Hematoxylin and Eosin (H&E). Panel A: Low-power micrograph showing adherent cells around each fiber (160x). Panel B and Panel C: Higher-power micrographs showing the clustering of bound leukocytes (400x). Panel D: High-power micrograph displaying predominance of neutrophils and monocytes in the adherent cell clusters (1600x)

The unique blood path within the SCD mimics capillary flow, providing a more stable microenvironment for the neutrophils and monocytes, enabling the cells to bind to the outer surface of the hollow fibers long enough for the critically low iCa to have its impact. This is then followed by cells being released back into circulation. (i.e. – “catch and release”).

Activated Leukocytes Adhere To Surface of Fibers In SCD



Our Market Opportunity

We are a commercial-stage healthcare company pursuing multiple indications, both small and large market opportunities, with our SCD therapy. Our clinical data was initially used to support an HDE submission to the FDA to request approval to market our SCD to hospitals and clinicians with pediatric patients suffering from AKI. Our clinical data has also been used to support the initiation of a pivotal study that would support a PMA submission in adult AKI which has an estimated incidence of approximately 200,000 patients annually in the United States. In the long term, based on preliminary clinical evidence, we intend to expand the application of our SCD technology to additional indications with large patient populations, including acute respiratory distress syndrome, chronic dialysis, cardiorenal syndrome and hepatorenal syndrome and others.

Our Initial Market Opportunity in Acute Kidney Injury

With over 5 million ICU admissions in the U.S. each year, and approximately 50-60% of these patients experiencing AKI, AKI has increasingly received the attention of healthcare professionals and academic publications that elucidate the devastating clinical and financial impact of what is most often a multi-organ syndrome. In fact, a 2017 study by Samuel A. Silver and Glenn M. Chertow titled “The Economic Consequences of Acute Kidney Injury” stated hospital costs associated with AKI in the U.S. are between \$5.4 billion and \$20 billion per year.

The kidneys are a silent killer within medical triage. They do not present clear symptoms or tell the body they are suffering like other major organs such as the heart or lungs. For example, one does not feel pain with a “kidney attack” and symptoms are delayed until irreversible damage may have already occurred. Kidneys also refrain from revealing the impact to the rest of body and organs (and vice-versa) and often are not considered systemically for co-treatment.

Globally consistent criteria for diagnosing AKI have recently emerged with the RIFLE classification (Risk, Injury, Failure, Loss of kidney function, and End-stage kidney disease), an international consensus classification for AKI staging and diagnosing guidelines introduced in 2004, the Acute Kidney Injury Network staging system in 2007, and finally the Kidney Disease: Improving Global Outcomes, AKI Staging and Diagnosing Guidelines published in 2012. These sources have helped clinicians to improve recognition, staging, diagnosing and subsequent documentation of less obvious cases of AKI secondary diagnoses. While our initial market is focused on AKI patients on CRRT, future indications will likely benefit from improved characterization and diagnosis of patients.

As a result, demand for ICU renal replacement therapy is growing. CRRT is the newest AKI dialysis modality in the market, first becoming available in 1997, and according to Fortune Business Insights, it is estimated that it has grown to a \$986 million global market (\$354 million market in the U.S.) as of 2019. The two largest operators in the CRRT market by revenue are Fresenius Medical Care Holdings, Inc. and Vantive, Inc. (formerly a business of Baxter International), which represent over 80% of the market today in the U.S.

Since 2010, a significant amount of data has been published to quantify the clinical and financial impact of AKI, resulting in a broadening AKI treatment “boom” beyond dialysis to areas of diagnostics, complementary therapies, and pharmacoeconomics. As hospital administrators and government officials gain an increasing understanding of the impact and burden of AKI, we believe that attention will continue to grow. According to Hobson in his article titled “Cost and Mortality Associated with Postoperative Acute Kidney Injury,” a 2015 study of 50,314 patients (over 11 years) found that upon greater scrutiny, AKI was found in 39% of post-surgical patients, and 19% of patients had stage 2 or 3 AKI with an average incremental cost of \$29,800 per patient. Additionally, with historical mortality rates of approximately 50%, treating AKI is of increasing interest to clinicians, hospitals, and product manufacturers alike.

The AKI patient population is growing on average 6.9% per year according to the Healthcare Cost and Utilization Project commissioned by the Agency for Healthcare Research and Quality, a U.S. federal agency. According to Massicotte and Azarniouch in their 2015 work titled “Acute Kidney Injury in the Intensive Care Unit: Risk Factors and Outcomes of Physician Recognition Compared with KDIGO Classification,” around 80% of moderate or severe cases of AKI are not diagnosed and documented, suggesting the U.S. AKI patient population is higher than the estimated 6 million patients annually. The pediatric population for AKI patients in the U.S. on CRRT is estimated to be less than 8,000 patients per year, which is a substantially small subset of the combined 6 million AKI adult and pediatric patient population.

AKI patients need new and effective solutions, and hospitals continue to search for and evaluate new products. For a product to succeed in the AKI space, it must demonstrate and achieve clear and significant clinical benefit to patients, while providing positive financial incentives for hospitals to generate revenue and profitability.

Our Growth Strategies

Key elements of our growth strategy include innovating and expanding our applications through clinical trials; differentiation through medical education; business development and out-licensing activities, and scaling production with manufacturing partners. We expect to employ several core growth strategies:

- **Execute on clinical plan through key relationships:** Our initial focus on the treatment of AKI in adults and pediatrics is supported by our long and established relationship with the UOM, which licenses to us certain key technology underpinning our novel immunomodulatory therapy, as well as other leading academic hospitals and institutions throughout the U.S. Such relationships enable us to expand and refine the design and execution of our clinical plans with a more targeted outcome and objectives. On February 21, 2024, we received the FDA HDE Approval Order, which allows sales of QUELIMMUNE to qualified healthcare facilities. In February 2023, we received FDA IDE approval for the adult AKI indication. Our patented and cell-directed SCD therapy has received the FDA BDD for use in adult AKI patients, which is expected to accelerate and streamline the regulatory approval process prior to the commercial launch of our product candidates. On September 28, 2023, we received BDD for our SCD therapy for use with 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. On October 18, 2023, we received a BDD for our SCD therapy for use with patients in the hospital ICU with AKI and acute on chronic liver failure. On November 6, 2024, we received BDD for our SCD therapy to treat chronic systemic inflammation in end-stage renal disease (ESRD) patients who require chronic hemodialysis, also known as chronic dialysis. On March 27, 2025, the FDA awarded two BDDs for our SCD therapy for the treatment of systemic inflammatory response, one in adults and one in pediatric patients, undergoing cardiac surgery, aimed at preventing post-operative complications and adverse outcomes. We have been granted six BDDs by the FDA for the SCD device, each of which is expected to expedite the clinical development and regulatory review of the SCD therapy for use in the designated patient population.
- **Differentiation through medical education:** We intend to dedicate resources to educate physicians, hospital clinicians and other decision makers in the medical communities on the role of neutrophils and monocytes in both acute and chronic indications, and the therapeutic benefit of controlling and modulating excessive inflammatory response. We intend to focus our marketing strategies not only on the therapeutic capabilities of our technology, but also the economic consequences of hyper-inflammation in the current standard of care and treatment infrastructure and highlight the differentiating factors of our SCD therapy that can provide a cost-effective solution.

- **Business development and out-licensing activities:** We intend to explore and pursue business development opportunities with major medical and pharmaceutical companies to establish partnerships, including outbound licensing arrangements. We believe that our clinical experience and depth, combined with our understanding of the scientific mechanism of our SCD and our regulatory submissions around the world, can drive value for our partners and reduce their market risk. We believe our partners will benefit from insight into other SCD trials around the world as well as data generation that is being conducted by our trials. We believe that our SCD therapy has the potential to apply to multiple indications. By pursuing and establishing business relationships with partners who may have strong capabilities beyond AKI, such as the markets for ESRD and respiratory distress syndrome, we may be able to expand our solutions to the chronic disease setting.
- **Scaling production with manufacturing partners:** As we progress through our planned clinical trials and the commercial launch of our QUELIMMUNE in pediatrics as well as potential additional adult indications for our SCD therapy if FDA approval is received, we are focused on identifying and securing various suppliers and manufacturing partners to scale production in response to the expected demand for our solutions. We continue to negotiate with suppliers of raw materials, including cartridges, tubing and other components, to establish redundancies and alternative sources to mitigate interruptions in the supply chain in the future. In addition, we may also explore strategic relationships with partners who can provide sources of raw materials while collaborating with us on the marketing and distribution of our product candidates.

Our Clinical Development of the SCD Product Candidates

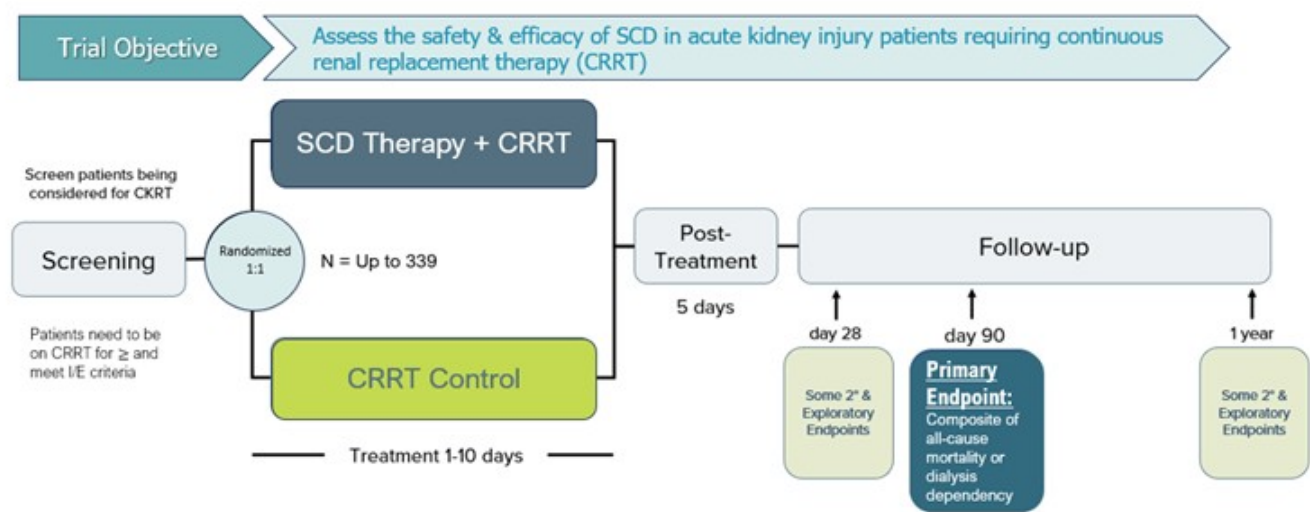
The following disclosure summarizes the key clinical studies in which our SCD product candidates (QUELIMMUNE for pediatrics) have been evaluated. All trials and studies below are conducted under IDEs approved by the FDA.

We submitted an HDE application for our SCD for the treatment of pediatric patients with acute kidney injury undergoing Continuous Renal Replacement Therapy (CRRT) to the FDA in June 2022. We obtained an Approvable Letter for the HDE in October 2023. On February 21, 2024, we announced a final Approval Order for the HDE, which allows us to commercialize QUELIMMUNE.

Clinical Progression

NEUTRALIZE-AKI Design

We are actively enrolling and treating patients in a pivotal clinical trial of the SCD for the treatment of AKI in adults, an indication awarded BDD by the FDA in April 2022. This trial (NCT05758077) is a 339 subject, prospective, multi-center, open-label, randomized, two-arm comparative pivotal study conducted in the United States. NEUTRALIZE-AKI is designed to assess a composite endpoint of both mortality or dialysis dependency at Day 90 (see schematic figure below). The control arm will consist of adults with AKI who undergo CRRT in hospital ICUs who typically have estimated mortality of nearly 50%. Among those with AKI who undergo CRRT and survive hospitalization, nearly one in four (25%) usually require long-term dialysis. The study design was published in the journal Nephron (Yessayan et al., Nephron. 2023 Jul 13. doi: 10.1159/000531880). The study title is also being referred to as NEUTRALIZE-AKI (NEUTrophil and monocyte deactivation via seLective cytopheretIc device – a randomiZed clinical trial in Acute Kidney Injury).



Current Trial Status

We submitted the NEUTRALIZE-AKI protocol to the FDA on January 6, 2023, and attained approval to proceed in March 2023. We began enrollment in the second quarter of 2023, and we anticipate the enrollment period to last up to 48 months. As of March 21, 2026, we have enrolled 181 patients into the NEUTRALIZE-AKI study. On April 29, 2022, we received a BDD for the use of our SCD in the treatment of immunomodulatory dysregulation in adult patients (18 and older) with AKI, which is expected to aid our discussions related to the regulatory review and PMA process for NEUTRALIZE-AKI.

Additional clinical studies under IDEs include cardiorenal syndrome and hepatorenal syndrome. We have also conducted exploratory clinical research with the University of Michigan to define the patient population for potential treatment with SCD product candidates, and any future studies will be based upon initial clinical data collected in these studies.

Other Clinical Studies in AKI

The table below lists the major studies conducted in AKI to date with our SCD. Except for SCD-003 and SCD-006, our clinical studies have not included a randomized control arm.

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. <i>ASAIO J.</i> 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. <i>Semin Dial.</i> 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. <i>PLOS One.</i> 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. <i>Kidney Int Rep.</i> 2020;6(3):775-784; Goldstein SL, et al. <i>Kidney Medicine.</i> 2024). 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. <i>Kidney Medicine.</i> 2024). 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. <i>Crit Care Explor.</i> 2022;4(5):e0694).

SCD-003: Additional Details

SCD-003 was a controlled, randomized, and multicenter clinical trial that was initiated in September 2011 and terminated in September 2013 under an FDA-approved IDE. For this trial, the control group received standard CRRT with regional citrate anticoagulation (“RCA”) and the SCD-treated group received up to seven days of SCD therapy. The study was sponsored by the Predecessor with the support of a third-party contract research organization.

The primary objective of the study was to determine if the SCD, when used in conjunction with CRRT, results in clinical and statistical improvement in mortality rate based on all causes through Day 60. Secondary objectives included an assessment of renal replacement therapy dependency at Day 60, mortality at Day 28, the number of ventilator free days at Day 28, and the mortality of the subset of patients with severe sepsis at Day 60. An overall two-sided 0.05 level of significance at 80% power was used to calculate a sample size of 344 patients, assuming a mortality rate of 50% for the control group and 35% for the treatment group. Adaptive design and interim analysis were planned at the mid-point of enrollment (i.e., 172 patients). Several exploratory biomarkers were also compared between the control and treatment groups, including urine output, serum levels of elastase, cytokines, and total absolute white blood cell, neutrophil and platelet counts throughout treatment. Patients receiving care in the ICU of each participating hospital were randomized to intensive care treatment for patients undergoing CRRT or CRRT + SCD. Each participating clinical site used their established RCA protocol for the CRRT + SCD circuits (treatment group) and for the CRRT only (control group). The recommended calcium (iCal) level (measured post SCD) in the CRRT and SCD blood circuit was specified to be between 0.25 and 0.40 mmol/L. Inclusion and exclusion criteria were similar to the previous IDE multicenter pilot clinical study except for an age range of 8-80 years and body weight of over 135 kilograms. Once the patient met all eligibility criteria, including being on CRRT for a minimum of four hours, but no longer than 24 hours, and had signed an informed consent, the subject was randomized in a 1:1 allocation utilizing a random permuted block design into either the control or treatment group, stratified by study center and the presence of severe sepsis.

During the second quarter of the enrollment period, a national calcium shortage occurred in the United States due to certain FDA-related quality manufacturing issues at major U.S. suppliers. At the time of the shortage a total of 134 patients had been enrolled in 21 United States Medical centers. Due to the reliance of the SCD on a narrow intra-circuit iCal range for functional efficacy, there was a concern that patients randomized to the SCD were not receiving effective therapy due to insufficient iCal levels. Enrollment was paused on May 24, 2013, to assess the clinical impact of the calcium shortage on study endpoints and the interim analysis was performed early using data from the 134 patients enrolled. The shortage of calcium infusion solutions resulted in a tendency to minimize citrate infusion rates. Accordingly, the iCal levels within the blood circuit tended to be above the recommended range of 0.25 to 0.40 mmol/L. No significant differences were noted between the control and treatment groups in terms of baseline characteristics. Of the 134 patients in the analysis, 69 received CRRT alone and 65 received CRRT + SCD therapy. No statistically significant difference was found between the treated and control patients with a 60-day mortality of 39% (27/69) and 36% (21/59), respectively. No statistically significant difference was found between the SAEs of the control and treatment groups. None of the SAEs were considered “definitely” device related per the principal investigator. The amount of time patients in both the control and treatment groups were maintained in the recommended iCal range (0.23 - 0.40 mmol/L), as specified in the study protocol, was substantially lower than expected. Of the 134 patients enrolled in the SCD-003 protocol at the time of the interim analysis, 19 SCD patients (CRRT + SCD) and 31 control patients (CRRT alone) were maintained in the protocol’s recommended range for greater or equal to 90% of the therapy time. The study was subsequently terminated.

No statistically significant difference was found between the SAEs of the control and treatment groups. The study reported 71 SAEs in the control group (40 of the 63 patients) and 80 SAEs in the SCD treatment group (45 of the 69 patients). The most frequent categories of SAEs were infections and infestations as well as cardiac, respiratory, thoracic and mediastinal disorders. None of the SAEs were considered “definitely” related to the SCD device per the principal investigator. Overall adverse events did not differ between the treatment and control groups in the intent to treat analysis.

Among the per-protocol (PP) cohort of patients who achieved the recommended iCal range, the composite of death or dialysis dependency at 60 days was observed in 16% (03/19) of SCD-treated subjects versus 58% (18/31) of control subjects. The incidence of serious adverse events did not differ between the treated and control groups.

SCD-PED-01 and 02 Studies – Additional Details

A multi-center, prospective pilot study SCD-PED-01 was undertaken to assess the safety and efficacy of our SCD in pediatric patients with AKI (weighing at least 20 kg) being treated with continuous kidney replacement therapy with RCA. The primary objective of the study was to evaluate the safety of up to seven consecutive 24-hour treatments of our SCD. The secondary objective was to evaluate the efficacy of up to seven consecutive 24-hour SCD treatments on all-cause mortality and dialysis dependency at Day 28 and Day 60. This study was sponsored by the Predecessor with the support of a third-party contract research organization.

Sixteen patients (eight male and eight female) were enrolled in the study at four United States pediatric medical centers, which ran from December 2016 through February 2020. The most common diagnosis leading to ICU admission was septic shock followed by, in diminishing order, pneumonia, rhabdomyolysis, pulmonary hypertension, hemolytic uremic syndrome, encephalomyelitis, disseminated adenoviral infection, cardiac arrest, acute respiratory failure and acute liver failure.

Twelve of the 16 patients survived (75%) to hospital discharge (versus historical control of 50%) and none of the 12 patients required dialysis at 60 days (versus historical control of 15% to 20%). There were 14 SAEs that occurred in fourteen patients in the study. None of the SAEs were device related.

A similar study known as SCD-PED-02 was undertaken in pediatric patients weighing between 10 and 20 kg. The study enrolled 6 patients (proposed maximum of up to 10 patients). 5 of the 6 (83%) patients survived to ICU discharge and all surviving patients were dialysis-independent by Day 60.

A combined pooled analysis of both the PED-01 and PED-02 studies (N=22 total) demonstrated a survival rate of ~77% at Day 60 in pediatric patients weighing at least 10 kg. This data was published in the journal *Kidney Medicine* in February 2024.

Study in Cardiorenal Syndrome Patients

Cardiorenal syndrome (“CRS”) is a clinical disorder in which therapy to relieve the congestive symptoms of chronic heart failure is limited by a decline in renal function. Up to one-third of patients with acute decompensated chronic heart failure admitted into a hospital in the United States present with this disorder and this condition is increasing in incidence. Once hospitalized, these patients are treated with a high dose of intravenous diuretics to relieve persistent congestion. The use of diuretics, however, frequently results in worsening renal function, progression of heart failure and death. Immune dysregulation plays a key role in cardiorenal syndrome.

We are actively enrolling patients in a clinical trial of our SCD therapy for the treatment of adult patients with acute or chronic systolic heart failure with worsening renal function due to CRS or severe right ventricular failure awaiting LVAD Implantation, an indication awarded BDD by the FDA in September 2023. This trial (NCT03836482) is a 20 subject, multi-center, open-label, feasibility study conducted in the United States. The study is designed to assess safety and a number of endpoints including mortality, the occurrence of acute myocardial infarction, or the need for continuous IV vasopressor support amongst others. Of note, SCD therapy in this study will be delivered for 4 hours a day for up to 6 consecutive days. This regimen is distinct from previous trials of our SCD therapy, all of which used continuous delivery for 24 hours a day.

Chronic Applications in Inflammatory Disorders and Corresponding Studies at the UOM

We are evaluating the safety and efficacy of our SCD in preliminary clinical trials that may lead to applications for our SCD in additional patient populations. The following are examples of our ongoing efforts to identify additional patient populations that may benefit from treatment with our SCD.

Pilot Feasibility Trial of SCD Therapy in ESRD Patients

The SCD therapy was evaluated in a cohort of 15 end-stage renal disease (ESRD) patients on chronic hemodialysis. The therapy promoted a shift in monocytes from a predominantly proinflammatory to a reparative anti-inflammatory phenotype for up to two weeks. Adverse events or serious adverse events (SAEs) were minimal during SCD treatment and RCA, with four of the 13 patients experiencing adverse events. None of these adverse events were definitively linked to SCD therapy.

Pilot Safety Trial of SCD Therapy in Cardiorenal Syndrome Patients

The CRS clinical trial (NEUTRALIZE-CRS) is a safety and efficacy dose escalation study in 20 patients that was designed to evaluate whether CRS, a disease with a dismal prognosis and currently ineffective therapy, will improve cardiac and renal (production of urine) functions after SCD therapy. In the study, an improvement of cardiac function is measured by the rate of ejection fraction, which is the percentage of blood leaving the heart each time it contracts. An improvement of renal function is measured by serum creatinine and blood urine nitrogen (two common biomarkers to assess renal function) levels. In addition, a variety of other biomarkers will also be measured. The effect of the SCD on cardiac function was recently demonstrated in a first-in-human case report of a 71-year-old male patient with cardiorenal syndrome including severe heart failure with reduced ejection fraction and was deemed ineligible for cardiac transplantation or LVAD due to worsening renal function (WRF) and right ventricular dysfunction. The patient was treated with the SCD and effectively bridged to LVAD and demonstrated proof-of-concept for an innovative approach to the treatment of CRS using our device. These initial results now provide important feasibility data for a follow-on study to undertake a controlled randomized clinical trial to evaluate the clinical efficacy of our SCD in CRS patients that have failed ultrafiltration therapy. Based on this data, our SCD recently received BDD for CRS in October 2023. These results were recently published in the journal *PLOS One* in April 2023 and an additional perspective article was published in the journal *European Journal of Heart Failure* in February 2024.

Pilot Safety Trial of SCD Therapy Hepatorenal Syndrome (HRS) Patients

Hepatorenal syndrome is characterized by an abrupt deterioration of kidney function, driven by a hyperinflammatory process in patients with advanced liver cirrhosis, and is associated with an unacceptably high mortality. Without treatment, the prognosis for patients with hepatorenal syndrome is poor with most dying within weeks of the onset of renal failure. In fact, the mortality rate for patients with severe acute or chronic liver failure with four or more organ failures at 28 days is 100%. Approximately 700,000 cases of hepatorenal syndrome are reported in the U.S. annually. In 2019 the economic burden for hepatorenal syndrome hospitalization was estimated at \$4.2 billion.

The NCT04898010 study is an investigator-initiated pilot study to assess the safety and efficacy of the SCD in treating up to 10 ICU patients with AKI and HRS Type I. The study aims to understand the effect of 7 days of treatment with the SCD on white blood cells in the bloodstream of patients with hepatorenal syndrome and its impact on blood circulation and kidney function. Two patients with type 1 hepatorenal syndrome have been treated to date in this study. Positive clinical outcomes were seen in both cases - one patient with hepatorenal syndrome due to acute alcoholic hepatitis was alive at day 90 after seven days of SCD treatment and undergoing liver transplantation evaluation, and the other patient with hepatorenal syndrome due to non-alcoholic steatohepatitis or NASH had a successful liver transplantation 6 days after SCD therapy ended. This suggested a role of SCD immunomodulation to treat acute or chronic liver failure, regardless of the etiology, as a bridge to evaluation or successful intervention for liver transplantation. Both of these cases were recently published in the American Society for Artificial Internal Organs Journal in August of this year (Yessayan et al., ASAIO J. 2023., doi: 10.1097/MAT.0000000000002033). This led to the FDA granting the SCD a BDD for HRS in October 2023.

Pilot Safety Trial of SCD Therapy in Myocardial Ischemia in End-Stage Renal Disease Patients on Chronic Hemodialysis

A major cause of death in patients on chronic dialysis is due to cardiovascular disease. Novel interventions need to be identified and tested to ameliorate the high morbidity and mortality of myocardial disease in these patients. Multiple hemodynamic and inflammatory factors contribute to the elevated risk of cardiac disease in chronic hemodialysis patient populations. Hemodialysis treatment is associated with repetitive ischemic events, or myocardial stunning, and is identified with regional wall motion abnormalities on echocardiograms. This repetitive ischemic stress results in progressive damage resulting in declines in left ventricular ejection fraction and risk for sudden cardiac death. Both acute and chronic inflammation and its cellular immunologic effector, the activated monocyte, are central to the accelerated cardiovascular disease in patients with chronic end-stage renal disease.

A pilot safety and efficacy study in 10 patients to evaluate the reduction in myocardial stunning events in hemodialysis patients is planned at the UOM. The primary outcome is expected to measure the change in regional wall abnormalities identified on an echocardiogram. Initial results are expected to provide important feasibility data for a follow-on study to undertake a controlled randomized clinical trial to evaluate the clinical efficacy of our SCD in myocardial stunning hemodialysis patients.

Suppliers

We procure conventional components such as tubing sets, clamps, fittings, and labels from various suppliers. These components are then used in our assembly of SCD clinical kits. Critical components are procured from suppliers that have been approved and qualified through our supplier management program. Fresenius Medical Care North America (“FMCNA”) is the current supplier of the cartridges used in our SCD.

In March 2022, we entered into a supply agreement (the “Supply Agreement”) with an FMCNA affiliate, Fresenius USA Marketing, Inc. (“FUSA”), to supply certain cartridges at an agreed amount per case for use in our SCD product, including in our upcoming clinical trial and any additional clinical trials. We may resell the cartridges as part of the SCD system under our HDE approval, pursuant to an Emergency Use Authorization application as well as a future PMA-approved product. Either party may terminate the Supply Agreement for uncured material breach or for the insolvency of the other party. In addition, either party may terminate the Supply Agreement if in the reasonable opinion of legal counsel for either party, any future changes in federal or state law or regulations make any portion of the Supply Agreement invalid or illegal and the parties are not able to agree on mutually acceptable addendum to the Supply Agreement. We have agreed to indemnify FUSA against certain third-party claims.

In December 2024, we entered into the Second Amendment to the initial Supply Agreement, which extended the Supply Agreement through December 31, 2027, updated a part number as well as clarified that FMCNA has 90 days to provide notice to us in the event that FUSA intends to switch the fibers within the SCD as well as the first right of refusal to be the exclusive distributor of the SCD in the United States. In addition to the Supply Agreement with FUSA, we are developing a second source for both adult and pediatric cartridges, which will enable us to better manage potential supply disruptions.

Additionally, use of the SCD in hospital settings requires the administration of RCA and calcium replacement into CRRT circuitry for safe and effective use. Both components are intravenous (“IV”) solutions, which are commonly stocked by hospital systems. However, there are limited manufacturers/suppliers of these IV solutions nationwide, and any supply chain disruptions may have detrimental effects to the utilization of CRRT, and subsequently, use of commercial QUELIMMUNE or the adult SCD in clinical studies.

Distribution

The Supply Agreement contains a provision granting FUSA a right of first refusal for the first three years after regulatory approval of our SCD product candidate to distribute the adult SCD products in the United States. If during such period, we elect to promote and sell the SCD through distributors, we will be required to provide FUSA with a right of first refusal to be our exclusive distributor of the SCD in the United States and its territories, provided that the SCD is not promoted or sold in a manner that is incompatible with any devices manufactured and/or sold by FUSA or its affiliates.

On December 27, 2022, we entered into a license and distribution agreement with Nuwellis. We appointed Nuwellis as our exclusive distributor for the sale and distribution of SCD product throughout the United States once we received written authorization from the FDA to market our SCD for pediatric use pursuant to our HDE application. In May 2024, we provided notice to Nuwellis that Nuwellis had breached the Distribution Agreement and that the Distribution Agreement would terminate effective August 18, 2024. Nuwellis disputed the validity of the termination and, on October 20, 2024, we entered into the Settlement Agreement with Nuwellis, pursuant to which we agreed to pay Nuwellis an aggregate of \$900,000 payable in three installments through December 31, 2025. As of December 31, 2025, we fulfilled all of our obligations to Nuwellis and have hired sales and marketing employees focused on the commercialization of QUELIMMUNE into the U.S. market.

Third-Party Reimbursement

We anticipate that coverage and reimbursement by Centers for Medicare and Medicaid Services (“CMS”) and private payors will be necessary for most adult patients and health care providers to pay for our treatments, particularly in the applications of continuous renal replacement therapy for dialysis access and the treatment of hyperinflammatory conditions, including AKI. Accordingly, future sales of our products will depend substantially, both domestically and abroad, on reimbursement by government authorities, private health coverage insurers and other third-party payors. Our strategy around reimbursement focuses on achieving alignment and agreement from CMS on coding and payment pathways; both are critical to influencing and achieving optimal reimbursement payment from private payor sources. Therefore, we continue to develop a comprehensive reimbursement strategy including CMS, private payors and other key stakeholders to ensure a clear and sustainable reimbursement path for all SCD product opportunities.

We are pursuing a regulatory reimbursement strategy to ensure separate Medicare payment for our SCD at an appropriate price. The regulatory strategy includes engaging CMS political and career staff directly on coverage, payment and coding followed by submission of formal applications in these areas once FDA approval is obtained. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for fundamentally novel products. See “*Risk Factors — Risks Related to Our Business Operations — Should our products be approved for commercialization, lack of third-party coverage and reimbursement for our devices could delay or limit their adoption.*”

Intellectual Property

We currently have multiple U.S. and foreign patents and patent applications that protect our proprietary technologies. We strive to protect the proprietary technologies that we believe are important to our business. We have and will continue to seek patent protection for our SCD product and related technologies, as well as for any future products. In addition to seeking patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We also rely on know-how, confidentiality agreements, license agreements and other agreements to establish and protect our proprietary rights. Our success depends in large part on our ability to protect our proprietary technology, including our SCD technologies, and to operate without infringing the proprietary rights of third parties.

The term of individual patents depends on the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent. The term of a U.S. patent may be shortened, if a patent is terminally disclaimed by its owner, over another patent.

We currently have 17 issued U.S. patents. We also have 29 issued foreign patents and 1 pending foreign patent application. We have issued patents that have terms expiring from 2025 through 2032, although terminal disclaimers, patent term extension or patent term adjustment can shorten or lengthen the patent term.

The following table summarizes the number of our patents and patent applications as of December 31, 2025:

	U.S. Patents	Foreign Patents	U.S. Applications	Foreign Applications
SCD Technology (Patent Families 1-5)	15	29	—	1
Other Technology (Patent Families 6-9)	2	—	—	—
Total	17	29	—	1

With respect to our SCD technologies, we own patents and patent applications in four patent families. The patents and applications in Patent Family 1 are co-owned by us and the UOM. The patents and applications in Patent Families 2-4 are solely owned by us. The inventions disclosed in Patent Families 1-4 were developed with U.S. government funding and are subject to the obligations under the Bayh-Dole Act.

Patent Family 1 contains nine U.S. patents directed to systems and methods for processing leukocytes and for treating subjects with various inflammatory conditions using a SCD cartridge, and to a SCD cartridge. These patents will expire from 2028-2031, assuming that the required maintenance fees are paid. We also co-own with the UOM counterpart patents granted in Canada, Europe, Japan and New Zealand, with the European patent having been validated in Austria, Belgium, Denmark, Finland, France, Germany, Italy, The Netherlands, Spain, Sweden, and The United Kingdom. These counterpart patents will expire in 2028, assuming that the required maintenance fees are paid. The patents and applications in Patent Family 1 are as follows:

Patent Family 1†

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Granted	2031	Methods for processing leukocytes and methods for treating subjects having inflammatory conditions using such methods
United States	Granted	2029	Methods for treating subjects undergoing a cardiopulmonary bypass
United States	Granted	2029	Methods for treating subjects with end-stage renal disease
United States	Granted	2029	Methods for treating subjects with acute renal failure
United States	Granted	2029	Methods for treating subjects with sepsis
United States	Granted	2031	A device that processes activated leukocytes and platelets
United States	Granted	2029	Methods for treating acute lung injury and acute respiratory distress syndrome
United States	Granted	2029	Systems for treating activated platelets
United States	Granted	2028	Systems for treating activated leukocytes
Canada	Granted	2028	Systems and methods for processing leukocytes and platelets and systems for treating inflammatory conditions
Canada	Granted	2028	A device for processing activated leukocytes and platelets
Japan	Granted	2028	A device and methods for treating leukocytes
Japan	Granted	2028	A device for processing activated leukocytes
New Zealand	Granted	2028	Systems and methods for processing leukocytes and platelets and for treating inflammatory conditions
Austria, Belgium, Denmark, Finland, France, Germany, Italy, Netherlands, Spain, Sweden, and United Kingdom	Granted	2028	A device that processes platelets or leukocytes

† This patent family was developed with U.S. federal government funding and is subject to obligations under the Bayh-Dole Act.

Pursuant to a license agreement with the UOM (as amended and restated, the “UOM License Agreement”), UOM has granted us a worldwide, royalty bearing, exclusive license to their interest in the co-owned patents and applications in Patent Family 1 in the field of medical devices for use in human therapeutics for certain technologies used in the SCD technology platform, including composition of matter and methods of use patents. In consideration for such exclusive license, during the term of the UOM License Agreement, we agreed to pay the UOM a royalty fee equal to 1% of net sales as well as a one-time milestone payment of \$0.1 million upon FDA approval of the first licensed product under the license (paid in 2024), and to reimburse patent costs. As of December 31, 2025, we have incurred less than \$20 thousand in royalties owed from sales of the QUELIMMUNE. Since January 2020, we have paid approximately \$0.1 million to the UOM to reimburse patent costs under the license. Under the UOM License Agreement, the UOM’s liability is limited and we agreed to indemnify and hold the UOM harmless in connection with the use of the licensed technology and activities related to the products created using such licensed patents and/or technology. In October 2024, the parties amended the agreement to eliminate the 10% of any milestone payments, fees, etc. in exchange for extending the 1% royalty on net sales until the later of (a) expiration of the last to expire of the patent rights or (b) the ten (10) year anniversary of the first commercial sale, unless sooner terminated as provided in another specific article of this agreement.

The UOM License Agreement will remain in effect until the later of the expiration of all licensed patents or the ten-year anniversary of the first commercial sale under the agreement, unless terminated early. If we materially breach the terms of the UOM License Agreement, the UOM has a right to terminate the agreement. In some cases, we may have an opportunity to cure a material breach within 30 days or 90 days, but in some cases the UOM may terminate the agreement immediately upon our breach. We may also terminate the agreement by giving the UOM 90-day advance notice provided certain conditions are met.

In addition to the co-owned patents and patent applications in Family 1, we also solely own three additional patent families (Families 2-4) directed to the SCD technology. Patent Family 2 includes 3 U.S. patents directed to a second generation of the SCD cartridge and methods for using our SCD cartridge to process leukocytes. The patents will expire from 2031 to 2032, assuming that the required maintenance fees are paid. Counterpart patents have been granted in Australia, Canada, Europe, and Japan with the European patent having been validated in France, Germany, Italy, Spain, and the United Kingdom. These patents will expire in 2031, assuming that the required maintenance fees are paid. The patents and the application in Patent Family 2 are as follows:

Patent Family 2†

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Granted	2032	Cartridge for treating leukocytes or platelets
United States	Granted	2032	Methods for processing leukocytes or platelets and for treating a subject with an inflammatory condition
United States	Granted	2031	Methods for processing leukocytes or platelets and for treating a subject with an inflammatory condition
Australia	Granted	2031	Cartridge for treating leukocytes or platelets and methods for treating a subject with an inflammatory condition
France, Germany, Italy, Spain and the United Kingdom	Granted	2031	Cartridge for sequestering leukocytes or platelets
Canada	Granted	2031	Cartridge for processing leukocytes or platelets
Japan	Granted	2031	Cartridge for treating leukocytes or platelets
Japan	Granted	2031	Cartridge for treating leukocytes or platelets

† This patent family was developed with U.S. federal government funding and is subject to obligations under the Bayh-Dole Act.

Patent Family 3 includes one U.S. patent directed to methods of treating chronic heart failure using a SCD cartridge, which will expire in 2032, assuming that the required maintenance fees are paid. A counterpart patent has been granted in Japan, that will expire in 2032, assuming that the required maintenance fees are paid. The patents and applications in Patent Family 3 are as follows:

Patent Family 3†

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Granted	2032	Methods for treating chronic heart failure
Japan	Granted	2032	Device for use in treating chronic heart failure

† This patent family was developed with U.S. federal government funding and is subject to obligations under the Bayh-Dole Act.

Patent Family 4 includes two U.S. patents directed to methods of treating chronic heart failure and acute decompensated heart failure using a SCD cartridge. These patents will expire in 2032, assuming that the required maintenance fees are paid. Counterpart patents have been granted in Australia and Canada, and a patent application is pending in Europe. These patents, and patent application, if granted, will expire in 2032, assuming that the required maintenance fees are paid. The patents and applications in Patent Family 4 are as follows:

Patent Family 4†

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Granted	2032	Methods for increasing myocardial function in subject with acute decompensated heart failure
United States	Granted	2032	Methods for increasing myocardial function in subject with chronic heart failure
Australia	Granted	2032	Methods for increasing myocardial function in a subject with acute chronic heart failure or chronic heart failure
Australia	Granted	2032	Methods, cartridges, and systems for improving myocardial function and treating inflammation associated with acute decompensated heart failure and chronic heart failure
Canada	Granted	2032	Devices for use in treating subjects with chronic heart failure and acute decompensated heart failure
Europe	Pending	2032*	Devices for use in treating subjects with chronic heart failure or acute decompensated heart failure

* Expiration date if application is granted.
† This patent family was developed with U.S. federal government funding and is subject to obligations under the Bayh-Dole Act.

With respect to our other technologies, we solely own patents and patent applications in two additional patent families (Patent Families 5-6) which are summarized as follows:

Patent Family 5

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Granted	2027	Extracorporeal cell-based therapeutic device and delivery system for renal cells

Patent Family 6

Jurisdiction	Status	Expiration Date	Subject Matter
United States	Granted	2031	Methods for enhanced propagation of renal cells

In addition to seeking patent protection, we also rely on trade secrets and other confidential information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Competition

The industry for treating inflammation is extremely competitive, and companies developing new treatment procedures face significant capital and regulatory challenges. As our SCD product is a clinical-stage device in adults and commercial stage device in pediatrics, we have the additional challenge of establishing medical industry support, which will be driven by treatment outcomes data resulting from human clinical studies and commercial usage. With QUELIMMUNE cleared by the FDA in pediatrics or any future regulatory body of another country, we may face significant competition from well-funded pharmaceutical and medical device companies. Additionally, we would likely need to establish large-scale production of our device in order to be competitive. We believe that our SCD is able to compete effectively in the market and we are not aware of any similar device that has completed regulatory approval in any country for the treatment of adults or children with acute kidney injury requiring continuous renal replacement therapy.

In both the United States and international markets, the use of medical devices is related in part to the availability of reimbursement from third-party payors, such as government and private insurance plans. Healthcare providers that use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the medical procedures being performed or to compensate them for their patient care services. Therapies that present a cost-neutral to cost-beneficial impact to the health economic system are generally viewed as more favorable from a reimbursement perspective. To this end, we conducted health economic outcomes research (HEOR) to estimate the economic impact of the QUELIMMUNE within the pediatric AKI-CKRT patient population. Our analysis revealed that pediatric AKI hospitalizations involving CKRT were estimated to cost over \$450,000 per event, reflecting an enormous burden to healthcare institutions. The median length of stay (“LOS”) was 31 days per hospitalization. QUELIMMUNE therapy was projected to be cost-beneficial by lowering mortality as well as reducing hospital LOS by 3 days in pediatric AKI patients requiring CKRT, with estimated savings of ~\$40,000 per hospitalization after six days of QUELIMMUNE use. These data were presented at the American Society of Nephrology Kidney Week 2024 and at the AKI-CRRT Annual meeting in March 2025, and were published in the Journal of Medical Economics, titled "Projected hospitalization cost impact of selective cypheretic device in pediatric acute kidney injury" on December 28, 2025 (1): 1467-1475 (doi: 10.1080/1369998.2025.2550860). However, lack of third-party coverage and reimbursement for our devices could delay or limit their adoption, and as such harm our competitive advantage in the market.

Sales and Marketing

We use a direct model for marketing and sales of QUELIMMUNE. Since obtaining FDA HDE approval for pediatric patients with AKI in February 2024, we terminated a distribution agreement with a third party, built a customer-facing infrastructure to support our direct sales model and will efficiently expand our footprint as new customers are added and QUELIMMUNE utilization increases.

We have hired internal sales and marketing employees focused on the initial launch of QUELIMMUNE into the U.S. Pediatric Market. Our traction with QUELIMMUNE in pediatric hospitals continues to increase as we add new commercial accounts and work through the IRB process in target accounts. We are also conducting analyses and preparing for the launch of the SCD therapy in the U.S. in the adult AKI population. Our plans are focused on developing an optimal infrastructure for an effective U.S. commercial launch inclusive of commercial staff requirements, marketing, sales and reimbursement strategies and refinement of the target account universe.

Government Regulation

Our SCD product is subject to regulation by various regulatory bodies, primarily the FDA and comparable international regulatory agencies, as applicable. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing, storage, distribution, advertising and promotion, and post-marketing surveillance reporting of medical devices. The SCD therapy interacts with and deactivates the patient's hyperinflammatory cells prior to their return to the patient. As the primary therapeutic mode of action of our SCD is attributable to the device's impact on these autologous cells and their timely return to patients, FDA's Center for Biological Evaluation and Research has primary jurisdiction over the premarket development, review and approval of the SCD as a medical device. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as issuance of warning letters, import detentions, mandatory safety notifications, repair/replace/refund actions, recalls; and/or, civil monetary penalties and/or judicial sanctions, such as product seizures, injunctions and criminal prosecution.

FDA's Pre-market Clearance and Approval Requirements

Each medical device we seek to commercially distribute in the United States will require either a prior 510(k) clearance, unless it is exempt, a de novo request or a PMA or HDE approval from the FDA. Generally, if a new device has a predicate that is already on the market under a 510(k) clearance, the FDA will allow that new device to be marketed under a 510(k) clearance; otherwise, a de novo PMA or HDE application (if applicable) is required. Medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the general controls of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), such as provisions that relate to: adulteration; misbranding; registration and listing; notification, including repair, replacement, or refund; records and reports; and good manufacturing practices. Most Class I devices are classified as exempt from premarket notification under section 510(k) of the FD&C Act, and therefore may be commercially distributed without obtaining 510(k) clearance from the FDA. Class II devices are subject to both general controls and special controls to provide reasonable assurance of safety and effectiveness. Special controls are usually device-specific and may include performance standards, post-market surveillance requirements, patient registries, special labeling requirements, premarket data requirements and guidelines. Most Class II devices require the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the devices. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, are classified as Class III. In addition, novel devices that have not been previously classified by the FDA or which have been deemed not substantially equivalent to a previously cleared 510(k) device are considered Class III by default, unless and until they are down-classified by the FDA (e.g., via the de novo request process). High risk devices formally classified as Class III by regulation or administrative order cannot be marketed in the U.S. unless the FDA approves the device after submission of a PMA or, if applicable, an HDE. Novel devices that are Class III by default may be eligible for down-classification through the de novo request process, if the device manufacturer can demonstrate that the device is lower risk and should therefore be classified as Class I or Class II. The FDA can also impose post-market sales, marketing, or other restrictions on devices in order to ensure that they are used in a safe and effective manner. The SCD is classified as a Class III medical device and as such is subject to PMA or HDE submission and approval.

Premarket Approval Pathway

A PMA application must be submitted to the FDA for Class III devices for which the FDA has required a PMA. The PMA application process is more extensive than the 510(k) premarket notification and de novo request processes. A PMA application must be supported by extensive data, including but not limited to technical, preclinical, clinical, manufacturing and labeling to demonstrate to the FDA's satisfaction reasonable evidence of safety and effectiveness of the device.

After a PMA application is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. The FDA has 180 days of FDA review time to review a filed PMA application, although the review of an application generally occurs over a significantly longer period of time due to hold periods during which the submitting sponsor (the Company) gathers information to address FDA requests for additional information. The total review process is highly variable and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device.

Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA's overall decision-making process. In addition, the FDA generally conducts a preapproval inspection of the manufacturing facilities to ensure compliance with the Quality System Regulation. The agency also may inspect one or more clinical sites to ensure compliance with FDA's regulations.

Upon completion of the PMA review, the FDA may: (i) approve the PMA that authorizes commercial marketing with specific prescribing information for one or more indications, which can be more limited than those originally sought; (ii) issue an approvable letter that indicates the FDA's belief that the PMA is approvable and states what additional information the FDA requires, or the post-approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter that outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

Humanitarian Device Exemption Pathway

In accordance with the Orphan Drug Act of 1984, a rare disease is defined as a disease or condition that affects fewer than 200,000 people in the U.S. Currently, in the U.S., only a portion of the 7,000 known rare diseases have approved treatments. By definition, rare diseases or conditions occur in a small number of patients. As a result, it has been difficult to gather enough clinical evidence to meet the FDA standard of reasonable assurance of safety and effectiveness.

In order to address the challenge of rare diseases in the medical device realm, Congress included a provision in the Safe Medical Devices Act of 1990 to create a new regulatory pathway for products intended for diseases or conditions that affect small (i.e., rare) populations, which is the Humanitarian Device Exemption program.

A Humanitarian Use Device ("HUD") is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the U.S. per year.

Once a Class III medical device has HUD designation, an HDE application can be submitted per Section 520(m) of the FD&C Act. An HDE application has most of the same requirements as a PMA application. However, an HDE is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions.

Under section 520(m)(6)(A)(i) of the FD&C Act, an HUD is only eligible to be sold for profit after receiving an HDE approval if the device is intended for the treatment or diagnosis of a disease or condition that either:

- occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or
- occurs in adult patients and does not occur in pediatric patients or occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

HDE applicants whose devices meet one of the eligibility criteria above and wish to sell their HUD for profit should provide adequate supporting documentation to FDA in the original HDE application. HDE holders who wish to sell their devices for profit and who did not submit the request in the original HDE application may submit a supplement and provide adequate supporting documentation to demonstrate that the HUD meets the eligibility criteria.

FDA approval of an HDE application is predicated on evidence that the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment (per Section 520(m)(2)(C) of the FD&C Act and 21 CFR 814.104(b)(3)). In addition, FDA must determine that the device would not be available to a person with the disease or condition in question without the HDE application approval and that there is no comparable device, other than another device under an HDE or IDE, available to treat or diagnose the disease or condition.

HDE amendments, supplements, and reports are generally subject to similar requirements as those for PMAs, and in fact the requirements for each of these types of HDE submissions refers back to the regulatory requirements for its PMA counterpart. FDA's decision to "file" or "not file" an HDE application will be made within 30 calendar days from the date the HDE application was received. Overall, an HDE must be reviewed and a final determination made by FDA within 75 days from the date of the application being filed; however, the review of the application may occur over a significantly longer period of time due to hold periods during which the submitting sponsor (the company) gathers information to address FDA requests for additional information.

Upon completion of the HDE review, FDA may: (i) issue an Approval Order, which authorizes commercial distribution in accordance with any prescribed conditions of approval; (ii) issue an Approvable Letter that indicates FDA's belief that the HDE is approvable and states what additional information FDA requires (generally resolution of minor deficiencies or completion of an FDA inspection); (iii) issue a Major Deficiency Letter to inform the applicant that the HDE application lacks significant information necessary for FDA to complete the review and that the application must be amended to provide the necessary information (e.g., additional clinical experience, additional non-clinical data, scientific rationale for data already provided, or new validation data and analyses); (iv) issue a Not Approvable Letter which indicates that FDA does not believe that the application can be approved 'as-is' because of significant deficiencies. The letter will, where practical, identify measures to place the application in an approvable form. These measures are typically more onerous than those in a Major Deficiency Letter or an Approvable Letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (v) deny the application.

If FDA issues an Approvable Letter, Major Deficiency Letter, or Not Approvable letter, the review clock is stopped, and the application is placed on hold. Once the applicant submits a response, the review clock is restarted with a new 75-day FDA response timeframe.

Once an HDE application is approved, the HUD may be marketed. The HDE holder is responsible for ensuring that a HUD under an approved HDE is administered only in facilities having IRB or appropriate local committee oversight in accordance with FDA's regulations governing IRBs. Approval by an IRB or an appropriate local committee is required before a HUD under an approved HDE can be used at a facility for clinical care (with the exception of emergency use).

The number of HDE devices that may be sold for profit is limited to a quantity known as the Annual Distribution Number ("ADN"). If the FDA determines that an HDE holder is eligible to sell the device for profit, the FDA will determine the ADN and notify the HDE holder.

The ADN is calculated by taking the number of devices reasonably necessary to treat or diagnose an individual per year and multiplying it by 8,000. For example, if the typical course of treatment using an HDE device, in accordance with its intended use, requires the use of seven devices per patient per year, then the ADN for that HDE device would be 56,000 (i.e., $7 \times 8,000$).

If the number of devices distributed in a year exceeds the ADN, the sponsor can continue to sell the device but cannot earn a profit for the remainder of the year.

We received the Final Approval Order on February 21, 2024, to sell QUELIMMUNE, the SCD therapy, for profit, to treat critically ill pediatric patients with life-threatening AKI.

Clinical Trials

Clinical trials are almost always required to support PMA and are sometimes required for 510(k) clearance. In the U.S., for significant risk devices, these trials require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. The clinical protocol under an IDE must be approved in advance by the FDA for a specific number of patients at specified study sites. During the trial, the sponsor must comply with various FDA requirements and regulations. For example, the investigators must obtain patient informed consent, follow the investigational plan, control the disposition of investigational devices and comply with all reporting and recordkeeping requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards ("IRBs") at the clinical trial sites. An IRB is an appropriately constituted group that has been formally designated to review and monitor medical research involving subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety and welfare of human research subjects. The FDA and/or the IRB at each site at which a clinical trial is being performed may withdraw approval of a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits or a failure to comply with FDA or IRB requirements. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and effectiveness of the device, may be equivocal or may otherwise not be sufficient to obtain approval or clearance of the product.

Ongoing Regulation by the FDA

Even after a device receives clearance or approval and is placed on the market, numerous regulatory requirements may apply. These include:

- Upkeep of establishment registration and device listing;
- Adherence to quality system regulations, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- Adherence to labeling regulations and the FDA prohibitions against the promotion of products for uncleared, unapproved or “off-label” uses and other requirements related to promotional activities;
- Adherence to medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury, or if their device malfunctioned and the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; and
- Adherence to corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FD&C Act that may present a risk to health.

Some changes to an approved PMA or HDE device, including changes in indications, labeling or manufacturing processes or facilities, require submission and FDA approval of a new PMA/HDE or PMA/HDE supplement, as appropriate, before the change can be implemented. Supplements to a PMA or HDE often require the submission of the same type of information required for an original PMA or HDE, except that the supplement is generally limited to that information needed to support the proposed change from the device covered by the original PMA or HDE. The FDA uses the same procedures and actions in reviewing PMA or HDE supplements as it does in reviewing original PMAs and HDEs. PMA supplements also require the submission of a user fee, which varies depending on the type of supplement.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning or untitled letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delay in processing submissions or applications for new products or modifications to existing products;
- withdrawing approvals that have already been granted; and
- criminal prosecution.

In addition, the FDA imposes requirements on labeling and promotion, including requirements that all statements be truthful, accurate, not misleading, adequately substantiated, and fairly balanced and prohibits an approved device from being marketed for off-label use. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Newly discovered or developed safety or effectiveness data may require changes to a product’s labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA’s policies may change, which could delay or prevent regulatory clearance or approval of our products under development.

Healthcare Regulation

In addition to the FDA's restrictions on marketing of pharmaceutical products and medical devices, the United States healthcare laws and regulations that may affect our ability to operate include: the federal fraud and abuse laws, including the federal anti-kickback and false claims laws, federal data privacy and security laws, and federal transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. Many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. For example, states have anti-kickback and false claims laws that may be broader in scope than analogous federal laws and may apply regardless of payer. In addition, state data privacy laws that protect the security of health information may differ from each other and may not be preempted by federal law. Moreover, several states have enacted legislation requiring pharmaceutical manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, report information related to drug pricing, require the registration of sales representatives, and prohibit certain other sales and marketing practices. These laws may adversely affect our sales, marketing, and other activities with respect to any product candidate for which we receive approval to market in the United States by imposing administrative and compliance burdens on us.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities, particularly any sales and marketing activities after a product candidate has been approved for marketing in the United States, could be subject to legal challenge and enforcement actions. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. For example, in the U.S., the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, among other things, reduced and/or limited Medicare reimbursement to certain providers and imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions. The Further Consolidated Appropriations Act, signed into law on December 20, 2019, has now permanently repealed the medical device excise tax. In addition, the Budget Control Act of 2011, as amended by subsequent legislation, further reduces Medicare's payments to providers by two percent through fiscal year 2027. These reductions may reduce providers' revenues or profits, which could affect their ability to purchase new technologies. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Legislation could be adopted in the future that limits payments for our products from governmental payors.

Coverage and Reimbursement

In both the United States and international markets, the use of medical devices is dependent in part on the availability of reimbursement from third-party payors, such as government and private insurance plans. Healthcare providers that use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the medical procedures being performed or to compensate them for their patient care services. Should our products under development be approved for commercialization by the FDA, any such products may not be considered cost-effective, reimbursement may not be available in the United States or other countries, if approved, and reimbursement may not be sufficient to allow sales of our future products on a profitable basis. The coverage decisions of third-party payors will be significantly influenced by the assessment of our future products by health technology assessment bodies. If approved for use in the United States, we expect that any products that we develop will be purchased primarily by medical institutions, which may in turn bill various third-party payors for the health care services provided to patients at their facility. Payors may include CMS, which administers the Medicare program and works in partnership with state governments to administer Medicaid, other government programs, and private insurance plans. The process involved in applying for coverage and reimbursement from CMS is lengthy and expensive. Further, Medicare coverage is based on our ability to demonstrate that the treatment is "reasonable and necessary" for Medicare beneficiaries. Even if products utilizing our technology receive FDA and other regulatory clearance or approval, they may not be granted coverage and reimbursement by any payor, including by CMS. Many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies and amounts. However, no uniform policy for coverage and reimbursement for medical devices exists among third-party payors in the United States. Therefore, coverage and reimbursement can differ significantly from payor to payor.

Employees

As of December 31, 2025, we had 17 full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements.

Corporate History

We were initially incorporated as the Predecessor under the name Nephron, Inc. on June 6, 2007. On August 3, 2007, we amended our corporate name to CytoPherx, Inc. On June 19, 2019, we amended our corporate name to SeaStar Medical, Inc., herein the Predecessor as defined above.

On October 28, 2022, LMF Acquisition Opportunities, Inc. (as defined above “LMF”), a Delaware special purpose acquisition company, consummated a series of transactions that resulted in the combination of LMF Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of LMF (“Merger Sub”), and the Predecessor, a Delaware corporation, pursuant to an Agreement and Plan of Merger, dated April 21, 2022 (the “Merger Agreement”), by and among LMF, Merger Sub and the Predecessor (the “Transaction”). Pursuant to the terms of the Merger Agreement, Merger Sub merged with and into the Predecessor, with the Predecessor surviving the merger as a wholly-owned subsidiary of LMF (the “Business Combination”). Following the consummation of the Business Combination, LMF was renamed “SeaStar Medical Holding Corporation” (the “Company”).

Available Information

We make available free of charge on or through our website, <https://seastarmedical.com>, our Annual Reports, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, and all amendments to those filings as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission (“SEC”). Information contained on, or that may be accessed through our website, is not part of, and is not incorporated into this Annual Report.

In addition, the SEC maintains a website that contains reports, proxy statements, and other information about issuers, such as us, who file electronically within the SEC. The address of the website is www.sec.gov.

Item 1A. Risk Factors.

Investing in our securities involves risks. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under “Cautionary Note Regarding Forward-Looking Statements,” you should carefully consider the specific risks set forth herein. If any of these risks actually occur, it may materially harm our business, financial condition, liquidity and results of operations. As a result, the market price of our securities could decline, and you could lose all or part of your investment. Additionally, the risks and uncertainties described herein in any document incorporated by reference herein are not the only risks and uncertainties that we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may become material and adversely affect our business.

Risk Factor Summary

- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We have not generated substantial revenue to date and we may never be profitable.
- We may suffer from lack of availability of additional funds.
- There is substantial doubt about our ability to continue as a going concern.
- In the event we pursue a restructuring or reorganization under applicable law, we will be subject to the risks and uncertainties associated with such proceedings.
- We have a limited operating history, which makes it difficult to forecast our future results of operations.
- Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.
- We may become a defendant in one or more stockholder derivative, class-action, and other litigation.
- We may face challenges in obtaining additional FDA approvals to market our product.
- The United States could change tariff, trade, or tax provisions related to the manufacturing and sales of our products in ways that we currently cannot predict.
- We may not be able to manage our growth effectively.
- Changing priorities within the U.S. government resulting in the loss of government grant funding could adversely impact our future growth plans.
- We will initially depend on revenue generated from a single product.
- We may fail to comply with extensive regulations of United States and foreign regulatory agencies.
- Delays in successfully completing our planned clinical trials could jeopardize our ability to obtain regulatory approval.
- Delays, interruptions, or the cessation of production by our third-party suppliers of important materials or delays in qualifying new materials, may prevent or delay our ability to manufacture or process our SCD device.
- Difficulties in manufacturing our SCD could have an adverse effect upon our revenue and expenses.
- Our SCD technology may become obsolete.
- We face intense competition in the medical device industry.
- If our products, or the malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations.
- We outsource many of our operational and development activities for which we may not have full control.
- A lack of third-party coverage and reimbursement for our devices could delay or limit their adoption.
- Adverse changes in reimbursement policies and procedures by payors may impact our ability to market and sell our products.
- We may be subject to enforcement action if we engage in improper marketing or promotion of our products.
- We are and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should litigation be pursued.
- United States legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

- We are subject to stringent and changing privacy laws, regulations and standards
- Our business operations will be adversely affected if our security measures, or those maintained on our behalf, are compromised, limited or fails.
- We depend on key personnel and our inability to attract and retain qualified personnel could impede our ability to achieve our business objectives.
- Our products may in the future be subject to product recalls.
- Our forecasted operating and financial results rely upon assumptions and analyses development by us and actual results could be significantly below forecasts.
- Our estimates of market opportunity, industry projections and forecasts of operating and financial results and market growth may prove to be inaccurate.
- Conflicts, military actions, terrorist attacks, political events, public health crises, changes in regulatory regimes and general instability, could adversely affect our business.
- We rely upon exclusively licensed patent rights from third parties which are subject to termination or expiration.
- If we are unable to obtain and maintain sufficient patent protection for our products, our ability to commercialize such products successfully may be adversely affected.
- We may not be able to obtain protection under the Hatch-Waxman Act and similar non-United States legislation for extending the term of patents covering our products.
- We could become involved in intellectual property litigation that could be costly, require us to pay damages, prevent us from selling commercially available products at all or reduce margins we may realize from our products.
- Issued patents covering one or more of our products could be found invalid or unenforceable if challenged in patent office proceedings, or in court.
- If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be adversely and materially affected, and our business could be harmed.
- The United States government may exercise certain rights with regard to our inventions, or licensors' inventions, developed using federal government funding.
- Changes to the patent law in the United States and other jurisdictions could diminish the value of our patents in general, thereby impairing our ability to protect our products.
- Intellectual property rights do not necessarily address all potential threats to our competitive advantage.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies.
- We may obtain only limited geographical protection with respect to certain patent rights,
- We do not have long-term experience operating as a United States public company.
- Our Common Stock may be delisted from Nasdaq if we do not maintain compliance with Nasdaq's continued listing requirements. If our Common Stock is delisted, it could negatively impact us.
- Our inability to develop and maintain an effective system of internal controls of financial reporting could impact ability to accurately report financial results in a timely manner.
- The sale of our Common Stock in at-the-market offerings, through our standby equity purchase agreement or through similar arrangements may cause substantial dilution to our existing shareholders.
- We may redeem your unexpired warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.
- The trading price of our Common Stock has been volatile and is likely to be volatile in the future.
- If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.
- Future sales, or the possibility of future sales, of a substantial number of shares of our Common Stock could adversely affect the price of the shares and dilute stockholders.
- We have not paid cash dividends in the past and do not expect to pay dividends in the future.
- We are an "emerging growth company" and will continue to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies.

Risks Relating to Our Financial Condition

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have incurred significant net losses since our inception and had an accumulated deficit of \$151.7 million and \$139.6 million as of December 31, 2025 and 2024, respectively.

We have devoted most of our financial resources to research and development, including clinical trials and non-clinical development activities, and obtaining regulatory approval of our SCD product candidates. If our product candidates are not successfully developed or commercialized, or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail.

We expect to continue to incur substantial and increased expenses as we expand research and development activities and advance clinical programs through the regulatory approval process. We also expect an increase in our expenses associated with commercialization of our products and creating additional infrastructure to support operations as a public company. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future.

We have not generated substantial revenue to date and we may never be profitable.

Our ability to generate meaningful future revenue from product sales depends heavily on our success with the following items:

- commercializing QUELIMMUNE, including securing adoption and increasing awareness;
- completing the clinical development of our adult SCD;
- obtaining regulatory approval for our adult SCD, including the PMA from the FDA;
- scaling our commercial operations, including building a hospital-directed sales force and potentially collaborating with third parties;
- obtaining third-party reimbursement status from government agencies and insurance carriers; and
- entering into collaboration agreements and partnerships to commercialize our products.

Because of the numerous risks and uncertainties associated with medical device commercialization and product development, we are unable to predict the timing or amount of expenses, or when, or if, we will be able to achieve profitability. In addition, our expenses could increase beyond expectations if we are required by the FDA to perform additional, unanticipated studies.

Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. In the case of our SCD therapy for the treatment of pediatric AKI, we will be limited in our ability to sell and distribute QUELIMMUNE due to certain restrictions under the HDE requirements that limit the number of units that can be sold on an annual basis, which will further limit the amount of revenue that could be generated by us.

We may suffer from lack of availability of additional funds.

We expect to have ongoing needs for working capital in order to fund our operations and we will need to raise additional funds through equity and debt financings. However, there can be no assurance that we will be successful in securing additional capital on favorable terms, if at all. If we are successful, whether the terms are favorable or unfavorable, there is a potential that we will fail to comply with the terms of such financing, which could result in liability for us. Further, the sale of convertible debt securities or additional equity securities could result in additional and potentially substantial dilution to our shareholders. The incurrence of indebtedness would result in additional debt service obligations and could result in operating and financing covenants that would restrict our operations and liquidity.

If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we will need to curtail development and commercialization efforts, including completing the clinical trials and regulatory approval process for our SCD product candidates, which would have a material adverse impact on our business, results of operations and financial condition.

In addition, if we are unable to generate adequate cash from operations, and if we are unable to find sources of funding, it may be necessary for us to forego business development opportunities, sell all or a portion of our assets, enter into a business combination, or reduce or eliminate operations. These possibilities, to the extent available, may be on terms that result in significant dilution to our shareholders or that result in our shareholders losing all of their investment in us.

There is substantial doubt about our ability to continue as a going concern, and we will need additional financing to execute our business plan, to fund our operations and to continue as a going concern, and if we are unable to obtain additional financing, we may be required to pursue a restructuring of our operations or reorganization proceedings under applicable U.S. bankruptcy or insolvency laws.

We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs. As of December 31, 2025 and December 31, 2024, we had positive working capital of \$9.8 million and negative working capital of \$3.0 million, respectively. We currently do not have sufficient capital to support our operations and complete our planned regulatory approval process for the adult AKI patient indications. We will need to secure additional capital to continue our operations, and such funding may not be available on acceptable terms, or at all.

There is substantial doubt regarding our ability to continue as a going concern. Our independent registered public accounting firm has expressed in its auditors' report on our 2025 financial statements, included in our Annual Report on Form 10-K filed on March 26, 2026, an emphasis of matter paragraph relating to our ability to continue as a "going concern," meaning that our recurring losses from operations and negative cash flows from operations raise substantial doubt regarding our ability to continue as a going concern. We have prepared our financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our financial statements do not include any adjustment to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty, with the exception that all borrowings are classified as current on the balance sheets.

In the event we pursue a restructuring or reorganization under applicable law, we will be subject to the risks and uncertainties associated with such proceedings.

In the event we seek to pursue a restructuring, or if we file for relief under the United States Bankruptcy Code, either Chapter 7, Chapter 11 or other proceedings, our operations, our ability to develop and execute our business plan and our continuation as a going concern will be subject to the risks and uncertainties associated with bankruptcy proceedings, including, among others: our ability to execute, confirm and consummate a plan of reorganization; the high costs of bankruptcy proceedings and related fees; our ability to obtain sufficient financing to allow us to emerge from bankruptcy and execute our business plan post-emergence, and our ability to comply with terms and conditions of any such financing; our ability to continue our operations in the ordinary course; our ability to maintain our relationships with our customers, business partners, counterparties, employees and other third parties; our ability to obtain, maintain or renew contracts that are critical to our operations on reasonably acceptable terms and conditions; our ability to attract, motivate and retain key employees; the ability of third parties to use certain limited safe harbor provisions to terminate contracts; and the actions and decisions of our stakeholders and other third parties who have interests in our proceedings that may be inconsistent with our operational and strategic plans.

Any delays in our proceedings would increase the risks of our being unable to reorganize our business and emerge from any such proceedings and may increase our costs associated with the process or result in prolonged operational disruption for us. Also, we would need the prior approval of a court for transactions outside the ordinary course of business during the course of any such proceedings, which may limit our ability to respond timely to certain events or take advantage of certain opportunities. Because of the risks and uncertainties associated with any such proceedings, we cannot accurately predict or quantify the ultimate impact of events that could occur during any such proceedings. There can be no guarantees that if we seek available protections, we will emerge from protection as a going concern or that holders of our common stock will receive any recovery.

We have a limited operating history, which makes it difficult to forecast our future results of operations.

We received HDE approval from the FDA for our pediatric SCD in February 2024 and shipped our first commercial QUELIMMUNE units in July 2024. As a result, we have a limited commercial operating history, making it difficult to accurately forecast future results of our operations and subjecting us to a number of uncertainties and risks, including our ability to plan for and model future growth. Even if we receive regulatory approval to market and sell our other SCD product candidates, our revenue growth could slow in the future, or our revenue could decline or fluctuate for a number of reasons, including slowing demand for our products, increasing competition, changing demand in the markets, new scientific or technological developments, a decrease in the growth of our overall market, our failure to attract more customers, the inability to obtain reimbursement for our products by government agencies and insurers, or our failure, for any reason, to continue to take advantage of growth opportunities. If our assumptions regarding these risks and uncertainties and our future revenue growth are incorrect or change, or if we do not address these risks successfully or forecast our results accurately, our operating and financial results could differ materially from our expectations, and our business could suffer.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2025, we had net operating loss (“NOL”) carryforwards for federal and state income tax purposes of \$117.9 million and \$52.5 million, respectively, which may be available to offset taxable income in the future. Under the Tax Cuts and Jobs Act of 2017, as modified by the Coronavirus Aid, Relief, and Economic Security Act, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80 percent of taxable income. Federal NOLs incurred before 2018 may be carried forward 20 years but are not subject to the taxable income limitation. Under current law, California NOLs generally may be carried forward 20 years (with a limited extension for California NOLs incurred in 2020-2021) without a taxable income limitation. Our federal NOLs include \$65.0 million that can also be carried forward indefinitely, and the remaining \$52.8 million of federal NOLs expire in various years beginning in 2027 for federal purposes. The California NOLs expire beginning in 2039 if not utilized.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” (as defined in Section 382 of the Code and applicable Treasury Regulations) is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We may experience a future ownership change under Section 382 of the Code that could affect our ability to utilize the NOLs to offset our income. We have not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of NOL and research tax credit carryforwards available to offset future taxable income and income tax liabilities in future years may be significantly restricted or eliminated. Further, deferred tax assets associated with such NOLs, and research tax credits could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382. Furthermore, our ability to utilize NOLs of companies that we may acquire in the future may be subject to limitations. There is also a risk that due to legislative or regulatory changes, such as suspensions on the use of NOLs or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities, including for state tax purposes. For these reasons, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our business, results of operations and financial condition.

We may become a defendant in one or more stockholder derivative, class-action, and other litigation, and any such lawsuits may adversely affect our business, financial condition, results of operations and cash flows.

We may in the future become defendants in one or more stockholder derivative actions or other class-action lawsuits. For example, certain former directors have threatened litigation for purported harm to us in connection with certain allegations made by the former directors against other members of our Board of Directors and management. The former directors have also made demands in connection with certain alleged contractual rights and purported agreements with us. We and the Board of Directors dispute these allegations and believe they are unfounded.

In addition, on July 5, 2024, Forrest A K Wells (the “Plaintiff”), a purported stockholder of ours, filed a putative class action complaint in the United States District Court for the State of Colorado (the “Class Action”), alleging that we and our management members made material misstatements or omissions regarding our business and operations, including disclosures relating to FDA approval of our product candidates, allegedly culminating in the restatement of our consolidated financial statements as disclosed in the Form 8-K filed on March 27, 2024. The Class Action asserts claims under Section 10(b) of the Exchange Act against us, our Chief Executive Officer and former Chief Financial Officer (collectively, the “Defendants”), as well as claims under Section 20(a) of the Exchange Act against the Defendants. Among other remedies, the Class Action seeks to recover compensatory and other damages. On March 4, 2025, the Plaintiff filed an amended complaint. The Defendants moved to dismiss the complaint. The Defendants’ motion to dismiss the complaint was referred to United States District Court Magistrate Judge Timothy P. O’Hara. On February 27, 2026, Magistrate Judge O’Hara issued a written report and recommendation to United States District Judge Regina M. Rodriguez that the complaint be dismissed with leave to amend (“R&R”). Lead Plaintiff filed an objection to the R&R on March 13, 2026, and Defendants are expected to respond on March 27, 2026. We cannot predict whether the Magistrate Judge’s R&R will be adopted, modified or rejected by the District Court, or whether the Lead Plaintiff will amend the complaint.

On December 13, 2024, Jose Lazo, a purported stockholder of ours, filed a putative stockholder derivative action complaint in the United States District Court for the District of Colorado (the “Derivative Action”). The factual allegations of the Derivative Action are substantially similar to the Class Action. On January 30, 2025, upon joint motion of the parties, the Court stayed the Derivative Action pending the Court’s resolution of an anticipated motion to dismiss to be filed in the Class Action.

Such lawsuits could divert our management’s attention and resources from our ordinary business operations, and we would likely incur significant expenses associated with their defense (including, without limitation, substantial attorneys’ fees and other fees of professional advisors and potential obligations to indemnify current and former officers and directors who are or may become parties to such actions). The ultimate resolution of these matters and any future matters could have a material adverse effect on our business, financial condition, results of operations and cash flow and, consequently, could negatively impact the trading price of our common stock.

Risks Related to Our Business Operations

We may face challenges in obtaining additional FDA approvals to market our products in the United States or abroad.

We may encounter various challenges and difficulties in our application to seek approval from the FDA to sell and market our SCD product candidates, including the pivotal trial for adult AKI indication.

On April 29, 2022, we received a BDD for the use of our SCD in the treatment of immunomodulatory dysregulation in adult patients (18 and older) with AKI, which is expected to accelerate the regulatory approval process subsequent to the completion of our ongoing pivotal trial.

While we expect the BDD to expedite the clinical development and regulatory review of the SCD therapy for use in this patient population, there is no guarantee that we will be able to expedite the clinical development or obtain regulatory approval.

While we have obtained approval from the FDA to conduct the pivotal trial for SCD therapy in the adult AKI patient population, there is no guarantee that we will be able to complete such trial in a timely manner, or at all, nor can there be any assurance that positive data will be generated from such trials. Even if we are able to generate positive results from this trial, the FDA and other regulatory agencies may require us to conduct additional trials to support the study or disagree with the design of the trial and request changes or improvements to such design. We are also subject to numerous other risks relating to the regulatory approval process, which include but are not limited to:

- an inability to secure and obtain support and references from collaborators and suppliers required by the FDA;
- a disagreement with the FDA regarding the design of the trial, including the number of clinical study subjects and other data, which may require us to conduct additional testing or increase the size and complexity of our pivotal study;
- a failure to obtain a sufficient supplies to conduct our trial;
- an inability to enroll a sufficient number of subjects;
- a shortage of necessary raw materials, such as calcium or IV fluids; and
- delays and failures to train qualified personnel to operate the SCD therapy.

Even if we obtain approval, the FDA or other regulatory authorities may require expensive or burdensome post-market testing or controls. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some physicians from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

Delays or rejections may occur based on changes in governmental policies for medical devices during the period of product development. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our inability to demonstrate the safety or effectiveness of the SCD or any other product we develop to the FDA's satisfaction;
- insufficient data from our preclinical studies and clinical trials, including for our SCD, to support approval;
- failure of the facilities of our third-party manufacturers or suppliers to meet applicable requirements;
- inadequate compliance with preclinical, clinical or other regulations;
- our failure to meet the FDA's statistical requirements for approval; and
- changes in the FDA's approval policies, or the adoption of new regulations that require additional data or additional clinical studies.

If we are not able to obtain regulatory approval of our other product candidates in a timely manner or at all, we may not be able to continue to operate our business and may be forced to shut down our operations.

The United States could change tariff, trade, or tax provisions related to the manufacturing and sales of our products in ways that we currently cannot predict.

The U.S. presidential administration has instituted or proposed changes in trade policies that include the imposition of higher tariffs on imports into the U.S., economic sanctions on individuals, corporations or countries, and other government regulations affecting trade between the U.S. and other countries where we conduct business. The new tariffs and other changes in U.S. trade policy could trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing trade sanctions on certain U.S. goods. The U.S. presidential administration has indicated a focus on policy reforms that discourage corporations from outsourcing manufacturing and production activities to foreign jurisdictions, including through tariffs or penalties on goods manufactured outside the U.S., which may require us to change the way we conduct business. These changes in U.S. and foreign laws and policies have the potential to adversely impact the U.S. economy or certain sectors thereof, our industry and the demand for our products, and as a result, could have a material adverse effect on our business, financial condition and results of operations. As of December 31, 2025, we do not import materials from Canada or China, but we do source tubing sets from Medtronic that are manufactured in Mexico.

We plan to expand our operations and we may not be able to manage our growth effectively, which could strain our resources and delay or derail implementation of our business objectives.

We will need to significantly expand our operations to implement our longer-term business plan and growth strategies, including building and expanding our internal organizational infrastructure to complete the regulatory approval process with the FDA. We will also be required to manage and form new relationships with various strategic partners, technology licensors, customers, manufacturers and suppliers, consultants and other third parties. This expansion and these new relationships will require us to significantly improve or replace our existing managerial, operational and financial systems, and procedures and controls; to improve the coordination between our various corporate functions; and to manage, train, motivate and maintain a growing employee base. We cannot assure that we will institute, in a timely manner or at all, the improvements to our managerial, operational and financial systems, procedures and controls necessary to support our anticipated increased levels of operations and to coordinate our various corporate functions, or that we will be able to properly manage, train, motivate and retain our anticipated increased employee base. If we cannot manage our growth initiatives, we will be unable to commercialize our products on a large scale in a timely manner, if at all, and our business could fail.

We may pursue government funding in the future. Changing priorities within the U.S. government resulting in the loss of government grant funding could adversely impact our future growth plans.

As a commercial-stage medical device company, there are grants and other funding provided by the U.S. government that we could apply for and receive. However, the current U.S. presidential administration has indicated that there will not only be a pause on government funding, but there will also be a change in who is eligible to receive it and for what purpose. These changes are not predictable and may impact our ability to receive government funding in the future. An inability to receive government funding could adversely impact our future growth plans.

We currently depend on revenue generated from a single product and in the foreseeable future will be significantly dependent on a limited number of products.

We currently depend on revenue generated from QUELIMMUNE and, if approved, our SCD product candidate for adult patients with AKI. Given that, for the foreseeable future, our business will depend on a single or limited number of products, to the extent a particular product is not well-received by the market, our sales volume, prospects, business, results of operations and financial condition could be materially and adversely affected.

If we fail to comply with extensive regulations of United States and foreign regulatory agencies, the commercialization of our products could be delayed or prevented entirely.

Our SCD product candidate and research and development activities are subject to extensive government regulations related to its development, testing, manufacturing and commercialization in the United States and other countries. We have received FDA approval for our pediatric SCD under the HDE (QUELIMMUNE), but the SCD product has not received regulatory approval from the FDA, or any foreign regulatory agencies, for use with adult patients. The process of obtaining and complying with FDA and other governmental regulatory approvals and regulations in the United States and in foreign countries is costly, time-consuming, uncertain and subject to unanticipated delays. Obtaining such regulatory approvals, if any, can take several years. Despite the time and expense exerted, regulatory approval is never guaranteed. We are also subject to the following risks and obligations, among others:

- the FDA may refuse to approve an application if it believes that applicable regulatory criteria are not satisfied;
- the FDA may require additional testing for safety and effectiveness;
- the FDA may interpret data from pre-clinical testing and clinical trials in different ways than we interpret them;
- if regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution; and
- the FDA may change its approval policies and/or adopt new regulations.

Failure to comply with these or other regulatory requirements of the FDA may subject us to administrative or judicially imposed sanctions up to a total or partial suspension of production.

Delays in successfully completing our planned clinical trials could jeopardize our ability to obtain regulatory approval.

Our business prospects will depend on our ability to complete studies, clinical trials, including our planned pivotal trials of our SCD for adult AKI indication, obtain satisfactory results, obtain required regulatory approvals and successfully commercialize our SCD product candidate. The completion of our clinical trials, the announcement of results of the trials and our ability to obtain regulatory approvals could be delayed for a variety of reasons, including:

- slow patient enrollment;
- insufficient hospital supplies or staffing;
- serious adverse events related to our medical device candidates;
- insufficient funding to engage or continue to engage a contract research organization to execute the trials;
- unsatisfactory results of any clinical trial;
- the failure of principal third-party investigators to perform clinical trials on our anticipated schedules; and
- different interpretations of our pre-clinical and clinical data, which could initially lead to inconclusive results.

Our development costs will increase if we have material delays in any clinical trial or if we need to perform more or larger clinical trials than planned. If the delays are significant, or if any of our product candidates do not prove to be safe or effective or do not receive regulatory approvals, our financial results and the commercial prospects for our product candidates would be harmed. Furthermore, our inability to complete our clinical trials in a timely manner could jeopardize our ability to obtain regulatory approval.

Delays, interruptions, or the cessation of production by our third-party suppliers of important materials or delays in qualifying new materials, may prevent or delay our ability to manufacture or process our SCD device.

We currently rely on a single supplier for the cartridges and blood tubing sets used in the SCD device for the pediatric and adult AKI indications pursuant to supply agreements. In the event this supplier is unable to meet its obligations under the agreement, we may not be able to obtain a sufficient number of cartridges or blood tubing sets to conduct our clinical trials and commercialize our products. FDA review and approval of a new supplier may be required if these materials become unavailable from our current suppliers. Although there may be other suppliers that have equivalent materials that would be available to us, FDA review of any alternate suppliers, if required, could take several months or more to obtain, if they are able to be obtained at all. Any delay, interruption, or cessation of production by our third-party suppliers of important materials, or any delay in qualifying new materials, if necessary, would prevent or delay our ability to manufacture our SCD.

Additionally, use of the SCD in the hospital setting requires the administration of RCA and calcium replacement into CRRT circuitry for safe and effective use. Both components are IV solutions which are commonly stocked by hospital systems. However, there are limited manufacturers/suppliers of these IV solutions nationwide, and any supply chain disruptions may have detrimental effects to the utilization of CRRT, and subsequently the commercial use of QUELIMMUNE or the use of adult SCD in clinical studies.

Difficulties in manufacturing our SCD could have an adverse effect upon our revenue and expenses.

We outsource the manufacturing of component parts of our SCD and complete final assembly of our SCD kits in-house. The outsourced manufacturing of SCD cartridges is complex and specialized. To support our current clinical trial needs, we comply with and intend to continue to comply with current Good Manufacturing Practice (“cGMP”) for outsourced manufacturing and in-house assembly of our products. Our ability to adequately supply our SCD in a timely manner is dependent on the uninterrupted and efficient operation of our third-party manufacturers, and those of the third parties producing raw materials and supplies upon which we rely on for the manufacturing of our products. The manufacturing of our products may be impacted by:

- the availability or contamination of raw materials and components used in the manufacturing process, particularly those for which we have no other supplier;
- our ability to comply with new regulatory requirements and cGMP;
- potential facility contamination by microorganisms or viruses;
- updating of our manufacturing specifications;
- product quality success rates and yields; and
- disruptions outside of our control, such as global viruses and pandemics.

If efficient manufacture and supply of the component parts of our SCD are interrupted, we may experience delayed shipments or supply constraints. If we are at any time unable to provide an uninterrupted supply of our SCD, our ongoing clinical trials and commercialization of QUELIMMUNE may be delayed, which could materially and adversely affect our business, results of operations and financial condition.

Our SCD technology may become obsolete.

Our SCD product candidates may become obsolete prior to commercialization by new scientific or technological developments, or by others with new treatment modalities that are more efficacious and/or more economical than our products. Further, new technological and scientific developments within the hospital setting could cause our SCD product candidates to become obsolete. For example, the SCD relies on the existing footprint of CRRT pump systems in ICUs, as well as the growing use and adoption of RCA. Further developments in these areas could require us to reconfigure our SCD product candidates, which may not be commercially feasible, or cause them to become obsolete. Lastly, our ability to achieve significant and sustained growth in our key target markets will depend upon our success in hospital penetration, utilization, publication, our SCD's reimbursement status and medical education. If we fail to sell products that satisfy our customers' demands or respond effectively to new product announcements by our competitors, then market acceptance of our products could be reduced and our business, results of operations and financial condition could be adversely affected.

We face intense competition in the medical device industry.

We compete with numerous United States and foreign companies in the medical device industry, and many of our competitors have greater financial, personnel, operational and research and development resources than us. Our commercial opportunities will be reduced or eliminated if our competitors develop and market more effective products for any of the diseases we target; have fewer or less severe adverse side effects; are better tolerated; are easier to administer; or are less expensive than our products or our product candidates.

Even if we successfully develop the adult SCD and any other future products and obtain FDA and other regulatory approvals necessary for commercializing them, our products may not compete effectively with other products. Our competitors include fully integrated pharmaceutical and medical device companies and biotechnology companies, universities, and public and private research institutions. If our competitors develop more effective treatments for infectious disease or hyperinflammation or bring those treatments to market before we can commercialize the SCD for such uses, we may be unable to obtain any market traction for our products, or the diseases we seek to treat may be substantially addressed by competing treatments. If we are unable to successfully compete against larger companies in the pharmaceutical industry, we may never generate significant revenue or be profitable.

If our products, or the malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us. Any such adverse event involving our products could also result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending against potential lawsuits, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

A lack of third-party coverage and reimbursement for our devices could delay or limit their adoption.

Healthcare providers that use medical devices generally rely on third-party payors to pay for all or part of the costs and fees associated with the medical procedures being performed or to compensate them for their patient care services. Should our products under development be approved for commercialization by the FDA, reimbursement may not be available in the United States or other countries or, even if approved, the amount of reimbursement may not be sufficient to allow sales of our future products, including the SCD, on a profitable basis. The coverage decisions of third-party payors will be significantly influenced by the assessment of our future products by health technology assessment bodies. These assessments are outside our control, and any such evaluations may not be conducted or have a favorable outcome.

We expect that any products that we develop, including the SCD, will be purchased primarily by medical institutions through their operations budget. Payors may include the CMS, which administers the Medicare program and works in partnership with state governments to administer Medicaid, other government programs and private insurance plans. The process involved in applying for coverage and incremental reimbursement from CMS is lengthy and expensive. Further, Medicare coverage is based on our ability to demonstrate that the treatment is “reasonable and necessary” for Medicare beneficiaries. Even if products utilizing our SCD technology receive FDA and other regulatory clearance or approval, they may not be granted coverage and reimbursement by any payor, including by CMS. For some governmental programs, such as Medicaid, coverage and adequate reimbursement differ from state to state and some state Medicaid programs may not pay adequate amounts for the procedure products utilizing our technology system, or any payment at all. Moreover, many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies and amounts. Therefore, coverage and reimbursement can differ significantly from payor to payor. If CMS or other agencies limit coverage or decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors for any future products of ours.

Adverse changes in reimbursement policies and procedures by payors may impact our ability to market and sell our products.

Third-party payors are increasingly challenging the prices charged for medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. Additionally, executive orders have directed governmental agencies to review and reconsider policies that affect healthcare access and reimbursement, which could lead to further changes impacting our business.

In addition, Congress is considering additional healthcare reform measures. Legislation could be adopted in the future that limits payments for our products from governmental payors. Furthermore, commercial payors such as insurance companies, could adopt similar policies that limit reimbursement for medical device manufacturers' products. Therefore, it is possible that our products or the procedures or patient care performed using our products will not be reimbursed at a cost-effective level.

We face similar risks relating to adverse changes in reimbursement procedures and policies in other countries where we may market our products. Reimbursement and healthcare payment systems vary significantly among international markets. Our inability to obtain international reimbursement approval, or any adverse changes in the reimbursement policies of foreign payors, could negatively affect our ability to sell our products in foreign markets and have a material adverse effect on our business, results of operations and financial condition. However, we currently have no plans to expand sales of QUELIMMUNE outside the U.S.

If we or our contractors or service providers fail to comply with laws and regulations, we or they could be subject to regulatory actions, which could affect our ability to develop, market and sell our product candidates and any other future product candidates and may harm our reputation.

If we or our manufacturers or other third-party contractors fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to regulatory actions, which could affect our ability to successfully develop, market and sell our SCD product candidate or any future product candidates under development and could harm our reputation and lead to reduced or non-acceptance of our proposed product candidates by the market. Even technical recommendations or evidence by the FDA through letters, site visits, and overall recommendations to academia or biotechnology companies may make the manufacturing of a clinical product extremely labor intensive or expensive, making the product candidate no longer viable to manufacture in a cost-efficient manner. The mode of administration or the required testing of the product candidate may make that candidate no longer commercially viable. The conduct of clinical trials may be critiqued by the FDA, or a clinical trial site's Institutional Review Board or Institutional Biosafety Committee, which may delay or make impossible the clinical testing of a product candidate.

Even with FDA approval, we may still be subject to enforcement action if we engage in improper marketing or promotion of our products.

We are not permitted to promote or market our product candidates until FDA approval is obtained. After approval, our promotional materials and training methods must comply with the FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved or off-label use. Practitioners may use our products off-label, as the FDA does not restrict or regulate a practitioner's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. Other federal, state, or foreign enforcement authorities might also take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, which may lead to reduced or non-acceptance of our proposed product candidates by the market. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert the attention of our management, result in substantial damage awards against us, and harm our reputation.

We intend to outsource and rely on third parties in part for the clinical development and manufacture, sales and marketing of our SCD or any future product candidates that we may develop, and our future success will be dependent on the timeliness and effectiveness of the efforts of these third parties, for which we will not have full control.

We do not have the required financial and human resources to carry out on our own all the pre-clinical and clinical development for our SCD product candidate or any other or future product candidates that we may develop, and do not have the full capability and resources to manufacture, market or sell our SCD product candidate or any future product candidates that we may develop without the potential reliance on third parties. We rely on third-party consultants, vendors and distributors to manage and implement much of the day-to-day responsibilities of conducting clinical trials and manufacturing and distribution of our current products and product candidates. Our dependence on third parties includes key suppliers and third-party service providers supporting the development, manufacturing, distribution and regulatory approval of our SCD, as well as support for our information technology systems and other infrastructure. While our management team oversees these vendors, the failure of any of these third parties to meet their contractual, regulatory, and other obligations, or the development of factors that materially disrupt the performance of these third parties, could have a material adverse effect on our business, results of operations and financial condition.

We are and will be exposed to product liability risks, and clinical and preclinical liability risks, which could place a substantial financial burden upon us should litigation be pursued.

Our business exposes us to potential product liability and other liability risks that are inherent in the testing, manufacturing, and marketing of medical devices. We may not be able to continue to obtain or maintain adequate product liability insurance on acceptable terms, if at all, and such insurance may not provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, results of operations and financial condition.

Our SCD product candidate may be used in connection with medical procedures where those products must function with precision and accuracy. If medical personnel or their patients suffer injury as a result of any failure of our products to function as designed, we may be subject to lawsuits seeking significant compensatory and punitive damages. We have obtained general clinical trial liability insurance coverage; however, our insurance coverage may not be adequate or available. In addition, we may not be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, and such insurance may not provide adequate coverage against potential liabilities. Any product recall or lawsuit in excess of any product liability insurance coverage that we may obtain could have a material adverse effect on our business, results of operations and financial condition. Moreover, a product recall could generate substantial negative publicity about our products and business and inhibit or prevent commercialization of other future product candidates.

United States legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations will be changed, and what the impact of such changes, if any, may be on our new product development efforts.

We are subject to stringent and changing privacy laws, regulations and standards as well as policies, contracts and other obligations related to data privacy and security.

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, and share personal information and other information (“Process” or “Processing”), including information we collect in connection with clinical trials, as necessary to operate our business, for legal and marketing purposes, and for other business-related purposes.

There are numerous federal, state, local and international laws, regulations and guidance regarding privacy, information security and Processing, the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent. We are subject, and may become subject in the future, to certain of these laws, regulations, and guidance, and we are also subject to the terms of our external and internal privacy and security policies, representations, certifications, standards, publications, frameworks, and contractual obligations to third parties related to privacy, information security and Processing.

If we fail, or it is perceived we have failed, to address or comply with such obligations, it could:

- increase our compliance and operational costs;
- expose us to regulatory scrutiny, actions, fines and penalties;
- result in reputational harm; interrupt or stop our clinical trials;
- result in litigation and liability; result in an inability to process personal data or to operate in certain jurisdictions; or
- harm our business operations or financial results or otherwise result in material harm to our business.

The California Consumer Privacy Act of 2018 (“CCPA”) is an example of the increasingly stringent data protection legislation in the United States. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt-out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA created civil penalties for violations, as well as a private right of action for data breaches and statutory damages ranging from \$100 to \$750 per violation, which is expected to increase data breach class action litigation and result in significant exposure to costly legal judgments and settlements. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how they are interpreted.

Our business operations will be adversely affected if our security measures, or those maintained on our behalf, are compromised, limited or fail.

In the ordinary course of our business, we handle and process proprietary, confidential and sensitive information, including personal data, intellectual property, trade secrets, and proprietary business information owned or controlled by us or other third parties, or collectively. We may use and share such sensitive information with service providers and other third parties. If we, our service providers, partners, or other relevant third parties have experienced, or in the future experience, any security incident or incidents that result in any data loss; deletion or destruction; unauthorized access to; loss, unauthorized acquisition, disclosure, or exposure of, confidential and sensitive information, it may adversely affect our business, results of operations and financial condition, including the diversion of funds to address the breach, and interruptions, delays, or outages in our operations and development programs.

Cyberattacks, malicious internet-based activity and online and offline fraud are prevalent and continue to increase, including the possibility that the ongoing conflict between Russia and Ukraine or other regional conflicts, could result in cyberattacks or cybersecurity incidents that may have a direct or indirect impact on our operations. In addition to threats from traditional computer “hackers,” threat actors, software bugs, malicious code (such as viruses and worms), employee theft or misuse, denial-of-service attacks (such as credential stuffing) and ransomware attacks, sophisticated nation-state and nation-state supported actors now engage in attacks (including advanced persistent threat intrusions). We may also be the subject of phishing attacks, viruses, malware installation, server malfunction, software or hardware failures, loss of data or other computer assets, or other similar issues any of which could have a material and adverse effect on our business, results of operations and financial condition.

We depend on key personnel and our inability to attract and retain qualified personnel could impede our ability to achieve our business objectives.

Our success depends on the continuing service of key employees, especially our Chief Executive Officer, Eric Schlorff. The loss of any of these individuals could have a material and adverse effect on our business, results of operations and financial condition. We will also be required to hire and recruit highly skilled managerial, scientific, and administrative personnel to fully implement our business plan and growth strategies. Due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific, technical and managerial personnel. Competition for these individuals is intense and we may not be able to attract, assimilate or retain additional highly qualified personnel in the future. Also, if we are required to attract personnel from other parts of the United States or abroad, we may have significant difficulty doing so because of the costs associated with moving personnel to the area. If we cannot attract and retain qualified staff and executives, we may be unable to develop our products and achieve regulatory clearance, and our business could fail.

Our products may in the future be subject to product recalls.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in their design or manufacture. For the FDA, the authority to require a recall must be based on a finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may recall a product if any material deficiency in a device is found. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, business, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands.

We may also be subject to liability claims, be required to bear other costs, or take other actions that may have a negative impact on our future sales and our ability to generate profits. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or the competent authority of another country. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. Moreover, the FDA could take enforcement action for failing to report recalls. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals.

Our forecasted operating and financial results rely in large part upon assumptions and analyses developed by us. If these assumptions and analyses prove to be incorrect, our actual operating and financial results may be significantly below our forecasts.

We have previously provided projected financial and operating information that reflected our estimates of future performance. Whether actual operating and financial results and business developments will be consistent with our expectations and assumptions as reflected in our forecast depends on a number of factors, many of which are outside our control, including, but not limited to:

- whether we can obtain sufficient capital to develop and commercialize our SCD product candidates and grow our business;
- whether we can manage relationships with key suppliers or contract research organizations;
- the ability to obtain necessary regulatory approvals;
- demand for our products;
- the timing and cost of new and existing marketing and promotional efforts;
- competition, including from established and future competitors;
- our ability to retain existing key management, to integrate recent hires and to attract, retain and motivate qualified personnel;
- the overall strength and stability of the economies in the markets in which we operate or intend to operate in the future; and
- regulatory, legislative and political changes.

Unfavorable changes in any of these or other factors, most of which are beyond our control, could materially and adversely affect our business, results of operations and financial condition.

Our estimates of market opportunity, industry projections and forecasts of market growth may prove to be inaccurate.

The market opportunity estimates and growth forecasts included in this Annual Report, including information concerning our industry and the markets in which we intend to operate, are obtained from publicly available information released by independent industry and research organizations and other third-party sources. Although we are responsible for the disclosure provided in this Annual Report and believe such third-party information is reliable, we have not independently verified any such third-party information. In addition, projections, assumptions and estimates of the future performance of the industry in which we operate are subject to uncertainty and risk due to a variety of factors. As a result, inaccuracies in third-party information, or in the projections, may adversely impact the assumptions that are relied upon for our internal business planning and in the analysis of investors.

Conflicts, military actions, terrorist attacks, political events, public health crises, changes in regulatory regimes and general instability, could adversely affect our business.

Conflicts, military actions, terrorist attacks, political events and public health crises have precipitated economic instability and turmoil in international commerce and the global economy. The uncertainty and economic disruption resulting from hostilities, military action or acts of terrorism may impact our operations or those of our suppliers or customers. Accordingly, any conflict, military action or terrorist attack that impacts us or any of our suppliers or customers, could have a material adverse effect on our business, results of operations, financial condition and/or liquidity.

Risks Relating to Our Intellectual Property

We rely upon exclusively licensed patent rights from third parties which are subject to termination or expiration. If licensors terminate the licenses or fail to maintain or enforce the underlying patents, our competitive position could be materially harmed.

We rely in part upon exclusively licensed patent rights for the development of our SCD technology. For example, we co-own with, and exclusively licensed from, the UOM patents related to the SCD technology. If the UOM were to terminate its license with us, we would no longer have exclusive rights to the co-owned patents and the UOM would be free to license the UOM's interest in the co-owned patents to a competitor of ours.

We may become reliant in the future upon licenses to certain third-party patent rights and proprietary technologies necessary to develop and commercialize our SCD technology or other technologies. If we are unable to timely obtain these licenses on commercially reasonable terms, if at all, our ability to commercially exploit such products may be inhibited or prevented. If these licenses do not provide exclusive rights to use the subject intellectual property in all relevant fields of use and all territories in which we choose to develop or commercialize our technology and products, we may not be able to prevent competitors from developing and commercializing competitive products in such territories.

Should any of our current or future licenses be prematurely terminated for any reason, or if the patents and intellectual property owned by its licensors are challenged or defeated by third parties, our research and commercialization efforts could be materially and adversely affected. Our licenses may not continue in force for as long as is required to fully develop and market our products. It is possible that if the licenses are terminated or the underlying patents and intellectual property are challenged or defeated, suitable replacements may not be obtained or developed on terms acceptable to us, if at all. There is also the related risk that we may not be able to make the required payments under any patent license, in which case the licensor may terminate the license.

Further, our licensors may not successfully prosecute the patent applications which it has licensed and on which our business depends or may prosecute them in a manner not in our best interests. Further, licensors may fail to maintain licensed patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement or may fail to defend against counterclaims of patent invalidity or unenforceability.

In addition, despite our best efforts, a licensor could claim that we have materially breached a license agreement and terminate the license, thereby removing our ability to obtain regulatory approval for and to market any product covered by such license. If our licenses are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, identical products.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know how resulting from the joint creation or use of intellectual property by us and our licensors; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevents or impairs our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

If we are unable to obtain and maintain sufficient patent protection for our products, if the scope of the patent protection is not sufficiently broad, or if the combination of patents, trade secrets and contractual provisions upon which we rely to protect our intellectual property are inadequate, our competitors could develop and commercialize similar or identical products, and our ability to commercialize such products successfully may be adversely affected.

Our success depends in large part on our ability to protect our proprietary rights to the technologies incorporated into our products, including our ability to obtain and maintain patent protection in the United States and other countries related to our SCD technology and other technologies that we deem important to our business. We rely on a combination of patent protection, trade secret laws and nondisclosure, confidentiality, and other contractual restrictions to protect our proprietary technology. If we do not adequately protect our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business, result of operations and financial condition. To protect our proprietary technologies, we have pursued patent protection in the United States and abroad related to our SCD technology and other technologies that are important to our business. The patent application and approval process are expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Failure to protect, obtain, maintain, or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products. The enforcement, defense and maintenance of such patents and other intellectual property rights may be challenging and costly.

We cannot be certain that any patents that we have been issued or granted will not later be found to be invalid and/or unenforceable. We cannot be certain that pending patent applications will be issued in a form that provides it with adequate protection to prevent competitors from developing competing products. As a medical device technology company, our patent position is uncertain because it involves complex legal and factual considerations. The standards applied by United States Patent and Trademark Office (“USPTO”), and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable as methods of medical treatment. Consequently, patents may not be issued from any applications that are currently pending or that are filed in the future. As such, we do not know the degree of future protection that we will have for our technology. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Only issued patents can be enforced against third parties practicing the technology claimed in such patents. Pending patent applications cannot be enforced unless and until patents get issued from such applications. Assuming the other requirements for patentability are met, currently, patents are granted to the party who was the first to file a patent application. However, prior to March 16, 2013, in the United States, patents were granted to the party who was the first to invent the claimed subject matter. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or by the USPTO or by foreign patent offices. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in post-grant review procedures such as oppositions, derivations, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of third parties. An adverse determination in any such challenges may result in the loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar products, or limit the duration of our patent protection. In addition, given the amount of time required for the development, testing and regulatory review of medical devices, our patents might expire before or shortly after such products receive FDA approval and are commercialized, or before we receive approval to market our products in a foreign country.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States patent law.

Although we believe that certain of our patents and applications, if they are granted, will help protect the proprietary nature of our SCD technology, this protection may not be sufficient to protect us during the development of that technology. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with any of our products. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or technologies sufficient to achieve our business objectives.

If we do not obtain protection under the Hatch-Waxman Act and similar non-United States legislation for extending the term of patents covering our products, our business, results of operations and financial condition may be materially harmed.

Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Even if patents related to our products, or their uses are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our products might expire before or shortly after such products receive FDA approval and are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing similar or identical products.

Depending upon the timing, duration and requirements of FDA marketing approval of our product candidates, our United States patents, if issued, may be eligible for a limited patent term extension under the Hatch-Waxman Act, or under similar legislation in other countries. However, our patent and patent applications are only eligible for a patent term extension under the Hatch Waxman Act if they relate to a medical device classified by the FDA as a Class III device. Therefore, if our product candidates are not classified as Class III devices, we will not be able to apply for an extension of term for any patents covering such approved products. If eligible, the Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product candidate approval, and only one patent related to an approved product candidate may be extended. However, we may not receive an extension if it fails to apply within applicable deadlines, fails to apply prior to expiration of relevant patents or otherwise fails to satisfy applicable requirements. Moreover, the length of the extension could be less than requested.

Accordingly, if we are unable to obtain a patent term extension or the term of any such extension is less than requested, the period during which we can enforce our patent rights for that product will be shortened and competitors may obtain approval to market competing products sooner than expected. As a result, our business, results of operations and financial condition could be adversely and materially affected.

We could become involved in intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, prevent us from selling our commercially available products and/or reduce the margins we may realize from our products.

Our commercial success depends, in part, on our ability to develop and market our SCD technology, as well as any future technologies that we develop, without infringing the intellectual property and other proprietary rights of third parties.

The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the determination is often uncertain. There may be existing patents of which we are unaware that our products under development may inadvertently infringe. The likelihood that patent infringement claims may be brought against us increases as the number of competitors increases, as it introduces new products and achieves more visibility in the marketplace.

Any infringement claim against us, even if without merit, may cause us to incur substantial costs, and would place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. In some cases, litigation may be threatened or brought by a patent holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence. If we are found to infringe any patents, we could be required to pay substantial damages. We also could be forced, including by court order, to cease developing, manufacturing, or commercializing infringing products. We also could be required to pay royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. We may not be able to obtain a license enabling us to sell our products on reasonable terms, or at all. If we fail to obtain any required licenses or make any necessary changes to our technologies or products, we may be unable to commercialize one or more of our products or may have to withdraw products from the market, either of which would have a material adverse effect on our business, results of operations and financial condition.

In the event a competitor infringes upon any of our patents or other intellectual property rights, enforcing our rights may be difficult, time consuming and expensive, and would divert management's attention from managing our business. We may not be successful on the merits in any enforcement effort. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights.

Issued patents covering one or more of our products could be found invalid or unenforceable if challenged in patent office proceedings, or in court.

Competitors may infringe our patents, trademarks, or other intellectual property. To counter infringement or unauthorized use of our intellectual property, we may be required to initiate legal proceedings against a third party to enforce our intellectual property rights. If we were to file a claim against a third party to enforce a patent covering one of our products, the defendant could counterclaim that our patent rights are invalid and/or unenforceable (a common practice in the United States).

Grounds for a validity challenge could be an alleged failure to meet one or more statutory requirements for patentability. Grounds for an unenforceability assertion could be based on an allegation that someone connected with prosecution of the patent intentionally withheld relevant information from the USPTO or made a misleading statement, during prosecution.

In any patent infringement proceeding, there is a risk that a court will decide that a company patent is invalid or unenforceable, in whole or in part. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention at issue. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those other parties and other competitors, which may curtail or preclude our ability to exclude third parties from selling similar products. Any of these occurrences could adversely and materially affect our business, results of operations and financial condition.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Additionally, third parties are able to challenge the validity of issued patents through administrative proceedings in the patent offices of certain countries, including the USPTO and the European Patent Office.

With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware of during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose some or all of the patent protection for one or more of our products. Such a loss of patent protection could have a material adverse impact on its business, results of operations and financial condition.

Other parties may challenge certain of our foreign patent applications. If any such parties are successful in opposing our foreign patent applications, we may not gain the protection afforded by those patent applications in particular jurisdictions and may face additional proceedings with respect to similar patents in other jurisdictions, as well as related patents. The loss of patent protection in one jurisdiction may influence our ability to maintain patent protection for the same technology in other jurisdictions.

In addition, the European Unified Patent Court, or the UPC, came into force during 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. Although we have decided, and may continue to decide, to opt out certain of our European patents and patent applications from the UPC, if certain formalities and requirements are not met, then our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. Thus, we cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC. This could enable third parties to seek revocation of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of our European patents.

Further, disputes may arise regarding the ownership or inventorship of our patents. While we have entered into assignment of intellectual property agreements with our employees, consultants, and collaborators and believe that we own our patents and applications, the assignment and other ownership agreements that we rely on could be challenged. If a court or administrative body determined that we do not own certain of our patents or patent applications, or that inventorship of certain of its patents is incorrect, our title to our patents could be invalidated and our ability to develop and commercialize our technology could be materially harmed.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be adversely and materially affected, and our business could be harmed.

We have also entered into non-disclosure and confidentiality agreements with all of our employees, advisors, consultants, contract manufacturers, clinical investigators and other third parties involved in the development and commercialization of our technology in order to protect our intellectual property and other proprietary technologies some of which may not be amenable to patent protection. However, these agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, time consuming, and the outcome is unpredictable. Accordingly, we may not be able to obtain adequate remedies for such breaches, despite any legal action we might take against persons making such unauthorized disclosure.

If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom the third party communicates such technology or information, from using that technology or information to compete with us, and our business, results of operations and financial condition could be adversely affected.

Those with whom we collaborate on research and development related to current and future technologies and products may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. But these contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

The United States government may exercise certain rights with regard to our inventions, or licensors' inventions, developed using federal government funding.

The United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (as amended, the “Bayh-Dole Act”). Certain of our exclusively owned patents and patent applications and those patents and applications that we co-own with and exclusively license from the University of Michigan were developed using federal funding from the National Institutes of Health, the U.S. Department of Defense, and/or the U.S. Army Medical Research and Materiel Command. Consequently, pursuant to the Bayh-Dole Act, the U.S. government has certain rights in patents and applications that cover our SCD technology, in particular, to those patents and applications identified in the section of this Annual Report titled “*Business – Intellectual Property*” belonging to Patent Families 1-4.

The U.S. federal government has certain rights, including so-called “march-in rights,” to any patent rights that were funded in part by the U.S. government and any products or technology developed from such patent rights. When new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the U.S. government to use the invention for non-commercial purposes. These rights may permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or to allow third parties to use our licensed patents, including certain patents relating to SCD product candidates. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve the practical application of government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Furthermore, the U.S. government may have the right to take title to government-funded inventions if we fail to disclose the inventions to the government in a timely manner or fails to file a patent application within specified time limits.

If the U.S. government exercises such march-in rights, we may not be able to develop or commercialize our product candidates effectively or profitably, or at all, which could harm our business, results of operations and financial condition. In addition, if any intellectual property owned or licensed by us becomes subject to any of the rights or remedies available to the U.S. government or third parties pursuant to the Bayh-Dole Act, this could impair the value of our intellectual property and could adversely affect our business.

We also sometimes collaborate with academic institutions to accelerate our research or development. We try to avoid engaging our academic partners in projects in which there is a risk that federal funds may be co-mingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely and materially affected.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Obtaining and enforcing patents in the medical device industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the United States and other countries could increase those uncertainties and costs. The United States Supreme Court has ruled on several patent cases, either narrowing the scope of patent protection available or weakening the rights of patent owners in certain circumstances. Depending on future actions by Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in ways that would weaken our ability to obtain new patents or to enforce our existing and future patents.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are the same as or similar to our products but that are not covered by the claims of patents that we own or have rights to;
- we or our licensors or any current or future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by our patents or pending patent applications;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering the inventions in our patents or applications;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- our pending patent rights may not lead to issued patents, or the patents, if granted, may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties manufacturing or testing our products or technologies could use the intellectual property of others without obtaining proper licenses;
- we may not develop additional technologies that are patentable; and
- third parties may allege that our development and commercialization of our products infringe their intellectual property rights, and the outcome of any related litigation may have an adverse effect on our business, results of operations and financial condition.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are owed to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or the lapse of a patent or patent application, resulting in the partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our products, our competitive position would be adversely affected.

We may obtain only limited geographical protection with respect to certain patent rights, which may diminish the value of our intellectual property rights in those jurisdictions and prevent us from enforcing our intellectual property rights throughout the world.

We have not and in the future may not file for patent protection in all national and regional jurisdictions where such protection may be available because it is cost prohibitive. In addition, we may decide to abandon national and regional patent applications before grant, or to not pay maintenance fees on granted patents in certain jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

Competitors may use our technologies to develop their own products in jurisdictions where we have not obtained patent protection and, further, may export otherwise infringing products to territories where we have patent protection, but where patent enforcement is not as strong as that in the United States. These products may also compete with our products in jurisdictions where we do not have any issued or licensed patents or where our patent or other intellectual property rights are not effective or sufficient to prevent these products from competing with us.

Additionally, some countries do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights in these countries. Competitors may use our technologies to develop their own products in jurisdictions where we have not obtained patent protection. Furthermore, they may export otherwise infringing products to jurisdictions where we have patent protection, if our ability to enforce our patents to stop the infringing activities in those jurisdictions is inadequate.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we may not be able to initiate or maintain similar efforts in all jurisdictions in which we wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

Risks Related to Being a Public Company

We do not have long-term experience operating as a United States public company and may not be able to adequately implement the governance, compliance, risk management and control infrastructure and culture required for a public company, including compliance with the Sarbanes-Oxley Act.

We are building experience operating as a United States public company and our executive officers have limited experience in managing a United States public company, which makes their ability to comply with applicable laws, rules, and regulations uncertain. Our failure to comply with all laws, rules and regulations applicable to United States public companies could subject us and our management to regulatory scrutiny or sanction, which could harm our reputation and share price. Although we are developing and implementing governance, compliance, risk management and control framework and culture required for a public company, we may not be able to meet the requisite standards expected by the SEC and/or our investors.

As a United States public reporting company, we incur significant costs for legal, accounting, insurance, compliance, and other expenses. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. Compliance with reporting, internal control over financial reporting and corporate governance obligations may require members of our management and our finance and accounting staff to divert time and resources from other responsibilities to ensure these new regulatory requirements are fulfilled.

Other challenges in complying with these regulatory requirements may arise because we may not be able to complete our evaluation of compliance and any required remediation in a timely fashion. Furthermore, any current or future controls may be considered as inadequate due to changes or increased complexity in regulations, our operating environment or other reasons.

Due to inadequate governance and internal control policies, misstatements, or omissions due to error or fraud may occur and may not be detected, which could result in failures to make required filings in a timely manner and make filings containing incorrect or misleading information. Any of these outcomes could result in SEC enforcement actions, monetary fines, or other penalties, as well as damage to our reputation, business, financial condition, operating results and share price.

Our Common Stock may be delisted from Nasdaq if we do not maintain compliance with Nasdaq's continued listing requirements. If our Common Stock is delisted, it could negatively impact us.

Continued listing of a security on Nasdaq is conditioned upon compliance with various continued listing standards. There can be no assurance that we will be able to comply with the applicable listing standards. We have in the past received notifications of noncompliance with Nasdaq's continued listing standards and there is no guarantee that we will not receive such notifications in the future.

Pursuant to Nasdaq Listing Rule 5815(d)(4)(B), we are subject to a Mandatory Panel Monitor until July 1, 2026. If, within that one-year monitoring period, the Nasdaq Listing Qualifications staff (the "Staff") finds us again out of compliance with the Minimum Stockholders' Equity Requirement, notwithstanding Nasdaq Listing Rule 5810(c)(2), we would not be permitted to provide the Staff with a plan of compliance with respect to that deficiency and the Staff would not be permitted to grant additional time for us to regain compliance with respect to that deficiency, nor would we be afforded an applicable cure or compliance period pursuant to Nasdaq Listing Rule 5810(c)(3). Instead, the Staff would issue a "Delist Determination Letter" and we would have an opportunity to request a new hearing with the initial Panel or a newly convened Hearings Panel if the initial Panel is unavailable.

On July 31, 2025, we received a letter from Nasdaq notifying us that we were not in compliance with the \$1.00 per share minimum bid price requirement for continued inclusion on Nasdaq pursuant to Nasdaq Listing Rule 5550(a)(2), (the "Minimum Bid Price Rule"). This letter had no immediate effect on the listing of the Company's Common Stock on Nasdaq and we had 180 calendar days from the date of the notice, or until January 27, 2026, to regain compliance with the Bid Price Requirement.

On January 20, 2026, the Company received a letter from Nasdaq confirming that the Company has regained compliance with the minimum bid price requirement of the Minimum Bid Price Rule.

There can be no assurance that we will successfully maintain with the Minimum Stockholder's Equity Requirement or maintain compliance with other Nasdaq listing requirements. If we fail to regain compliance with Nasdaq's continued listing standards during any period granted by the Panel, the Securities could be subject to delisting from Nasdaq, unless another exception is granted by Nasdaq.

If our Common Stock ultimately were to be delisted for any reason, it could negatively impact us by (i) reducing the liquidity and market price of our Common Stock; (ii) reducing the number of investors willing to hold or acquire our Common Stock, which could negatively impact our ability to raise equity financing; (iii) limiting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing us from accessing the public capital markets; and (iv) impairing our ability to provide equity incentives to our employees.

If we are unable to develop and maintain an effective system of internal controls over financial reporting, we may not be able to accurately report our financial results in a timely manner, which may materially and adversely affect our business, results of operations and financial condition.

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP. Our management also evaluates the effectiveness of our internal controls, and we disclose any changes and material weaknesses identified through such evaluation of our internal controls. A material weakness is a deficiency, or a combination of deficiencies, in the internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 (“the Sarbanes-Oxley Act”), and the rules and regulations of the applicable listing standards of Nasdaq. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting, and financial compliance costs, make some activities more difficult, time-consuming, and costly, and place significant strain on our personnel, systems, and resources.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. However, as an emerging growth company, an attestation of an independent registered public accounting firm will initially not be required. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs, and significant management oversight. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. We may need to upgrade our legacy information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we are unable to hire the additional accounting and finance staff necessary to comply with these requirements, we may need to retain additional outside consultants. If we or, if required, our independent registered public accounting firm, are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting, which could negatively impact the price of our securities.

Our management and other personnel will need to devote a substantial amount of time to compliance initiatives applicable to public companies, including compliance with Section 404 of the Sarbanes-Oxley Act and the evaluation of the effectiveness of our internal controls over financial reporting within the prescribed timeframe. In the event that we identify additional deficiencies, we may be required to further restate our financial statements and our results of operations and financial condition could be negatively affected.

We have in the past identified material weaknesses in our internal controls over financial reporting. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines that we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our securities could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Risks Related to Ownership of Our Common Stock

The sale of our Common Stock in at-the-market offerings, our standby equity purchase agreement or through any similar arrangements may cause substantial dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the price of our Common Stock to decline.

We have used at-the-market, or ATM, offerings to fund a meaningful portion of our operations in the past year, and we may continue to use ATM offerings, our standby equity purchase agreement or any similar arrangement to raise additional capital in the future. For example, in 2025, we sold an aggregate of approximately 900 thousand shares of our Common Stock for net proceeds of approximately \$5.9 million under our At-the-Market offering program. While sales of shares of our Common Stock in ATM offerings may enable us to raise capital at a lower cost compared with other types of equity financing transactions, such sales may result in dilution to our existing stockholders, and such sales, or the anticipation of such sales, may cause the trading price of our Common Stock to decline

The trading price of our Common Stock has been volatile and is likely to be volatile in the future.

The trading price of our Common Stock has been and is expected to remain volatile because it is influenced by many factors beyond our control. These include overall market conditions, economic trends, interest rate changes, investor sentiment, and industry-specific developments. Company-specific events such as earnings announcements, changes in management, strategic decisions, or unexpected news can also cause sharp price fluctuations. In addition, external factors like geopolitical events and regulatory changes can increase uncertainty in the market, contributing to continued volatility in the trading price of our Common Stock. Such fluctuations could subject us to securities class action litigation, which could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We may redeem your unexpired warrants prior to their exercise at a time that is disadvantageous to you, thereby making your warrants worthless.

For those warrants traded on the Nasdaq under the ticker symbol (ICUCW) (herein the "Public Warrants"), we have the ability to redeem outstanding warrants at any time after they become exercisable and prior to their expiration, at a price of \$0.01 per warrant, provided that the last reported sales price of our Common Stock equals or exceeds \$18.00 per share (as adjusted for stock splits, stock dividends, reorganizations, recapitalizations and the like) for any 20 trading days within a 30 trading-day period ending on the third trading day prior to the date on which we gave proper notice of such redemption and provided certain other conditions are met. If and when the Public Warrants become redeemable by us, we may exercise our redemption right even if we are unable to register or qualify the underlying securities for sale under all applicable state securities laws. Redemption of the outstanding Public Warrants could force Public Warrant holders (i) to exercise the Public Warrants and pay the exercise price therefore at a time when it may be disadvantageous for Public Warrant holders to do so, (ii) to sell the Public Warrants at the then-current market price when the Public Warrant holders might otherwise wish to hold the Public Warrants or (iii) to accept the nominal redemption price which, at the time the outstanding Public Warrants are called for redemption, is likely to be substantially less than the market value of the Public Warrants.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our Common Stock is impacted by the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinions of our stock, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

Future sales, or the possibility of future sales, of a substantial number of shares of our Common Stock could adversely affect the price of the shares and dilute stockholders.

Future sales of a substantial number of shares of our Common Stock, or the perception that such sales will occur, could cause a decline in the market price of our Common Stock. This is particularly true if we sell our stock at a discount. If our stockholders sell substantial amounts of Common Stock in the public market, or the market perceives that such sales may occur, the market price of our Common Stock and our ability to raise capital through an issue of equity securities in the future could be adversely affected.

In addition, in the future, we may issue additional shares of Common Stock or other equity or debt securities convertible into Common Stock in connection with financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the market price of our Common Stock to decline.

We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our Common Stock.

We have never paid cash dividends on our Common Stock and do not anticipate doing so in the foreseeable future. The payment of dividends on our Common Stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors (the “Board”) may consider relevant. Further, the agreements governing our indebtedness limit our ability to make dividends on our Common Stock. If we do not pay dividends, our Common Stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 and we intend to continue to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our Common Stock being less attractive to investors and adversely affect the market price of our Common Stock or make it more difficult to raise capital as and when we need it.

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), and we intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved, and exemptions from any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor’s report on the financial statements.

If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years.

Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our business, results of operations, financial condition and cash flows, and prospects may be materially and adversely affected.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Our Board considers cybersecurity and other information technology risks as part of its risk management and compliance oversight function. The Board oversees management's implementation of our cybersecurity risk management processes and receives reports from management on our cybersecurity risks annually. In addition, management updates the Board, as necessary, regarding any significant cybersecurity incidents. The Board receives briefings from management on our cyber risk management processes, and it receives presentations on cybersecurity topics from management as part of the Board's risk oversight function and continuing education on topics that impact public companies.

We have an information security program designed to identify, protect, detect and respond to and manage reasonably foreseeable cybersecurity risks and threats. To protect our information systems from cybersecurity threats, we use various security tools that help prevent, identify, escalate, investigate, resolve and recover from identified vulnerabilities and security incidents in a timely manner. These include, but are not limited to, internal reporting, monitoring and detection tools. We regularly assess risks from cybersecurity and technology threats and monitor our information systems for potential vulnerabilities. We utilize third-party information technology services help identify, measure, and prioritize cybersecurity and technology risks, as well as to develop related security controls and safeguards.

While we have not, as of the date of this Form 10-K, experienced a cybersecurity threat or incident that resulted in a material adverse impact to our business or operations, there can be no guarantee that we will not experience such an incident in the future. Such incidents, whether or not successful, could result in our incurring significant costs related to, for example, rebuilding our internal systems, implementing additional threat protection measures, defending against litigation, responding to regulatory inquiries or actions, paying damages, providing customers with incentives to maintain a business relationship with us, or taking other remedial steps with respect to third parties, as well as incurring significant reputational harm. In addition, these threats are constantly evolving, thereby increasing the difficulty of successfully defending against them or implementing adequate preventative measures.

Item 2. Properties.

We lease our headquarters on a month-to-month basis and our facility for final assembly, warehousing and fulfillment pursuant to an annual lease agreement at 3513 Brighton Boulevard, Denver, Colorado 80216. We believe this property is adequate to operate our business.

Item 3. Legal Proceedings.*Shareholder Derivative Claims*

On July 5, 2024, Forrest A K Wells, a purported stockholder of ours, filed a putative class action complaint in the United States District Court for the District of Colorado, captioned Wells v. SeaStar Medical Holding Corporation et al, Case No. 1:24-cv-0187 (D. Colorado) (the "Class Action"). The Class Action alleges that we, our Chief Executive Officer and former Chief Financial Officer made or caused to be made material misstatements or omissions regarding our business and operations, allegedly culminating in our restatement of our consolidated financial statements, disclosed in a Form 8-K and filed on March 27, 2024. The Class Action asserts claims pursuant to the Securities Exchange Act of 1934, including Section 10(b), Rule 10b-5 promulgated thereunder and Section 20(a). The Class Action seeks to recover, among other remedies, compensatory damages. On March 4, 2025, the Plaintiff filed an amended complaint. The Defendants moved to dismiss the complaint. The Defendants' motion to dismiss the complaint was referred to United States District Court Magistrate Judge Timothy P. O'Hara. On February 27, 2026, Magistrate Judge O'Hara issued a written report and recommendation to United States District Judge Regina M. Rodriguez that the complaint be dismissed with leave to amend ("R&R"). Lead Plaintiff filed an objection to the R&R on March 13, 2026, and Defendants are expected to respond on March 27, 2026. We cannot predict whether the Magistrate Judge's R&R will be adopted, modified or rejected by the District Court, or whether the Lead Plaintiff will amend the complaint.

On December 13, 2024, Jose Lazo, a purported stockholder of ours, filed a putative stockholder derivative action complaint captioned Lazo v. Schlorff et. al., C.A. No. 1:24-cv-3444 in the United States District Court for the District of Colorado (the "Derivative Action"). The factual allegations of the Derivative Action are substantially similar to the Class Action. On January 30, 2025, upon joint motion of the parties, the Court stayed the Derivative Action pending the Court's resolution of an anticipated motion to dismiss to be filed in the Class Action.

The Derivative Action alleges, among other things, that our Chief Executive Officer, former Chief Financial Officer, and certain of the Company's current and former directors violated Section 14(a) of the Exchange Act, breached fiduciary duties and were unjustly enriched by making or allowing to be made purportedly false and misleading statements regarding our prospects for success in obtaining FDA approval for our SCD. The Derivative Action further alleges that there were purported deficiencies in the Company's internal financial controls and procedures and improper accounting for classification of certain financial instruments leading to our restatement of previously issued financial statements. The Derivative Action also asserts claims under Section 10(b) and 21D of the Exchange Act against our Chief Executive Officer and former Chief Financial Officer. Among other remedies, the Derivative Action seeks to recover damages and restitution on behalf of us and certain injunctive relief concerning our corporate governance and internal controls. Additional stockholders may file substantially similar complaints in the future. The Company will not make separate disclosure of such complaints unless they are materially different than the Derivative Action.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Common Stock trades on The Nasdaq Capital Market under the symbol “ICU.”

Holders

As of March 1, 2026, there were 86 stockholders of record of our Common Stock.

The number of record holders is based upon the actual number of holders registered on our books at such date and does not include holders of shares in street name or persons, partnerships, associations, corporations, or other entities identified in security position listings maintained by depository trust companies.

Dividend Policy

We have not paid any cash dividends on Common Stock to date. Our Board may from time to time consider whether or not to institute a dividend policy. It is our present intention to retain any earnings for use in our business operations and accordingly, we do not anticipate the Board declaring any dividends in the foreseeable future. The payment of cash dividends in the future will be dependent upon our revenues and earnings, if any, capital requirements and general financial condition. The payment of any cash dividends will be within the discretion of our Board.

Recent Sales of Unregistered Securities and Use of Proceeds

None.

Issuer Purchases of Equity Securities By the Issuer and Affiliated Purchases

None.

Item 6. [Reserved]

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

Objective

The following discussion and analysis are intended to help you understand our business, financial condition, results of operations, liquidity, and capital resources. You should read this discussion in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report. In addition to historical financial analysis, this discussion and analysis contains forward-looking statements based upon current expectations that involve risks, uncertainties, and assumptions, as described under the heading “Cautionary Note Regarding Forward-Looking Statements.” Actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of various factors, risks and uncertainties, including those set forth under “Risk Factors” included elsewhere (or incorporated by reference) in this Annual Report.

Unless the context otherwise requires, references in this “Management’s Discussion and Analysis of Financial Condition and Results of Operations” to “SeaStar Medical”, “we”, “us”, and “our”, are intended to mean the business and operations of SeaStar Medical Holding Corporation and its consolidated subsidiaries (the “Company”, “We”, “SeaStar Medical” or “Us”) following the October 28, 2022, merger between LMF Acquisition Opportunities Inc. (“LMF”), and SeaStar Medical, Inc. (the “Predecessor”) (the transaction herein defined as the “Business Combination” or “Merger”). In connection with the Business Combination, the Predecessor was determined to be the accounting acquirer.

Overview

On October 28, 2022, LMAO consummated a series of transactions that resulted in the combination of LMF Merger Sub, Inc. and the Predecessor pursuant to an Agreement and Plan of Merger. Immediately upon consummation of the Business Combination, LMAO was renamed SeaStar Medical Holding Corporation (as defined above).

We are a commercial-stage healthcare company focused on transformational treatments for critically ill patients facing organ failure and potential loss of life. Our Selective Cytopheretic Device (“SCD”) 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. It has broad potential applications for patients suffering from both acute and chronic kidney diseases as well as cardiovascular and other serious inflammatory diseases.

We received Food and Drug Administration (“FDA”) approval on February 21, 2024, under a Humanitarian Device Exemption (“HDE”) for our pediatric SCD therapy. It is the only FDA-approved product for use in pediatric patients with acute kidney injury (“AKI”) due to sepsis or a septic condition requiring continuous renal replacement therapy (“CRRT”). We shipped our first commercial pediatric SCD (“QUELIMMUNE”) in July 2024. In addition, we are currently conducting a pivotal clinical trial (“NEUTRALIZE-AKI”) to assess the safety and efficacy of the SCD therapy in critically ill adult patients with AKI requiring CRRT.

Our SCD therapy has been awarded Breakthrough Device Designation (“BDD”) for six therapeutic indications by the FDA, including the use of the SCD therapy for adult patients with AKI, patients with cardiorenal syndrome awaiting left ventricular assist device (“LVAD”) implantation, patients with hepatorenal syndrome, patients with end stage renal disease (“ESRD”) and adult and pediatric patients undergoing cardiac surgery. The BDD enables the potential for a speedier pathway to approval and the ability to have more frequent and flexible meetings with the FDA.

The inflammatory response is essential to the healing process of critical organs; however, the overactivation of inflammatory cells, which can be triggered by many different bodily insults such as trauma, surgery or infection, can send the body into shock and cause severe damage to a variety of critical organs such as the heart, lungs and kidney. Central to inflammation are the cells within blood and lymph circulatory systems, called white blood cells (primarily neutrophils and monocytes). In a normal inflammatory response, neutrophils are the first immune cells to arrive at the site and are key to the entire immune response that kills pathogens and promotes tissue repair. These inflammatory cells release chemicals (cytokines) that trigger the immune system to eliminate foreign pathogens or damaged tissue, enhancing the immune response.

If the inflammatory response becomes excessive and dysregulated (referred to as proinflammatory), the inflammatory cells will continue to produce cytokines and other damaging molecules, further enhancing the dysregulated immune response, and altering feedback mechanisms that regulate the immune system. This results in damaging hyperinflammation spreading uncontrollably to other parts of the body, often leading to acute chronic solid organ dysfunction or failure, including the heart, lung, kidney, liver, and even death. This hyperinflammatory response is also known as the “cytokine storm,” referring to the body’s reaction to the category of small-secreted proteins released by hyperinflammatory cells that affect communication between cells. Currently, there are no therapeutic options that specifically neutralize the white blood cells that are primarily responsible for the destructive hyperinflammatory response.

Currently, few therapeutics are available to clinicians to address hyperinflammation and for those options that do exist, such options are either immunosuppressive or only target one cytokine. We believe our technology has the potential to overcome limitations in existing anti-inflammatory treatments and address the challenge of selectively targeting activated neutrophils and monocytes.

We are leveraging our patent protected and scalable SCD technology platform to develop proprietary therapies that are organ agnostic and target both acute and chronic indications. Preclinically, our SCD was tested in various animal models, which include acute myocardial infarction, intracranial hemorrhage, chronic heart failure, sepsis, and acute respiratory distress syndrome. The animal models demonstrated the inflammatory response and how it was modified by our SCD. We will continue to explore the application of our SCD technology across a broad range of markets and indications where proinflammatory activated neutrophils and monocytes may contribute to disease progression or severity in both acute and chronic indications.

We are using our SCD initially to clinically validate several acute organ injury indications, including kidneys and lungs. Our investigational SCD for adults is an extracorporeal synthetic membrane device that is currently being evaluated in a pivotal clinical trial in the U.S. for premarket clearance by the FDA. The SCD for adults is designed to be easily integrated into existing CRRT systems that are commonly installed in hospitals, including in ICUs throughout the United States. Similar to QUELIMMUNE, once approved and commercialized, our adult SCD is expected to initially target acute kidney injury in adults on CRRT. In addition, we are developing our SCD to address inflammation associated with liver disease, acute respiratory distress syndrome, chronic dialysis and chronic heart failure in adult populations. See Part I, Item 1A “Risk Factors” for additional information.

We have incurred net losses in each year since our inception in 2007. As of December 31, 2025 and 2024, we had an accumulated deficit of approximately \$151.7 million and \$139.6 million, respectively. Our net losses were \$12.2 million and \$24.8 million for the years ended December 31, 2025 and 2024, respectively. The majority of our net losses for the years-ended December 31, 2025 and 2024, respectively, resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. The remaining net losses primarily resulted from non-cash, non-operating changes in fair value of our financial instruments recognized in our statement of operations for the same two fiscal years. For the year ended December 31, 2025, these non-cash, non-operating losses related to change in fair value of convertible notes, change in fair value of liability classified warrants, and interest expense, which were partially offset by interest income.

As of December 31, 2025, we had cash of approximately \$12.0 million. The Company does not hold any cash equivalents

The recurring losses, working capital deficiency, the need for capital to fund our operations, including clinical trial costs and regulatory approval expenses, and the amount of cash reserve are factors that raise substantial doubt about our ability to continue as a going concern for the twelve-month period following the issuance date for the consolidated financial statements for the year ended December 31, 2025. See Note 1 to our audited consolidated financial statements for the year ended December 31, 2025, included elsewhere in this Annual Report for additional information on our assessment.

Our accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and liabilities in the normal course of business. Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should we be unable to continue as a going concern.

Our need for additional capital will depend in part on the scope and costs of our development activities. To date, we have not generated significant revenue from the sale of commercialized products. Our ability to generate significant product revenue will depend on the successful development of our adult SCD and eventual ongoing commercialization of QUELIMMUNE. Until such time, if ever, we expect to finance our operations through the sale of equity or debt, borrowings under credit facilities, potential collaborations, other strategic transactions or government and other grants. Adequate capital may not be available to us when needed or on acceptable terms. If we are unable to raise capital, we could be forced to delay, reduce, suspend or cease our research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. See Part I, Item 1A “Risk Factors” for additional information.

Key Components of Results of Operations

Revenue

Our pediatric SCD therapy, QUELIMMUNE, received HDE approval from the FDA in February 2024. Since that time, we have been building out our commercial operations, developing our customer base and growing commercial sales of QUELIMMUNE. We shipped our first commercial QUELIMMUNE units in July 2024. We recognized \$1.2 million and \$0.1 million of revenue from the sale of QUELIMMUNE for the years ended December 31, 2025 and 2024, respectively. Historically, prior to 2024, revenue has been primarily derived from government and other grants. We will continue to focus our efforts on generating revenue in the future based on product sales of QUELIMMUNE, as well as potential future payments from license or collaboration agreements and government and other grants.

We expect that any revenue we generate will fluctuate from quarter to quarter as we continue to advance our sales of QUELIMMUNE to pediatric hospital customers. We also continue to develop our adult SCD for which we are currently enrolling patients in a pivotal study to support FDA approval. If we fail to complete the development of, or fail to obtain regulatory approval to commercialize our adult SCD in a timely manner, our ability to generate additional future revenue, and our results of operations and financial position, could be materially adversely affected.

Research and Development Expenses

Since inception, we have focused our resources on research and development activities, including conducting preclinical studies and clinical trials, and developing our process and activities related to regulatory filings for our products. Subject to the availability of additional funding, we plan to further increase our research and development expenses for the foreseeable future as we continue the development of our SCD as well as a next generation SCD. Research and Development expenses also include salaries and related costs for employees in clinical and medical affairs roles, which include stock-based compensation expenses and benefits for such employees.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive and finance roles, which also include stock-based compensation expenses and benefits for such employees.

Other significant general and administrative expenses include facilities costs, professional fees for accounting and legal services, sales and marketing expenses, and expenses associated with obtaining and maintaining patents and obtaining financing, and expenses related to SEC reporting and compliance. As we continue to expand and grow our operations, we expect that our general and administrative expenses will increase, including additional expenses relating to new hires, travel, an enterprise resource planning platform, and branding.

Loss from Operations and Operating Margin

Loss from operations consists of our gross profit less our operating expenses. Operating margin is loss from the operations as a percentage of our net sales.

Other Income (Expense), Net

Total other income (expense), net primarily consists of (i) interest expense relating to interest incurred on notes payable, (ii) a one-time charge for a financing fee related to our standby equity purchase agreement, (iii) changes in the fair value of liability classified warrants, and (iv) interest income derived from cash balances maintained at a commercial financial institution.

Net Loss

Net loss consists of our loss from operations, offset by other income, net and taxes.

Factors Affecting Our Operating Results

We believe that our performance and future success depend on several factors that present significant opportunities for us but also pose risks and challenges. Please see the factors discussed elsewhere in this Annual Report, including those discussed in Part I, Item 1A, “Risk Factors,” for additional information.

Results of Operations

Comparison of Year Ended December 31, 2025 to Year Ended December 31, 2024

The following table sets forth a summary of our results of operations. This information should be read together with our consolidated financial statements and related Notes included elsewhere in this Annual Report.

(\$ in thousands)	Year Ended December 31,		Change	
	2025	2024	\$	%
Revenue	\$ 1,234	\$ 135	\$ 1,099	814%
Cost of goods sold	53	—	53	*
Gross profit	1,181	135	1,046	775%
Operating expenses				
Research and development	7,518	9,105	(1,587)	(17)%
General and administrative	5,838	8,872	(3,034)	(34)%
Total operating expenses	13,356	17,977	(4,621)	(26)%
Loss from operations	(12,175)	(17,842)	5,667	(32)%
Total other income (expense)	28	(6,985)	7,013	(100)%
Loss before income tax provision	(12,147)	(24,827)	12,680	(51)%
Income tax provision	3	3	—	—
Net loss	\$ (12,150)	\$ (24,830)	\$ 12,680	(51)%

(*) - revenue or expenses which were new to the year ended December 31, 2025, compared to the year ended December 31, 2024.

Revenue

Net revenue increased \$1.1 million to \$1.2 million for the year-ended December 31, 2025, compared to \$0.1 million net revenue for the year-ended December 31, 2024. The increase is primarily attributable to (i) increased adoption of QUELIMMUNE, resulting in ten customers as of December 31, 2025, an increase from three as of December 31, 2024, and (ii) a full year of sales activity during the 2025 fiscal year compared to only six months of sales activity during the 2024 fiscal year, as sales did not commence until July 1, 2024.

Research and Development Expenses

The following table discloses the breakdown of research and development expenses:

(\$ in thousands)	Year Ended December 31,		Change	
	2025	2024	\$	%
Clinical trials	\$ 3,904	\$ 4,391	\$ (487)	(11)%
External services	602	1,254	(652)	(52)%
Payroll and personnel expenses	2,695	3,184	(489)	(15)%
Other research and development expenses	317	276	41	15%
	\$ 7,518	\$ 9,105	\$ (1,587)	(17)%

Research and development expenses for the years ended December 31, 2025 and 2024 were approximately \$7.5 million and \$9.1 million, respectively. The decrease in research and development expenses of \$1.6 million was primarily driven by (i) a \$1.0 million decline in consulting expenses as the Company both made a concerted effort to reduce usage of consultants and hiring key employees to bring certain critical skillsets in-house, (ii) a \$0.6 million decline in pre-clinical expenses as we started the NEUTRALIZE-AKI study in 2024, resulting in limited pre-clinical activities in 2025, (iii) a \$0.5 million decline in compensation and benefits as a result of certain voluntary recissions of accrued bonuses accrued, (iv) a \$0.4 million reduction in outside services as we switched clinical research organizations, and (v) \$0.4 million in contra-expenses were recognized in 2025 as we agreed to provide clinical research organization services to a third-party, for which the Company will be able to utilize the results of this study.

These decreases described above were partially offset by (i) a \$1.0 million increase in clinical trial costs, mostly driven by the increased activity relating to the NEUTRALIZE-AKI study, (ii) a \$0.2 million increase in the adult SCD related supply costs due to both the NEUTRALIZE-AKI study and device development efforts, and (iii) a \$0.1 million increase in medical affairs.

General and Administrative Expenses

General and administrative expenses for the years ended December 31, 2025 and 2024 were \$5.8 million and \$8.9 million, respectively. The decrease of \$3.1 million in general and administrative expenses is due primarily to (i) a \$1.0 million decline in accounting and legal related activities, primarily driven by the 2024 restatement of previously filed financial statements, with no such expense in the 2025 fiscal year, (ii) a \$0.6 million decline in Board compensation due to the voluntary rescission of accrued director fees, (iii) a decrease of \$0.5 million in compensation and benefits primarily due to the voluntary rescission of accrued bonuses, (iv) a \$0.5 million decline in other professional fees, and (v) a \$0.3 million reduction in costs as we had a one-time settlement in 2024 with a former distributor, and (vi) a \$0.2 million decline in travel and conference activity.

These decreases were partially offset by the increase of \$0.1 million due to due diligence fees paid to a third-party financial institution for a standby equity purchase agreement that we entered into during the fiscal year ended December 31, 2025.

Other Income (Expense)

Other income (expense) for the years ended December 31, 2025 and 2024 was other income, net of \$28 thousand and other expense, net of \$7.0 million, respectively. The change was the result of (i) interest income increasing \$0.2 million as a result of our increased cash during the 2025 fiscal year compared to the 2024 fiscal year, (ii) \$0.2 million decline in interest expense due to the reduction in our outstanding notes and convertible notes, (iii) a \$6.1 million loss on the change in fair value of convertible notes in the fiscal year ended December 31, 2024, with no such charge during the year ended December 31, 2025, and (iv) we recognized a \$32 thousand gain on the change in fair value of liability classified warrants for the year ended December 31, 2025, compared to a loss of \$0.7 million for the year ended December 31, 2024.

This was offset by a \$0.3 million financing charge related to the standby equity purchase agreement that we entered into during the year ended December 31, 2025.

Income Tax Provision (Benefit)

We recorded a provision for income taxes of \$3 thousand for each of the years ended December 31, 2025, and 2024, respectively.

Under Accounting Standards Codification (“ASC”) 740-10-30-5, Income Taxes, deferred tax assets should be reduced by a valuation allowance if, based on the weight of available evidence, it is more-likely-than-not (i.e., a likelihood of more than 50%) that some portion or all of the deferred tax assets will not be realized. We consider all positive and negative evidence available in determining the potential realization of deferred tax assets including, primarily, the recent history of taxable earnings or losses. Based on operating losses reported during 2025 and 2024, we concluded there was not sufficient positive evidence to overcome this recent operating history. As a result, we believe that a valuation allowance continues to be necessary based on the more-likely-than-not threshold noted above. A valuation allowance of \$32.0 million and \$28.5 million was recorded as of and for the years ended December 31, 2025 and 2024, respectively.

Net Loss

During the year ended December 31, 2025, we had a net loss of \$12.2 million compared to a net loss of \$24.8 million for the year ended December 31, 2024. The decline in net loss of \$12.7 million primarily resulted from (i) a \$1.0 million increase in revenue in 2025 compared to 2024, (ii) \$4.6 million decrease in operating expenses in 2025 compared to 2024, and (iii) \$7.0 million favorable change in other income or expense in 2025 compared to 2024.

Liquidity and Capital Resources

To date, we have financed our operations primarily through the sale of equity securities and convertible debt and, to a lesser extent, through grants from governmental and other agencies. Since our inception, we have incurred significant operating losses and negative cash flows. As of December 31, 2025 and 2024, we had an accumulated deficit of \$151.7 million and \$139.6 million, respectively.

As of December 31, 2025, we had cash of \$12.0 million. We expect that our existing cash will be insufficient to fund our operations for the twelve months from the filing date of this Annual Report for the year ended December 31, 2025, including clinical trial expenses and capital expenditure requirements. We believe that this raises substantial doubt about our ability to continue as a going concern. To finance our operations beyond that point, we would need to raise additional capital, and there is no guarantee that we will be able to secure additional funding on favorable terms, or at all. We have concluded that these circumstances raise substantial doubt about our ability to continue as a going concern within one year after the issuance date of this Annual Report. See Note 1 to our audited consolidated financial statements for the year ended December 31, 2025.

Cash Flows

The following table shows a summary of our cash flows for each of the periods shown below:

(\$ in thousands)	Year Ended December 31,	
	2025	2024
Statement of cash flow data:		
Total cash (used in)/provided by:		
Operating activities	\$ (13,599)	\$ (16,007)
Investing activities	—	—
Financing activities	23,760	17,650
Net increase in cash	\$ 10,161	\$ 1,643

Cash Flow from Operating Activities

Net cash used in operating activities for the fiscal year ended December 31, 2025 was \$13.6 million compared to \$16.0 million for the fiscal year ended December 31, 2024. The decrease in cash used for operating activities of \$2.4 million is primarily due to the decline in consulting, legal and accounting related activities (see *Results of Operations* above).

Cash Flow from Financing Activities

Net cash provided by financing activities for the fiscal year ended December 31, 2025, was \$23.8 million, primarily related to proceeds from the issuance of common stock from certain registered direct offerings and ATM issuances, and proceeds from the issuance of pre-funded warrants.

Net cash provided by financing activity for the fiscal year ended December 31, 2024, was \$17.7 million, primarily related to proceeds from the issuance of common stock from certain registered direct offerings and ATM issuances, proceeds from the issuance of convertible notes, and proceeds from the issuance of certain pre-funded warrants.

Capital Resources

Sources of Liquidity

We finance our operations from a combination of sales of common stock and warrants, through registered direct or public offerings, our at-the-market program, and our standby equity purchase agreement. We finance certain insurance needs through a short-term note payable.

Shelf Registration

On December 8, 2023, we filed a shelf registration statement on Form S-3 (File No. 333-275968), which was declared effective by the SEC on December 22, 2023. This shelf registration statement covered the offering, issuance and sale of up to an aggregate of \$100.0 million of our common stock, preferred stock, debt securities, warrants, rights and units (the “2023 Shelf”).

Since the date of effectiveness and through December 31, 2025, we have raised approximately \$44.1 million under the 2023 Shelf and have approximately \$55.9 million remaining for future offerings. However, actual availability for primary offerings is limited by the “baby shelf” restrictions applicable to our use of Form S-3.

At-The-Market Offering

On August 20, 2024, we entered into an At-The-Market Offering Agreement (the “ATM Agreement”) with Wainwright as sales agent, to sell shares of Common Stock, from time to time, through an “at the market offering” program under which Wainwright will act as sales agent. As of December 31, 2025, approximately \$1.2 million remained available for issuance under our ATM program as a result of baby shelf limitations, which is a component of the 2023 Shelf.

Standby Equity Purchase Agreement

On April 25, 2025, we entered into a standby equity purchase agreement (“SEPA”) with Lincoln Park Capital, LLC (“Lincoln Park”) pursuant to which we have the right to sell to Lincoln Park shares of Common Stock, subject to certain limitations, from time to time over the 36-month period commencing on the Commencement Date. As of December 31, 2025, approximately \$15.0 million in aggregate capacity remained available under the SEPA.

2025 Offering Activity

During the year ended December 31, 2025, we raised under the 2023 Shelf: (i) approximately \$14.4 million through three registered direct offerings and concurrent private placements of Common Stock, pre-funded warrants, warrants and placement agent warrants, and (ii) approximately \$6.1 million through our ATM Agreement. We also raised outside the 2023 Shelf: (i) approximately \$4.0 million through a best-efforts public offering of Common Stock, pre-funded warrants, warrants and placement agent warrants, and (ii) approximately \$40 thousand from the SEPA.

Future Funding Requirements

We expect to incur significant expenses in connection with our ongoing activities as we seek to (i) continue clinical development of our SCD product for approval by the FDA, and (ii) if regulatory approval is obtained, to launch and commercialize our products in the U.S. markets. We will need additional funding in connection with these activities. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- conditions in the capital markets;
- our ability to receive cash proceeds from our existing funding instruments, including our equity line of credit;
- the progress and results of our clinical trials and interpretation of those results by the FDA and other regulatory authorities;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the costs of operating as a public company, including hiring additional personnel as well as increased director and officer insurance premiums, audit and legal fees, investor relations fees and expenses related to compliance with public company reporting requirements under the Securities Exchange Act of 1934, as amended, and rules implemented by the SEC and Nasdaq.

Until such time, if ever, as we are able to successfully develop and fully commercialize our products, we expect to continue financing our operations through the sale of equity, issuance of debt, borrowings under credit facilities or through potential collaborations with other companies, other strategic transactions or government or other grants. Adequate capital may not be available when needed or on acceptable terms.

Based on our results of operations and liquidity as of December 31, 2025, we believe our cash is not sufficient to meet our operations, working capital and capital expenditure requirements for a period of at least twelve months from the date of our audited consolidated financial statements for the fiscal year ended December 31, 2025. In addition, we do not expect to receive significant cash proceeds from the exercise of warrants in the near term, because the trading price of our common stock is currently below the exercise price of the majority of the warrants. We will require additional cash to fund our growth through future debt or equity financing transactions; however, there can be no assurance that we will be able to obtain additional capital on terms acceptable to us, if at all, or that we will generate sufficient future revenues and cash flows to fund our operations. Our estimates of our results of operations, working capital and capital expenditure requirements may be different than our actual needs, and those estimates may need to be revised if, for example, our actual revenue is lower, and our net operating losses are higher than we project and our cash position is reduced faster than anticipated.

We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures. Debt financing would also result in fixed payment obligations. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce, suspend or cease our research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. See the section titled “Risk Factors” for additional risks associated with our substantial capital requirements.

Critical Accounting Policies and Estimates

The preparation of the consolidated financial statements and related disclosures in conformity with U.S. GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and income and expenses during the periods reported. Although actual results could materially differ from those estimates, such estimates are developed based on the best information available to management and management's best judgments at the time.

Significant estimates include the valuation of the (i) incurred-but-not-billed clinical trial site costs, (ii) liability classified warrants, and (iii) stock-based compensation expense.

While our significant accounting policies are described in Note 2 - Summary of Significant Accounting Policies to the notes to our audited consolidated financial statements included elsewhere in the Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our annual consolidated financial statements.

Incurred-But-Not-Billed Clinical Trial Site Costs. Our NEUTRALIZE-AKI clinical trial is being conducted at multiple qualified healthcare facilities as of December 31, 2025. We are responsible to cover the costs of these clinical trial efforts, including the cost of patient care relating to the adult SCD. It is common practice that the costs incurred by the clinical trial sites are incurred, but not billed until months after the event giving rise to the unbilled activity. Accordingly, we estimate the value of these "incurred-but-not-billed" activities at the end of each reporting period. Any impact to the consolidated statement of operations is recognized as a component of research and development expense and included as a component of accrued expenses on the consolidated balance sheet.

Liability Classified Warrants. We have entered into or assumed various financial instruments in the form of warrant agreements that require classification as liabilities. This classification requires us to measure the warrants at fair value at inception and then remeasure the fair value of the warrants at each reporting period. The liability classified warrants consist of the following (see Note 8 for more information):

- *Private Placement Warrants.* We assumed 22,952 Private Placement warrants as part of the Business Combination.
- *PIPE Warrants.* We issued PIPE Warrants concurrent with the Business Combination, and the PIPE Warrants include features similar to the Private Placement Warrants.

We use a Black-Scholes option pricing model to fair value liability classified warrants, using standard option pricing inputs such as the strike price of each warrant tranche, estimated volatility, time to maturity, and the risk-free interest rate. The risk-free interest rate is the U.S. Treasury rate at the date of issuance, and the time to maturity is based on the contractual life at the date of issuance. The change in fair value of liability classified warrants each reporting period is recorded to the change in fair value of warrants liability in the consolidated statement of operations.

Stock-Based Compensation Expense. We estimate the grant date fair value of all grants of equity-based awards (which has historically consisted of either stock options or restricted stock units). We use a Black-Scholes option pricing model to fair value of stock options, and use the price of our stock on the grant date for restricted stock units.

Emerging Growth Company Status

We are an emerging growth company (“EGC”), as defined in the JOBS Act. The JOBS Act permits companies with EGC status to take advantage of an extended transition period to comply with new or revised accounting standards, delaying the adoption of these accounting standards until they apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an EGC or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Since we intend to rely on such exemptions, we are not required to, among other things: (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act; (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act; (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the consolidated financial statements (auditor discussion and analysis); and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation.

We will remain an EGC under the JOBS Act until the earliest of (i) the last day of our first fiscal year following the fifth anniversary of the closing of the Business Combination, (ii) the last date of our fiscal year in which we have total annual gross revenue of at least \$1.235 billion, (iii) the date on which we are deemed to be a “large-accelerated filer” under the rules of the SEC with at least \$700.0 million of outstanding securities held by non-affiliates, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the previous three years.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2025:

(\$ in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual Obligations:					
Insurance Financing	525	525	—	—	—
Total contractual obligations	\$ 525	\$ 525	\$ —	\$ —	\$ —

Insurance Financing

In October 2025, we entered into a financing arrangement with a lender to finance a portion of the annual premium of an insurance policy in the amount of \$0.7 million. It is to be paid down in 10 monthly installments through August 2026. This financing arrangement is recorded as a note payable on our consolidated balance sheet.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of
SeaStar Medical Holding Corporation:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of SeaStar Medical Holding Corporation (the “Company”) as of December 31, 2025 and 2024, and the related consolidated statements of operations, changes in stockholders’ equity (deficit), and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company’s Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring operating losses and negative cash flows from operating activities since inception and expects to continue incurring operating losses and negative cash flows in the future. These matters raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

We have served as the Company’s auditor since 2023.

East Brunswick, New Jersey

March 25, 2026

PCAOB ID No. 100

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

	<u>December 31, 2025</u>	<u>December 31, 2024</u>
ASSETS		
Current assets		
Cash	\$ 11,980	\$ 1,819
Accounts receivable, net of allowance for credit losses of \$3 and \$0, respectively	237	112
Inventory	66	—
Prepaid expenses	1,297	1,835
Total current assets	<u>13,580</u>	<u>3,766</u>
Other assets	578	892
Total assets	<u>\$ 14,158</u>	<u>\$ 4,658</u>
LIABILITIES AND STOCKHOLDERS' EQUITY/(DEFICIT)		
Current liabilities		
Accounts payable	\$ 948	\$ 3,046
Accrued expenses	2,268	3,188
Notes payable, net of deferred financing costs	525	574
Liability classified warrants	1	33
Total current liabilities	<u>3,742</u>	<u>6,841</u>
Total liabilities	<u>3,742</u>	<u>6,841</u>
Commitments and contingencies (Note 11)		
Stockholders' equity/(deficit)		
Preferred stock - \$0.0001 par value, 10,000,000 shares authorized at December 31, 2025 and December 31, 2024; no shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock - \$0.0001 par value per share; 450,000,000 and 500,000,000 shares authorized at December 31, 2025 and December 31, 2024, respectively; 3,844,613 and 650,639 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	4	2
Additional paid-in capital	162,126	137,379
Accumulated deficit	<u>(151,714)</u>	<u>(139,564)</u>
Total stockholders' equity/(deficit)	<u>10,416</u>	<u>(2,183)</u>
Total liabilities and stockholders' equity/(deficit)	<u>\$ 14,158</u>	<u>\$ 4,658</u>

The accompanying notes are an integral part of these consolidated financial statements.

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

	Year Ended December 31,	
	2025	2024
Net revenue	\$ 1,234	\$ 135
Cost of goods sold	53	—
Gross profit	1,181	135
Operating expenses		
Research and development	7,518	9,105
General and administrative	5,838	8,872
Total operating expenses	13,356	17,977
Loss from operations	(12,175)	(17,842)
Other income (expense)		
Interest income	325	101
Interest expense	(31)	(244)
Other financing costs	(298)	—
Change in fair value of convertible notes	—	(6,145)
Change in fair value of warrants liability	32	(697)
Total other income (expense), net	28	(6,985)
Loss before provision for income taxes	(12,147)	(24,827)
Provision for income taxes	3	3
Net loss	\$ (12,150)	\$ (24,830)
Net loss per share of common stock, basic and diluted	\$ (5.86)	\$ (66.33)
Weighted-average shares outstanding, basic and diluted	2,073,087	374,356

The accompanying notes are an integral part of these consolidated financial statements.

SeaStar Medical Holding Corporation
Consolidated Statements of Changes in Stockholders' Equity/(Deficit)
(in thousands, except for share and per-share amounts)

For the Year Ended December 31, 2025 and 2024					
	Common Shares		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity/(Deficit)
	Shares	Amount			
Balance, December 31, 2023	254,520	\$ 1	\$ 100,863	\$ (114,734)	\$ (13,870)
Issuance of shares - conversion of convertible notes	60,077	—	10,215	—	10,215
Issuance of shares - exercise of warrants	35,208	—	3,960	—	3,960
Issuance of shares - equity offering (including pre-funded warrants), net of issuance costs	297,475	1	21,244	—	21,245
Issuance of shares - stock issued for Board compensation in lieu of cash	1,012	—	210	—	210
Issuance of shares - vesting of RSUs	1,314	—	—	—	—
Issuance of shares - stock issued for employee bonuses	1,033	—	73	—	73
Stock-based compensation	—	—	814	—	814
Net loss	—	—	—	(24,830)	(24,830)
Balance, December 31, 2024	650,639	\$ 2	\$ 137,379	\$ (139,564)	\$ (2,183)
Balance, December 31, 2024	650,639	\$ 2	\$ 137,379	\$ (139,564)	\$ (2,183)
Issuance of shares - equity offering (including pre-funded warrants), net of issuance costs	2,527,225	2	21,968	—	21,970
Issuance of shares - exercise of warrants	627,103	—	1,815	—	1,815
Issuance of shares - standby equity purchase agreement issuances	8,000	—	42	—	42
Issuance of shares - standby equity purchase agreement commitment fee	23,641	—	298	—	298
Issuance of shares - vesting of restricted stock units	8,005	—	—	—	—
Stock-based compensation	—	—	624	—	624
Net loss	—	—	—	(12,150)	(12,150)
Balance, December 31, 2025	3,844,613	\$ 4	\$ 162,126	\$ (151,714)	\$ 10,416

The accompanying notes are an integral part of these consolidated financial statements.

SeaStar Medical Holding Corporation
Consolidated Statements of Cash Flows
(in thousands, except for shares and per-share amounts)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (12,150)	\$ (24,830)
Adjustments to reconcile net loss to net cash used in operating activities		
Amortization of deferred financing costs	18	102
Change in fair value of convertible notes (issued, converted and outstanding)	—	6,145
Change in fair value of liability classified warrants (exercised and outstanding)	(32)	697
Shares issued for the standby equity purchase agreement commitment fee	298	—
Stock-based compensation	624	887
Change in operating assets and liabilities		
Accounts receivables, net	(125)	(112)
Inventory	(66)	—
Prepaid expenses	538	297
Other assets	314	313
Accounts payable	(2,098)	(1,281)
Accrued expenses	(920)	1,875
Other liabilities	—	(100)
Net cash used in operating activities	(13,599)	(16,007)
Cash flows from financing activities		
Proceeds from issuance of convertible notes	—	979
Payment of convertible notes	—	(700)
Proceeds from issuance of shares, net of offering costs	16,126	17,441
Proceeds from exercise of warrants	1,815	853
Proceeds from pre-funded warrants	5,886	3,766
Proceeds from issuance of notes payable	767	713
Payment of notes payable	(834)	(5,402)
Net cash provided by financing activities	23,760	17,650
Net increase in cash	10,161	1,643
Cash, beginning of year	1,819	176
Cash, end of year	\$ 11,980	\$ 1,819
Supplemental disclosure of cash flow information		
Cash paid for interest	\$ —	\$ 553
Cash paid for income taxes	\$ 3	\$ 3
Exercise of liability classified warrants	\$ —	\$ 3,106
Shares issued from conversion of convertible notes	\$ —	\$ 10,210
Offering cost incurred but not paid	\$ —	\$ 45
Board compensation settled in shares of common stock in lieu of cash	\$ —	\$ 210
Issuance of convertible note warrants	\$ —	\$ 586

The accompanying notes are an integral part of these consolidated financial statements.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Note 1. Description of Business***Organization and description of business***

SeaStar Medical Holding Corporation, a Delaware corporation, and its wholly owned subsidiary, SeaStar Medical, Inc. (the “Predecessor”), are collectively referred to as the “Company”. The Predecessor was incorporated as a Delaware corporation in June 2007, and it is headquartered in Denver, Colorado. The Company is a commercial stage business and also focused on product development. The Company is principally engaged in the research, development, and commercialization of a platform medical device technology designed to modulate inflammation in various patient populations. The initial target of this technology is for the treatment of acute kidney injuries in pediatric patients.

On October 28, 2022, LMF Merger Sub, Inc., a wholly owned subsidiary of LMF Acquisition Opportunities, Inc. (“LMF”), merged with and into the Predecessor (the “Business Combination”), with the Predecessor surviving the Business Combination as a wholly owned subsidiary of LMF. Following the consummation of the Business Combination, LMF was renamed to “SeaStar Medical Holding Corporation”.

Basis of Presentation

The Company’s consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”) and the rules and regulations of the Securities and Exchange Commission (“SEC”).

On June 7, 2024, the Company effected a 1-for-25 reverse-stock split (the “2024 Reverse Stock Split”) of its issued and outstanding shares of common stock, par value \$0.0001 (the “common stock”). Following the effect of the 2024 Reverse Stock Split, each 25 shares of the Company’s common stock that were issued and outstanding automatically converted into one outstanding share of common stock.

On January 5, 2026, the Company elected a 1-for-10 reverse-stock split (the “2026 Reverse Stock Split,” together with the 2024 Reverse Stock Split, the “Reverse Stock Splits”) of its issued and outstanding shares of common stock, par value \$0.0001 (the “common stock”). Following the effect of the 2026 Reverse Stock Split, each 10 shares of the Company’s common stock that were issued and outstanding automatically converted into one outstanding share of common stock.

Combined, this had the effect of a 1-for-250 reverse stock split. All stock options and warrants of the Company outstanding immediately prior to each of the Reverse Stock Splits were proportionally adjusted except for the Listed Warrants and the private placement warrants that were issued as part of the SPAC transaction that closed on October 28, 2022, which total 16,788,000 outstanding warrants in the aggregate (the “Unadjusted Warrants”). The Unadjusted Warrants each retained an \$11.50 exercise price and require the exercise of 250 warrants to purchase one share of common stock. Unless otherwise indicated, all other share and per share amounts in this annual report reflect the effect of the Reverse Stock Splits. The par value of the Company’s common stock remained unchanged at \$0.0001 per share and the number of authorized shares of common stock remained the same after each of the Reverse Stock Splits.

Liquidity and going concern

As of December 31, 2025, the Company has an accumulated deficit of approximately \$151.7 million and cash of approximately \$12.0 million. The Company does not believe that its cash on hand will be sufficient to enable it to fund its operations, including clinical trial expenses and capital expenditure requirements for at least 12 months from the issuance of these consolidated financial statements. The Company believes that these conditions raise substantial doubt about its ability to continue as a going concern.

The Company’s need for additional capital will depend in part on the scope and costs of its development activities. To date, the Company has generated approximately \$1.2 million in revenue from the sales of QUELIMMUNE. Its ability to generate meaningful product revenue will depend on the successful launch of QUELIMMUNE and development and eventual commercialization of the adult SCD. Until such time, if ever, it expects to finance its operations through the sale of equity or debt securities, borrowing under credit facilities, or through potential collaborations, other strategic transactions or government and other grants. Adequate capital may not be available to the Company when needed or on acceptable terms.

If the Company is unable to raise capital, it could be forced to delay, reduce, suspend, or cease its research and development programs or any future commercialization efforts, which would have a negative impact on its business, prospects, operating results and financial condition. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern and do not include adjustments that might result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company’s assets and the satisfaction of liabilities in the normal course of business.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Risks and uncertainties

The Company is subject to risks common to early-stage companies in the medical technology industry including, but not limited to, new medical and technological innovations, dependence on key personnel, protection of proprietary technology, and product liability. There can be no assurance that the Company's products or services will be accepted in the marketplace, nor can there be any assurance that any future products or services can be developed or deployed at an acceptable cost and with appropriate performance characteristics, or that such products or services will be successfully marketed, if at all. These factors could have a materially adverse effect on the Company's future financial results, financial position and cash flows.

Note 2. Summary of Significant Accounting Policies***Use of Estimates***

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of revenues and expenses during the period. Significant estimates for the year ended December 31, 2025, include the (i) valuation of the liability classified warrants, (ii) unbilled clinical trial costs, and (iii) stock-based compensation expense. Although actual results could differ from those estimates, such estimates are developed based on the best information available to management and management's best judgments at the time.

Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. The Company did not have any cash equivalents as of December 31, 2025 and 2024.

Concentrations of credit risk

Financial instruments that potentially subject the Company to a significant concentration of credit risk consist primarily of cash. Periodically, the Company may maintain deposits in financial institutions in excess of government insured limits. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

Accounts Receivable

The Company recognizes accounts receivables from sales to customers at the time revenue is recognized and a customer invoice is created. The need for a credit loss allowance is evaluated each reporting period based on the Company's assessment of the credit worthiness of its customers or any other potential circumstances that could result in a credit loss. The Company initially estimates credit losses based on a portfolio-wide method using an aging schedule at the end of each reporting period. Any customer specific collections subsequent to the reporting period are then adjusted accordingly. As of December 31, 2025 and 2024, the Company had a current expected credit loss reserve of \$3 thousand and \$0, respectively.

Income taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the consolidated financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates expected to apply to taxable income in the periods in which such differences are expected to reverse. A valuation allowance is provided when the realization of net deferred tax assets is not deemed more likely than not.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

The Company complies with the provisions of Accounting Standards Codification (“ASC”) 740, *Income Taxes*, which provides a comprehensive model for the recognition, measurement, and disclosure in consolidated financial statements of uncertain income tax positions that a company has taken or expects to take on a tax return. Under this guidance, a company can recognize the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position; otherwise, no benefit can be recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. Additionally, the Company accrues interest and related penalties, if applicable, on all tax exposures for which reserves have been established consistent with jurisdictional tax laws. Interest and penalties are classified as income tax expense in the consolidated financial statements.

Use of Derivative Instruments

The Company’s derivative instruments historically have consisted of financial instruments that arose as part of the Company’s ongoing efforts to raise capital to fund the Company’s operations. It is likely that ongoing efforts to raise capital in the future will result in additional derivative instruments to be issued as part of those efforts. The Company has not nor does it intend to utilize derivative instruments for risk management (i.e. hedging) or investing activities.

These derivative instruments have taken the form of warrants, convertible debt, and other financing arrangements such as a prepaid forward purchase option. The classification of these financial instruments as either a component of liabilities or equity is specific to the terms within each financial instrument agreement, and the application of U.S. GAAP. For those that are liability classified, the Company recognized changes in the fair value of each financial instruments as a “non-operating income / (expense)” component of the consolidated statement of operations and an adjustment to operating cash flows within the consolidated statement of cash flows each reporting period.

The issuance of each derivative instrument is reported as a proceed in the financing section to the consolidated statement of cash flows, while the ultimate settlement of each derivative instrument could be reported either as an adjustment to operating cash flows, paydown within financing cash flows, or a non-cash transaction depending on the settlement.

Fair value option of accounting

Generally, when financial instruments are first acquired that are not required to be recorded at fair value per U.S. GAAP, ASC 825, *Financial Instruments* allows an entity to elect the fair value option (“FVO”). The FVO may be elected on an instrument-by-instrument basis only at the time of acquisition and once elected is irrevocable. The FVO allows an entity to account for the entire financial instrument at fair value with subsequent changes in fair value recognized in earnings through the consolidated statements of operations at each reporting date. A financial instrument is generally eligible for the FVO if, amongst other factors, no part of the financial instrument is classified in stockholders’ equity.

Based on the eligibility assessment discussed above, the Company historically concluded that its previously held convertible notes were eligible for the FVO and accordingly elected the FVO for those debt instruments. This election was made because of operational efficiencies in valuing and reporting for these debt instruments at fair value in their entirety at each reporting date. The convertible notes contained certain embedded derivatives that otherwise would require bifurcation and separate accounting at fair value.

The convertible notes, inclusive of their respective accrued interest at the stated interest rates (collectively referred to as the “FVO debt instruments”) were initially recorded at fair value as liabilities on the consolidated balance sheets and subsequently re-measured at fair value at the end of each reporting period presented within the consolidated financial statements until they were settled in 2024. The changes in fair value of the FVO debt instruments are recorded in changes in fair value of convertible notes, included as a component of other income (expense), net, in the consolidated statements of operations.

The Company did not have any convertible notes outstanding during the year ended December 31, 2025.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Fair value of financial instruments

The following provides a summary of those assets or liabilities for which the Company is required to measure at fair value either on a recurring basis, the valuation techniques and summary of inputs used to arrive at the measure of fair value. Changes in fair value of these assets or liabilities are recognized as a component of net income in the consolidated statements of operations. Changes in fair value of these assets or liabilities are considered unrealized gains or losses and therefore are classified as non-cash adjustments to reconcile net income to operating cash flows. Significant increases (decreases) in unobservable inputs used in fair value measurements could, in isolation, potentially result in a significantly lower or higher valuation for those assets or liabilities requiring recurring fair value measurements at each reporting date.

Liability Classified Warrants. The Company has entered into or assumed various financial instruments, in the form of warrant agreements, that require classification as liabilities. This classification requires that the Company measure the warrants at each fair value at the end of each quarterly and annual reporting period.

The Company uses a Black-Scholes option pricing model to fair value the warrants, using standard option pricing inputs such as the strike price of each warrant tranche, estimated volatility, time to maturity, and the risk-free interest rate. The risk-free interest rate is the U.S. Treasury rate at the date of issuance, and the time to maturity is based on the contractual life at the date of issuance, which is five years. The change in fair value of the liability classified warrants each reporting period is recorded to the change in fair value of warrants liability in the consolidated statements of operations.

Operating Current Assets and Current Liabilities. The estimated fair value of cash, accounts receivables, prepaid expenses, accounts payable and accrued expenses approximate their fair value because of the short-term nature of these instruments.

Classification of Derivative Gains and Losses on the Consolidated Statement of Cash Flows. Changes in fair value related to the Company's derivative financial instruments consisting of (i) liability classified warrants and (ii) convertible notes are classified in operating cash flows as adjustments to net income. During the year ended December 31, 2025, the only activity related to liability classified warrants, as the Company fully settled all outstanding convertible notes during the year ended December 31, 2024.

Revenue Recognition

Overall

Under ASC Topic 606, the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of Topic 606, the Company evaluates the following criteria: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) performance obligations are satisfied.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation. Goods and services that are determined not to be distinct are combined with other promised goods and services until a distinct combined performance obligation is identified. The Company then allocates the transaction price to each performance obligation and recognizes the associated revenue when (or as) each performance obligation is satisfied. The estimate of the transaction price for each contract includes all variable consideration to which the Company expects to be entitled, subject to the constraint on variable consideration. The Company constrains revenue by giving consideration to factors that could otherwise lead to a probable reversal of revenue. Variable consideration is not constrained if the potential reversal of cumulative revenue recognized at the contract level is not significant.

The Company records any payments received from customers prior to the Company fulfilling its performance obligation(s) as contract obligations. Amounts expected to be recognized as revenue within the one year following the consolidated balance sheet date are classified as current contract obligations. Amounts not expected to be recognized as revenue within the one year following the consolidated balance sheet date are classified as contract obligations, net of current portion. See Note 3 – Revenues and Contract Obligations for further details.

Product Sales Revenue

The Company has sold and intends to continue to sell its products either through a combination of distributor(s) and/or directly to end-user qualified customers through the Company's own internal commercial/sales resources. The acting distributor during the year ended December 31, 2024 subsequently resold and was to continue to resell the products to present and future customers, until such time the Company terminated its agreement with the distributor (see Note 3).

- Timing of Revenue Recognition – During the brief history (commenced July 2024) of selling QUELIMMUNE, revenue has been recognized based on a *freight-on-board destination* (“FOB Destination”) requirement.
- Chargebacks, Government Rebates and Discounts – During the brief history of selling pediatric SCDs commercially, the Company has not agreed to chargebacks, government rebates or discounts.
- Returns – Returns are specific to each order, but generally the Company allows for returns of any damaged or non-conforming product within 30 days of receipt of product. Given the (i) overall rate of product shipped that is defective/damaged, (ii) overall volume of sales to individual end-user customers, (iii) expected supply in the customer channel, and (iv) expected usage by customers, the Company does not anticipate that there will be significant risk of product returns overall.
- Variable Consideration – the Company does not currently estimate a constraint on revenue recognized on product sales.
- Transaction Price – based on the above, as currently constructed, the Company's transaction price is fixed, based on the agreed-upon price per each purchase order submitted by each customer. Milestone or up-front payments unique to the former distributor, disclosed in Note 3, were not recognized as revenue, but were returned as a result of a settlement to cease the relationship with the distributor.
- Allocation of Consideration – each sale of a pediatric SCD is independent of any and all other sales. The entire transaction price for each pediatric SCD is allocated to the sale of that pediatric SCD.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

The Company will continue to monitor all of the above as the Company continues to commercialize and increase its customer base, which could result with each distributor or end-user customer agreement resulting in its own unique terms and conditions, that will potentially impact the timing and amount of revenue recognition pursuant to U.S. GAAP.

Cost of Goods Sold

Prior to July 2024, the Company manufactured/assembled QUELIMMUNE and adult SCDs only for research oriented and/or clinical trial related activities. Inventory purchased prior to July 2024 was expensed as a period expense at the time of purchase as a research and development expense. Accordingly, all QUELIMMUNE units sold prior to the three months ended June 30, 2025, had no recognized inventory value. During the year ended December 31, 2025, the Company recognized approximately \$53 thousand for cost of goods sold.

The Company purchases supplies for the production of QUELIMMUNE and adult SCDs, some of which is used in the production of both. The Company's policy for the accounting for these three categories of inventory as follows:

- *QUELIMMUNE Specific Inventory* – comprises raw materials used solely for the assembly of QUELIMMUNE inventory. It will be recognized to inventory as either raw materials, work-in-process, or finished goods depending on the stage of assembly. It will be charged to cost of goods sold upon shipment to a customer.
- *Commingled Inventory* – comprises raw materials that are used both for the assembly of QUELIMMUNE or adult SCDs. If used in the assembly of QUELIMMUNE, it will continue to be included in inventory as either work-in-process or finished goods depending on the stage of assembly and charged to cost of goods sold upon shipment to a customer.
- *Adult SCD Specific Inventory* – comprises raw materials used solely for the assembly of adult SCDs primarily to fulfill the demands of the NEUTRALIZE-AKI study. These supplies will be charged to research and development expense upon acquisition, until such time, that it is probable that these supplies could be assembled into adult SCD kits to be sold commercially.

Stock-based compensation

In accordance with ASC Topic 718, *Compensation – Stock Compensation*, the Company recognizes compensation expense for all stock-based awards issued to employees based on the estimated grant-date fair value, which is recognized as expense on a graded vesting approach over the requisite service period. The Company has elected to recognize forfeitures as they occur. The fair value of stock options is determined using the Black-Scholes option-pricing model. The determination of fair value for stock options on the date of grant using an option-pricing model requires management to make certain assumptions including implied volatility, expected term, risk-free interest rate and expected dividends (\$nil) in addition to the Company's common stock valuation. The determination of fair value of restricted stock units is valued based on the value of the Company's common stock on the grant date.

Research and development expenses

Expenditures made for research and development are charged to expense as incurred. External costs consist primarily of payments for laboratory supplies purchased in connection with the Company's discovery and preclinical activities, and process development and clinical development activities. Internal costs consist primarily of employee-related costs, consultants fees and costs related to compliance with regulatory requirements.

The Company records expenses related to external research and development services based on services received and efforts expended pursuant to invoices and contracts with consultants that supply, conduct, and manage preclinical studies and clinical trials on its behalf.

Funded Research & Development Expense

During the year ended December 31, 2025, the Company entered into an agreement to provide contract research services to an outside party, which involves a study of the Company's selective cytopheretic device relating to patients with severe, chronic heart failure. The Company is able to bill the outside party for a certain portion of the costs incurred to provide these services. The Company will own and is able to benefit from the knowledge gained from the results of this study. Accordingly, the Company will account for any funds paid by the outside party to the Company as a reimbursed expense, in accordance with ASC 730-20 as a funded research and development arrangement. Accordingly, any amounts incurred and billed will offset the Company's operating expenses categorized as research and development expense on the Company's condensed consolidated statement of operations for the year ended December 31, 2025. The reimbursed expenses for the year ended December 31, 2025, totaled approximately \$0.4 million. No funded research and development agreement existed in 2024.

Emerging growth company status

The Company is an "emerging growth company", as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. The Company has elected to use this extended transition period for complying with certain new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it is (1) no longer an emerging growth company or (2) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Net loss per share attributable to common stockholders

The Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period. The diluted net loss per share attributable to common stockholders is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. The dilutive effect of these potential common shares is reflected in diluted earnings per share by application of the treasury stock method. See Note 14 for disclosures on exclusion of certain instruments which would be anti-dilutive in circumstances where the Company is reporting a net loss for that earnings period. Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities as certain outstanding warrants are considered participating securities. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for the periods presented, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders for these periods. The significant increase in common stock outstanding is expected to impact the year-over-year comparability of the Company's net loss per share calculations.

Recently adopted accounting standards

Accounting Standards Update 2023-09 — In December 2023, the FASB issued ASU 2023-09 *Income Taxes (Topic 740) Improvements to Income Tax Disclosures*. ASU 2023-09 enhances the transparency and decision usefulness of income tax disclosures. The amendments in this update are effective for public business entities for annual periods beginning after December 15, 2024. Early adoption was permitted, but the Company elected not to early adopt and adopted for the year ended December 31, 2025. ASU 2023-09 requires the Company to consistently categorize and provide greater disaggregation of information in the rate reconciliation it must further disaggregate income taxes paid. However, as the Company is currently generating net operating losses, pays no federal and limited state taxes and does not operate in foreign jurisdictions, this does not have a significant impact to the Company's income tax disclosures (see Note 13).

Recently issued accounting standards not yet adopted

Accounting Standards Update 2024-03 — In November 2024, the FASB issued ASU 2024-03 - *Income Statement - Reporting Comprehensive Income – Expense Disaggregation (Subtopic 220-40): Disaggregation of Income Statement Expenses*. ASU 2024-03 requires the disclosure of additional information related to certain costs and expenses, including amounts of inventory purchases, employee compensation, and depreciation and amortization included in each income statement line item. The ASU is effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of adopting this guidance on its consolidated financial statements and disclosures.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Note 3. Revenues and Contract Obligations

In December 2022, the Company entered into a License and Distribution Agreement (the “Distribution Agreement”) with Nuwellis, Inc. (“Nuwellis”) granting exclusive distribution rights of the Company’s pediatric SCD within the United States of America. Under the terms of the Distribution Agreement, Nuwellis would pay the Company consideration comprising both (i) a per unit sales price for each unit shipped and (ii) a royalty for all units sold to customers.

In addition, Nuwellis also agreed to pay (i) a \$100 thousand upfront payment at contract inception (the “Up-front Payment”), and (ii) two contingent milestones payments consisting of (a) \$450 thousand payment upon meeting the regulatory milestone of receiving HDE approval from the FDA (the “Regulatory Milestone Payment”), and (b) \$300 thousand payment upon meeting a sales-based milestone (the “Sales Based Milestone Payment”).

The Company had the following performance obligations within the Distribution Agreement: (i) a material right to Nuwellis consisting of an exclusive option for Nuwellis to purchase additional pediatric SCDs during the term of the Distribution Agreement for a discounted price, (ii) to provide training to Nuwellis personnel and medical professionals at end-user customers of Nuwellis and (iii) upon each receipt of a valid Nuwellis purchase order, delivery of pediatric SCDs. The transaction price for the Nuwellis material right and training is comprised of the Upfront Payment, the Regulatory Milestone Payment and the Sales Based Milestone Payment. The transaction price for each pediatric SCD device sold was the actual price for each device and the estimated royalties to be received.

Prior to the Company’s termination of the Distribution Agreement discussed below, the Company received full consideration for the Up-front Payment and the Regulatory Milestone Payment for a total of \$550 thousand, which had been recorded as contract liabilities and was to be recognized over the remaining term of the Distribution Agreement. However, the Company and Nuwellis entered into a confidential settlement agreement on October 20, 2024 (the “Settlement Agreement”), in connection with the Company’s termination of the Distribution Agreement on August 18, 2024. Under the Settlement Agreement the Company agreed to refund Nuwellis the entire \$550 thousand comprising of the Upfront Payment and Regulatory Milestone plus an additional \$350 thousand for a total of \$900 thousand, of which the \$350 thousand was charged to general and administrative expense. The amounts were paid to Nuwellis in three installments during the quarter ended December 31, 2024.

As a result, the Company (i) was precluded from recognizing revenue of approximately \$0.1 million for product shipments to Nuwellis during the year ended December 31, 2024, (ii) was precluded from recognizing any revenues related to contract liabilities arising the Upfront Payment and Regulatory Milestone through December 31, 2024, (see below), and (iii) does not anticipate there will be any future shipments of pediatric SCDs to Nuwellis going forward. Due to the termination of the Distribution Agreement and related Settlement Agreement, the Company did not recognize any revenue from the Up-Front Payment or the Regulatory Milestone Payment as it refunded the payments to Nuwellis as part of the Settlement Agreement.

Since the termination of the Distribution Agreement, the Company developed its own commercial operations and sold approximately \$1.2 million and \$0.1 million to end-user customers during the years ended December 31, 2025 and 2024, respectively.

The following table summarizes the changes in the Company’s contract liability balance for the years ended December 31, 2025 and 2024:

(\$ in thousands)	Year Ended December 31,	
	2025	2024
Contract liabilities, beginning of period	\$ —	\$ 100
Consideration received	—	450
Consideration refunded	—	(550)
Contract liabilities, end of period	\$ —	\$ —

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

The Company had no contract assets at the beginning or end of the fiscal years ended December 31, 2025 and 2024. The accounting policies used to measure the profit and loss of the segment are the same as those described in the summary of significant accounting policies.

Note 4. Trade Accounts Receivable

The table below presents the opening and closing balances of accounts receivable, on a gross and net basis, with the total change in expected credit losses:

(\$ in thousands)	Accounts Receivable, Gross	Expected Credit Losses	Accounts Receivable, Net
December 31, 2024	\$ 112	\$ —	\$ 112
Changes in accounts receivable	128	(3)	125
December 31, 2025	<u>\$ 240</u>	<u>\$ (3)</u>	<u>\$ 237</u>

Note 5. Accrued Expenses

Accrued expenses consisted of the following amounts as of December 31, 2025 and 2024:

(\$ in thousands)	December 31, 2025	December 31, 2024
Accrued research and development	\$ 1,525	\$ 1,023
Accrued bonus	150	1,391
Accrued director compensation	70	391
Other	523	383
Total accrued expenses	<u>\$ 2,268</u>	<u>\$ 3,188</u>

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Note 6. Notes Payable

Notes payable consisted of the following as of December 31, 2025 and 2024, respectively:

(\$ in thousands)	December 31, 2025	December 31, 2024
Insurance financing	\$ 525	\$ 574
Less current portion	(525)	(574)
Non-current portion	<u>\$ —</u>	<u>\$ —</u>

Insurance Financing

In October 2025, the Company entered into a financing arrangement with a lender to finance a portion of the annual premium of an insurance policy in the amount of \$0.7 million. Interest on the financing agreement was 7.940% per annum. The October 2025 financing agreement is to be paid in 10 monthly installments, with the final installment set for August 2026.

In October 2024, the Company entered into a financing arrangement with a lender to finance a portion of the annual premium of an insurance policy in the amount of \$0.7 million. Interest on the financing agreement was 8.440% per annum. The October 2024 financing agreement was to be paid in 10 monthly installments, but was paid in full in June 2025.

Note 7. Equity Transactions

August 2025 Offering

On August 1, 2025, the Company closed on a registered direct offering with certain institutional investors (the “August 2025 Offering”), pursuant to which the Company sold and issued to the Purchasers, (i) 496,055 shares of the Company’s common stock par value \$0.0001 per share and (ii) in a concurrent private placement, warrants to purchase up to an aggregate of 496,055 shares of Common Stock (the “August 2025 Common Warrants”) at an exercise price of \$7.62 per share. The combined offering price for each share of common stock and accompanying August 2025 Common Warrant was \$8.87. The August 2025 Common Warrants are exercisable upon issuance and will expire on August 12, 2030.

The Company received aggregate gross proceeds from the August 2025 Offering of approximately \$4.4 million before deducting fees of approximately \$0.5 million in offering costs comprised of a cash fee of 7.00%, a management fee of 1.00%, legal fees and other fees. Also in connection with the August 2025 Offering, the Company agreed to issue to the placement agent or its designees warrants (the “August 2025 Placement Agent Warrants”) to purchase up to an aggregate of 34,724 shares of common stock. The August 2025 Placement Agent Warrants have an exercise price of \$11.08 per share (which represents 125% of the offering price per share of common stock and accompanying August 2025 Common Warrant), are exercisable upon issuance and will expire on July 31, 2030.

The August 2025 Common Warrants and August 2025 Placement Agent Warrants collectively herein are referred to as the “August 2025 Warrants”. No August 2025 Warrants have been exercised and all August 2025 Warrants remain outstanding as of December 31, 2025.

In accordance with ASC 815-40, *Derivatives and Hedging-Contracts in Entity’s own Equity*, the Company determined that all of the August 2025 Warrants issued in connection with the August 2025 Offering met the conditions for equity classification and were included as a component of stockholders’ equity/(deficit).

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

July 2025 Offering

On July 11, 2025, the Company closed on a registered direct offering with certain institutional investors (the “July 2025 Offering”), pursuant to which the Company sold and issued to the Purchasers, (i) 484,124 shares of the Company’s common stock par value \$0.0001 per share and pre-funded warrants to purchase up to 40,124 shares of common stock (the “July 2025 Pre-Funded Warrants”) at an exercise price of \$0.01 per share (the July 2025 Pre-Funded Warrants were fully exercised concurrent with the July 2025 Offering), and (ii) in a concurrent private placement, warrants to purchase up to an aggregate of 524,247 shares of common stock (the “July 2025 Common Warrants”) at an exercise price of \$6.378 per share. The combined offering price for each share of common stock and accompanying July 2025 Common Warrant was \$7.63. The July 2025 Common Warrants are exercisable upon issuance and will expire on August 12, 2030.

The Company received aggregate gross proceeds from the July 2025 Offering of approximately \$4.0 million before deducting fees paid of \$0.4 million in offering costs comprised of a cash fee of 7.00%, a management fee of 1.00%, legal fees and other fees. Also in connection with the July 2025 Offering, the Company agreed to issue to the placement agent or its designees warrants (the “July 2025 Placement Agent Warrants”) to purchase up to an aggregate of 36,698 shares of common stock. The July 2025 Placement Agent Warrants have an exercise price of \$9.538 per share (which represents 125% of the offering price per share of common stock and accompanying July 2025 Common Warrant), are exercisable upon issuance and will expire on July 10, 2030.

The July 2025 Common Warrants and July 2025 Placement Agent Warrants collectively herein are referred to as the “July 2025 Warrants”. No July 2025 Warrants have been exercised and all July 2025 Warrants remain outstanding as of December 31, 2025.

In accordance with ASC 815-40, *Derivatives and Hedging-Contracts in Entity’s own Equity*, the Company determined that all of the warrants issued in connection with the July 2025 Offering met the conditions for equity classification and were included as a component of stockholders’ equity/(deficit)

June 2025 Offering

In June 2025, the Company did a best efforts public offering (the “June 2025 Offering”) pursuant to which the Company issued an aggregate of (i) 493,539 shares of the Company's common stock, (ii) 121,847 pre-funded warrants to purchase up to 121,847 shares of common stock (the “June 2025 Pre-Funded Warrants”) with an exercise price of \$0.001, (iii) 615,385 Series A warrants to purchase up to 615,385 shares of common stock with an exercise price of \$6.50 (the “June 2025 Series A Warrants”), and (iv) 615,385 Series B warrants to purchase up to 615,385 shares of common stock at an exercise price of \$6.50 (the “June 2025 Series B Warrants”). All 121,847 June 2025 Pre-Funded Warrants were exercised as of December 31, 2025.

The Company received aggregate gross proceeds from the June 2025 Offering of approximately \$4.0 million, before deducting approximately \$0.5 million in offering costs comprised of cash fee of 7.00%, a management fee of 1.00%, legal fees and other fees. Also in connection with the June 2025 Offering, the Company agreed to issue to the placement agent or its designees warrants (the “June 2025 Placement Agent Warrants”) to purchase up to an aggregate of 43,077 shares of common stock. The June 2025 Placement Agent Warrants have an exercise price of \$8.13 per share (which represents 125% of the offering price per share of common stock and accompanying June 2025 Series A and Series B Warrants), are exercisable upon issuance and will expire on June 20, 2030. No June 2025 Placement Warrants have been exercised and all June 2025 Placement Warrants remain outstanding as of December 31, 2025.

The June 2025 Series A Warrants and June 2025 Series B Warrants were immediately exercisable with the June 2025 Series A warrants expiring on June 23, 2030 and the June 2025 Series B Warrants expiring on December 23, 2026. During the year ended December 31, 2025, 40,770 and 238,462 Series A June 2025 Warrants and Series B June 2025 Warrants have been exercised, respectively and 574,616 and 376,924 Series A June 2025 Warrants and Series B June 2025 Warrants remain outstanding, respectively, as of December 31, 2025.

In accordance with ASC 815-40, *Derivatives and Hedging-Contracts in Entity’s own Equity*, the Company determined that all the different warrants issued or amended in connection with the June 2025 Offering met the conditions for equity classification and were included as a component of stockholders’ equity/(deficit).

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

February 2025 Offering

In January 2025, the Company entered into a Securities Purchase Agreement with an institutional investor, pursuant to which the Company issued on February 3, 2025, to the investor, (i) in a registered direct offering, 71,300 shares of the Company's common stock, and pre-funded warrants to purchase 281,642 shares of common stock (the "February 2025 Pre-Funded Warrants") with an exercise price of \$0.001 per share, and (ii) in a concurrent private placement, warrants (the "February 2025 Common Warrants") to purchase 352,942 shares of common stock with an exercise price of \$17.00 (the "February 2025 Offering").

The Company received aggregate gross proceeds from the February 2025 Offering of approximately \$6.0 million, before deducting approximately \$0.5 million of fees and other estimated offering expenses payable by the Company. The February 2025 Pre-Funded Warrants did not have a set expiration and were exercisable upon issuance and at any time until all of the February 2025 Pre-Funded Warrants were exercised in full. During the year ended December 31, 2025, a total of 281,642 February 2025 Pre-Funded Warrants were exercised, and no February 2025 Pre-Funded Warrants remain outstanding.

The February 2025 Common Warrants became exercisable on March 28, 2025, the effective date of stockholder approval for the issuance of the shares of common stock issuable upon exercise of the warrants and expire on March 28, 2030.

Prior to their exercise, the February 2025 Pre-Funded Warrants had dividend participation rights, and any unexercised pre-funded warrants are included in the Company's weighted-average shares outstanding for calculation of the Company's net loss per share.

In connection with the February 2025 Offering, the Company amended the exercise price of the January 2024 Series A and January 2024 Series B Common Warrants (collectively the "January 2024 Warrants"), issued in a previous financing transaction with the same institutional investor in January 2024, to \$17.00 from the original exercise price of \$207.60. Furthermore, the expiration date of all 65,046 January 2024 Warrants was extended to January 30, 2029, upon stockholder approval on March 28, 2025. No January 2024 Warrants have been exercised and all January 2024 Warrants remain outstanding as of December 31, 2025.

The Company issued 24,706 warrants to its placement agent (the "February 2025 PA Warrants") to purchase shares of the Company's common stock at an exercise price of \$21.25. The February 2025 PA Warrants were exercisable upon issuance and expire on January 30, 2029. The February 2025 PA Warrants and February 2025 Common Warrants are herein defined as the "February 2025 Warrants". No February 2025 Warrants have been exercised and all February 2025 Warrants remain outstanding as of December 31, 2025.

In accordance with ASC 815-40, *Derivatives and Hedging-Contracts in Entity's own Equity*, the Company determined that all the different warrants issued or amended in connection with the February 2025 Offering met the conditions for equity classification and were included as a component of stockholders' equity/(deficit).

At-The-Market Offering

On August 20, 2024, the Company entered into an At-The-Market Offering Agreement (the "ATM Agreement") with Wainwright as sales agent, to sell shares of its common stock, from time to time, through an "at the market offering" program under which Wainwright will act as sales agent. The sales, if any, of the Company's Common Stock made under the ATM Agreement will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on or through the Nasdaq Capital Market or on any other existing trading market for the Company's common stock (the "ATM").

Through December 31, 2025, the Company has raised approximately \$10.4 million, net of offering costs of \$0.4 million utilizing the ATM since inception in August 2024, issuing approximately 1.1 million shares of the Company's Common Stock. During the year ended December 31, 2025, the Company raised approximately \$5.9 million, net of offering costs of \$0.2 million, issuing approximately 0.9 million shares of the Company's common stock.

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Standby Equity Purchase Agreement

On April 25, 2025, the Company entered into a standby equity purchase agreement (“Common Stock Purchase Agreement”) and related registration rights agreement (the “Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“Lincoln Park”), collectively the “SEPA”. Pursuant to the Common Stock Purchase Agreement, the Company has the right, but not the obligation, to direct Lincoln Park to purchase up to \$15.0 million in aggregate gross purchase price of newly issued shares of Common Stock, subject to certain limitations and conditions as described below (the “SEPA Program”) at a purchase price equal to 97% of the lesser of (i) the lowest sale price of the common stock on the purchase date or (ii) average of the three lowest closing sale prices of the common stock over the last ten business days prior to the purchase date.

The Company controls the timing and amount of any sales to Lincoln Park, which depend on a variety of factors including, among other things, market conditions, the trading price of the Company’s common stock, and determinations by the Company as to appropriate sources of funding for its business and operations. However, Lincoln Park’s obligation to purchase shares is subject to certain conditions, including the daily trading volume of the Company’s stock. In all instances, the Company may not sell shares of Common Stock under the Purchase Agreement if it would result in Lincoln Park and its affiliate beneficially owning more than 9.99% of outstanding voting power or shares of the Common Stock at any one point in time.

As part of the SEPA, the Company agreed to pay Lincoln Park 23,641 shares of the Company’s common stock, valued at approximately \$0.3 million on the date of issuance, April 25, 2025 (the “Commitment Fee”).

The Company evaluated the contract that includes the right to require Lincoln Park to purchase shares of common stock in the future (“put right”) considering the guidance in ASC 815-40, *Derivatives and Hedging — Contracts on an Entity’s Own Equity* and concluded that it is an equity-linked contract that does not qualify for equity classification, and therefore requires fair value accounting. The Company analyzed the terms of the freestanding put right and concluded that it has an immaterial value at the issuance date of April 25, 2025, and as of December 31, 2025.

Through December 31, 2025, the Company raised approximately \$40 thousand and issued 8,000 shares of the Company's common stock.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Note 8. Warrants

The Company has the following warrants outstanding at December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
<i>Liability Classified Warrants</i>		
Private Placement Warrants	22,952	22,952
PIPE Investor Warrants	2,000	2,000
<i>Subtotal</i>	24,952	24,952
<i>Equity Classified Warrants</i>		
August 2025 Warrants	530,779	—
July 2025 Warrants	560,944	—
June 2025 Warrants	994,616	—
February 2025 Warrants	377,648	—
July 2024 Warrants	101,422	101,422
January 2024 Warrants	67,213	67,213
Public Stockholders' Warrants	42,200	42,200
Legacy Warrants	150	196
<i>Subtotal</i>	2,674,972	211,031
<i>Grand Total</i>	2,699,924	235,983

The following tables provides the weighted average strike price and time to maturity for each warrant tranche as of December 31, 2025 and 2024:

December 31, 2025	Warrant Share Equivalents	Weighted-Average Strike Price	Weighted-Average Time to Expiration
<i>Liability Classified Warrants</i>			
Private Placement Warrants	22,952	\$ 2,875.00	1.82
PIPE Investor Warrants	2,000	\$ 2,875.00	1.82
<i>Equity Classified Warrants</i>			
August 2025 Warrants	530,779	\$ 7.85	4.61
July 2025 Warrants	560,944	\$ 6.59	4.61
June 2025 Warrants	994,616	\$ 6.57	3.15
February 2025 Warrants	377,648	\$ 17.34	4.24
July 2024 Warrants	101,422	\$ 107.23	3.53
January 2024 Warrants	67,213	\$ 23.82	3.44
Public Stockholders' Warrants	42,200	\$ 2,875.00	2.33
Legacy SeaStar Inc. Warrants	150	\$ 2,500.00	1.17

December 31, 2024	Warrant Share Equivalents	Weighted-Average Strike Price	Weighted-Average Time to Expiration
<i>Liability Classified Warrants</i>			
Private Placement Warrants	22,952	\$ 2,875.00	2.82
PIPE Investor Warrants	2,000	\$ 2,875.00	2.82
<i>Equity Classified Warrants</i>			
July 2024 Warrants	101,422	\$ 107.20	4.53
January 2024 Warrants	67,213	\$ 208.27	3.01
Public Stockholders' Warrants	42,200	\$ 2,875.00	2.82
Legacy SeaStar Inc. Warrants	196	\$ 2,500.00	1.38

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Below is the warrant activity for the year ended December 31, 2025, for those warrants with activity during the year ended December 31, 2025.

	August 2025 Warrants	July 2025 Warrants	June 2025 Warrants	February 2025 Warrants	Legacy Warrants
Outstanding as of December 31, 2024	—	—	—	—	196
Issuance	530,779	601,067	1,395,693	659,289	—
Exercised	—	(40,123)	(401,077)	(281,641)	—
Forfeited / cancelled	—	—	—	—	(46)
Outstanding as of December 31, 2025	<u>530,779</u>	<u>560,944</u>	<u>994,616</u>	<u>377,648</u>	<u>150</u>

During the year ended December 31, 2025, the Company recognized an unrealized gain of \$32 thousand from the change in fair value of all remaining liability classified warrants.

Note 9. Common Stock and Preferred Stock

As of December 31, 2025, the Company is authorized to issue 460,000,000 shares, consisting of (a) 450,000,000 shares of common stock and (b) 10,000,000 shares of preferred stock (the “Preferred Stock”). On December 18, 2025, the Company’s shareholders voted at a Special Meeting to reduce the authorized shares of common stock to 425,000,000. The change became effective on January 5, 2026.

Common stock

The charter of the Company (the “Charter”) provides the following with respect to the rights, powers, preferences, and privileges of the common stock.

SeaStar Medical Holding Corporation
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Voting power

Except as otherwise required by law or as otherwise provided in any certificate of designation for any series of preferred stock, the holders of common stock possess all voting power for the election of the Company's directors and all other matters requiring stockholder action. Holders of common stock are entitled to one voter per share on matters to be voted on by stockholders. The Charter does not provide for cumulative voting rights.

Dividends

Subject to the rights, if any, of the holders of any outstanding shares of preferred stock, under the Charter, holders of common stock will be entitled to receive such dividends, if any, as may be declared from time to time by the Board of Directors in its discretion out of funds legally available therefor.

Liquidation, dissolution and winding-up

In the event of the Company's voluntary or involuntary liquidation, dissolution, distribution of assets or winding-up, the holders of the common stock will be entitled to receive an equal amount per share of all of the Company's assets of whatever kind available for distribution to stockholders after the rights of the holders of the Preferred Stock have been satisfied and after payment or provision for payment of the Company's debts.

Preemptive or other rights

There are no preemptive rights or sinking fund provisions applicable to the shares of the Company's common stock.

Preferred stock

The Charter provides that shares of preferred stock may be issued from time to time in one or more series. The Board of Directors is authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional, or other special rights and any qualifications, limitations, and restrictions thereof, applicable to the shares of each series. The Company has no preferred stock outstanding at December 31, 2025 or 2024.

Note 10. Stock-Based Compensation Awards

The following table sets forth the total stock-based compensation cost included in the Company's consolidated statements of operations for the years ended December 31, 2025 and 2024:

(\$ in thousands)	Year Ended December 31,	
	2025	2024
Research and development	\$ 91	\$ 157
General and administrative	533	730
Total stock-based compensation	<u>\$ 624</u>	<u>\$ 887</u>

Equity incentive plan - summary

2022 Omnibus Incentive Plan

The Company's Board of Directors adopted, and the shareholders approved the 2022 Omnibus Incentive Plan to provide long-term incentive for its employees and non-employee service providers. The vesting of stock options is stated in each individual grant agreement, which is generally either one or four years. Options granted expire 10 years after the date of grant.

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2019 Stock Incentive Plan

The Company's Board of Directors adopted the 2019 Stock Incentive Plan on February 25, 2019, to provide long-term incentive for its employees and non-employee service providers. The Stock Incentive Plan was terminated on October 28, 2022, and no further awards were granted under such plan.

Stock Options

Option activity for the year ended December 31, 2025, is as follows:

2022 Omnibus Incentive Plan - Options

	Options	Weighted-Average Exercise Price	Total Intrinsic Value	Weighted-Average Remaining Contractual Life (Years)
Outstanding at December 31, 2024	1,315	\$ 460.00	\$ —	8.2
Exercised	—			
Issued	—			
Forfeited / cancelled	(192)			
Outstanding at December 31, 2025	1,123	\$ 460.00	\$ —	7.2
Vested and exercisable at December 31, 2025	1,123	\$ 460.00	\$ —	7.2

2019 Stock Incentive Plan - Options

	Options	Weighted-Average Exercise Price	Total Intrinsic Value	Weighted-Average Remaining Contractual Life (Years)
Outstanding at December 31, 2024	885	\$ 443.00	\$ —	5.5
Exercised	—			
Issued	—			
Forfeited / cancelled	(196)			
Outstanding at December 31, 2025	689	\$ 533	\$ —	4.4
Vested and exercisable at December 31, 2025	689	\$ 533	\$ —	4.4

Restricted Stock Units

A summary of the Company's restricted stock unit ("RSU") activity for the year ended December 31, 2025, is as follows:

2022 Omnibus Incentive Plan - RSUs

	Number of RSU	Weighted-Average Grant Date Fair Value (per share)
Outstanding at December 31, 2024	21,950	\$ 50.90
Granted	13,000	
Vested	(8,080)	
Forfeited / cancelled	(1,000)	
Outstanding at December 31, 2025	25,870	\$ 30.50

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2019 Stock Incentive Plan - RSUs

	Number of RSU	Weighted-Average Grant Date Fair Value (per share)
Outstanding at December 31, 2024	75	\$ 2,000.00
Granted	—	
Vested	(75)	
Forfeited / cancelled	—	
Outstanding at December 31, 2025	—	\$ —

Note 11. Commitments and Contingencies

Lease agreements

The Company is part of a membership agreement for shared office space and can cancel at any time, consisting of office space and dedicated space for warehousing and assembly of SCDs. Rent expense was approximately \$75 thousand and \$43 thousand for the years ended December 31, 2025 and 2024, respectively.

Litigation

On July 5, 2024, Forrest A K Wells, a purported stockholder of ours, filed a putative class action complaint in the United States District Court for the District of Colorado, captioned Wells v. SeaStar Medical Holding Corporation, et al., Case No. 1:24-cv-0187 (the “Class Action”). The Class Action alleges that the Company, our Chief Executive Officer, and former Chief Financial Officer made or caused to be made material misstatements or omissions regarding: (a) the projected timing for obtaining FDA approval of our SCD; and (b) our recognition of certain financial instruments, allegedly culminating in our restatement of our consolidated financial statements, disclosed in a Form 8-K and filed on March 27, 2024. The Class Action asserts claims pursuant to the Securities Exchange Act of 1934, including Section 10(b), Rule 10b-5 promulgated thereunder, and Section 20(a). The Class Action seeks to recover, among other remedies, compensatory damages. On March 4, 2025, the Plaintiff filed an amended complaint. The Defendants moved to dismiss the complaint. The Defendants’ motion to dismiss the complaint was referred to United States District Court Magistrate Judge Timothy P. O’Hara. On February 27, 2026, Magistrate Judge O’Hara issued a written report and recommendation to United States District Judge Regina M. Rodriguez that the complaint be dismissed with leave to amend (“R&R”). Lead Plaintiff filed an objection to the R&R on March 13, 2026, and Defendants are expected to respond on March 27, 2026. The Company cannot predict whether the Magistrate Judge’s R&R will be adopted, modified or rejected by the District Court, or whether the Lead Plaintiff will amend the complaint.

On December 13, 2024, Jose Lazo, a purported stockholder of ours, filed a putative stockholder derivative action complaint captioned Lazo v. Schlorff et. al., C.A. No. 1:24-cv-3444 in the United States District Court for the District of Colorado (the “Derivative Action”). The factual allegations of the Derivative Action are substantially similar to the Class Action. On January 30, 2025, upon joint motion of the parties, the Court stayed the Derivative Action pending the Court’s resolution of an anticipated motion to dismiss to be filed in the Class Action.

The Derivative Action alleges, among other things, that the Company’s Chief Executive Officer, former Chief Financial Officer, and certain of the Company’s current and former directors violated Section 14(a) of the Exchange Act, breached fiduciary duties and were unjustly enriched by making or allowing to be made purportedly false and misleading statements regarding the Company’s prospects for success in obtaining FDA approval for its SCD. The Derivative Action further alleges that there were purported deficiencies in the Company’s internal financial controls and procedures and improper accounting for classification of certain financial instruments leading to the restatement of its previously issued financial statements. The Derivative Action also asserts claims under Section 10(b) and 21D of the Exchange Act against the Company’s Chief Executive Officer and former Chief Financial Officer. Among other remedies, the Derivative Action seeks to recover damages and restitution on behalf of the Company and certain injunctive relief concerning the Company’s corporate governance and internal controls. Additional stockholders may file substantially similar complaints in the future. The Company will not make separate disclosure of such complaints unless they are materially different than the Derivative Action.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Note 12. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). Inputs used to measure fair value are classified into the following hierarchy:

Level 1 – quoted prices in active markets for identical assets and liabilities.

Level 2 – other significant observable inputs (including quoted prices for similar assets and liabilities, quoted prices for identical assets in inactive markets, interest rate, credit risk, etc.).

Level 3 – significant unobservable inputs (including the Company’s own assumptions in determining the fair value of assets and liabilities).

The fair value of the forward option on prepaid forward contracts, convertible notes, and the warrants liability is classified as Level 3 in the fair value hierarchy.

Fair Value Measurement Hierarchy

The following table presents the Company’s financial assets and/or liabilities that were accounted for at fair value on a recurring basis as of December 31, 2025 and 2024, by level withing the fair value hierarchy. There were no non-recurring fair value measurements, as the Company does not have any long-lived assets, including fixed assets, intangible assets or goodwill which can require non-recurring measurements for impairment.

Fair Value Measurements at December 31, 2025				
	(Level 1)	(Level 2)	(Level 3)	Total
Liabilities:				
Liability classified warrants	\$ —	\$ —	\$ 1	\$ 1
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1</u>	<u>\$ 1</u>
Fair Value Measurements at December 31, 2024				
	(Level 1)	(Level 2)	(Level 3)	Total
Liabilities:				
Liability classified warrants	\$ —	\$ —	\$ 33	\$ 33
Total	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 33</u>	<u>\$ 33</u>

Summary of Level 3 Input Changes

The following table presents the changes in the liability classified warrants for the years ended December 31, 2025 (in thousands):

	Liability Classified Warrants
Level 3 Roll Forward	
Balance December 31, 2024	\$ 33
Additions	—
Cash paid to settle	—
Shares issued upon conversion or exercise	—
Changes in fair value	(32)
Balance December 31, 2025	<u>\$ 1</u>

Level 3 Inputs

For assets or liabilities for which the Company is required to remeasure the fair value on a recurring basis at each reporting date, generally the Company is required to disclose certain quantitative data related to the inputs used at the most recent reporting period date. However, for those assets or liabilities for which the Company has elected to take the fair value option in accordance with *ASC 825, Financial Instruments*, then such quantitative disclosures are not required. As of December 31, 2025, there were no assets or liabilities for which the Company elected to take the fair value option.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Liability Classified Warrants

Significant assumptions used in valuing warrants which require liability classification were as follows as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Expected volatility	130.00%	130.00%
Remaining term	1.825	2.825
Risk-free rate	3.48%	4.27%
Dividend yield	0.00%	0.00%
Stock price	\$ 2.40	\$ 1.94
Strike price	\$ 2,875.00	\$ 287.50

The only liability classified warrants that were outstanding as of December 31, 2025 and 2024, were the Private and PIPE warrants. These warrants are valued using the same inputs into a Black-Scholes standard option pricing model and therefore, there is no range of inputs.

Note 13. Income Taxes

The Company recorded approximately \$3 thousand and \$3 of current income tax expense for the years ended December 31, 2025 and 2024, respectively. The Company paid approximately \$2 thousand to California, and less than \$1 thousand each to North Carolina and New Jersey during the year ended December 31, 2025, comprised of statutory minimum taxes.

The table below provides the updated requirements of ASU 2023-09 for 2025 (see Note 2. Summary of Significant Accounting Policies – Recent accounting pronouncements for additional details on the adoption of ASU 2023-09).

The effective income tax rate of the Company's provision for income taxes for the year ended December 31, 2025, differed from the federal statutory rate as follows (in thousands and percentages):

	Year Ended December 31, 2025	
	Amount	Percent
Federal tax at statutory rate	\$ (2,551)	\$ 21.00%
State Tax net of federal benefits	4	-0.03%
R&D tax credit	(275)	2.27%
Nontaxable or nondeductible items	(3)	0.01%
Change in Valuation Allowance	2,740	-22.44%
Other Adjustments	88	-0.85%
Tax Expense	<u>\$ 3</u>	<u>\$ -0.03%</u>

As previously disclosed for the years ended December 31, 2024, prior to the adoption of ASU 2023-09, the effective income tax rate differs from the statutory federal income rate as follows:

	Year Ended December 31, 2024	
	Amount	Percentages
Federal tax at statutory rate	\$ (5,214)	\$ 21.00%
State income tax	776	-3.12%
R&D tax credit	(197)	0.79%
Stock compensation expense	18	-0.07%
Unrealized gains and losses, net, for liability classified warrants	146	-0.59%
Unrealized gains and losses, net, for convertible debt	1,291	-5.20%
Adjustment to prior period federal deferred tax assets	95	-0.38%
Non-deductible expenses	6	-0.03%
Other	172	-0.68%
Change in valuation allowance	2,910	-11.72%
Total effective income tax rate	<u>\$ 3</u>	<u>\$ 0.00%</u>

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Significant components of deferred tax assets for federal and state income taxes were as follows:

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Net operating losses	\$ 26,779	\$ 23,936
Finance charges and origination fees	—	133
Accrued compensation	141	314
Stock-based compensation	87	47
Section 174 research and development capitalization	2,099	2,771
Section 59(e) research and development capitalization	1,292	—
Capitalized start-up fees	197	209
Tax credits	1,394	1,103
Total deferred tax assets	31,989	28,513
Valuation allowance	(31,989)	(28,513)
Net deferred tax assets	\$ —	\$ —

In accordance with U.S. GAAP, a valuation allowance should be provided if it is more likely than not that some or all of the Company's deferred tax assets will not be realized. The Company's ability to realize the benefit of its deferred tax assets will depend on the generation of future taxable income. Due to the uncertainty of future profitable operations and taxable income, the Company has recorded a full valuation allowance against its net deferred tax assets. For the years ended December 31, 2025 and 2024, the net increase in the valuation allowance was approximately \$3.5 million and \$2.8 million, respectively.

As of December 31, 2025 and 2024, the Company had federal net operating loss carryforwards of approximately \$117.9 million and \$108.4 million, respectively, of which approximately \$65.0 million of federal net operating loss carryforwards post 2017 will be carried forward indefinitely. The remaining \$52.8 million of federal net operating loss carryforwards begin expiring in 2027. The Company has also generated approximately \$11.4 million of net operating loss carryforwards in California carryforward for 20 years, first expiring in 2039, \$4.0 million of Florida net operating losses that carryforward indefinitely; \$7.1 million of Illinois net operating loss carryforwards that carryforward for 20 years, first expiring in 2044 and \$1.7 million of net operating loss carryforwards in Virginia that carryforward indefinitely. The Company has not used any net operating loss carryforwards to date.

The Company has not claimed any federal or state Research Credit carryforwards pre-2022. The Company believes that the Company has qualified research activities and qualified research expenses, but missed claiming the R&D credits in prior years. The tax provision reports no pre-2022 R&D credit carryforwards, consistent with the tax return filings through 2021. The Company will record R&D credit deferred tax assets (and the related valuation allowance) if/when the Company amends prior year tax filings to claim R&D credits.

The Company had federal energy credit carryforwards of approximately \$0.6 million as of December 31, 2025 and 2024, which will expire starting in 2027 if not utilized. The Company has federal research and development credit carryforwards of approximately \$0.7 million and \$0.5 million as of December 31, 2025 and 2024, respectively, which will expire starting in 2042 if not utilized.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, the Company's ability to use net operating losses ("NOL") and research tax credit carryforwards to offset future taxable income may be limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of NOL and research tax credit carryforwards available to offset future taxable income and income tax liabilities in future years may be significantly restricted or eliminated. Further, deferred tax assets associated with such NOLs, and research tax credits could be significantly reduced upon realization of an ownership change within the meaning of IRC Section 382.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

The Company files U.S. federal and state tax returns with varying statutes of limitations. Due to net operating loss and credit carryforwards, the 2019 to 2024 tax years remain subject to examination by the U.S. federal and some state authorities. The actual amount of any taxes due could vary significantly depending on the ultimate timing and nature of any settlement.

Uncertain Tax Benefits

The Company uses the “more likely than not” criterion for recognizing the income tax benefit of uncertain income tax positions and establishing measurement criteria for income tax benefits. As of December 31, 2025, the Company has approximately \$1.1 million of uncertain tax benefits, all of which are accounted for as contra deferred tax assets. The following schedule provides the roll forward of the Company’s uncertain tax positions during the year ended December 31, 2025:

	Uncertain Tax Position
Balance as of December 31, 2024	\$ 944
Increase in prior year	—
Increase in current year	127
Balance as of December 31, 2025	<u>\$ 1,071</u>

The Company has no accrued interest related to the uncertain tax benefits. The Company does not anticipate any significant changes to unrecognized tax benefits over the next 12 months as of December 31, 2025.

Note 14. Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of common shares outstanding during the period, including vested restricted stock units for which common shares have not yet been issued, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the warrants, common stock options, and unvested restricted stock units are considered to be potentially dilutive securities. As the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for all periods.

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive:

	As of December 31,	
	2025	2024
Liability classified warrants	24,952	24,952
Equity classified warrants	2,674,972	211,031
Employee based options to purchase common stock	1,812	22,653
Unvested employee based restricted stock units	25,870	40,068
Total	<u>2,727,606</u>	<u>298,704</u>

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

The following table presents the calculation of basic and diluted net loss per share (in thousands except share and per share information):

	Year Ended December 31,	
	2025	2024
Net loss	\$ (12,150)	\$ (24,830)
Weighted-average shares outstanding - basic and diluted	2,073,087	374,356
Basic and diluted net loss per share	<u>\$ (5.86)</u>	<u>\$ (66.33)</u>

Note 15. Segment Reporting

The Company is comprised of a single reportable segment, its Device Segment. This organizational structure aligns with how our Chief Operating Decision Maker (“CODM”), the Chief Executive Officer, manages the Company’s business, including resource allocation and performance assessment. The Company is focused entirely on the development, regulatory approval and commercialization of the Company’s adult and pediatric Selective Cytopheretic Devices (SCDs). The Company had a total of 17 employees at December 31, 2025, and total assets of \$14.2 and \$4.7 million, as of December 31, 2025 and 2024, respectively.

For segment reporting purposes, the CODM uses operating profit/(loss) to evaluate segment performance and allocate resources. As a Company that only recently began limited commercial sales of QUELIMMUNE, the CODM is primarily focused on evaluating the overall spending for research and development activities needed to fund further development of the SCDs, and general and administrative activities incurred to support the research and development activities of the Company. Accounting policies associated with the Company’s sole segment are the same as those described in Note 1.

All of the Company’s sales are located within the United States. As of the date of this report, the Company has obtained regulatory approval for commercial sales in the U.S. of QUELIMMUNE from the FDA. The Company does not have any inter-entity sales or transfers.

The following table represents the Company’s sole segment’s operating results for the years ended December 31, 2025 and 2024, respectively.

	Year Ended December 31,	
	2025	2024
Net Revenue	\$ 1,234	\$ 135
Cost of goods sold	53	—
Gross profit	<u>\$ 1,181</u>	<u>\$ 135</u>
Operating expenses		
Research and development	7,518	9,105
General and administrative	5,838	8,872
Total operating expenses	<u>\$ 13,356</u>	<u>\$ 17,977</u>
Loss from operations	<u>\$ (12,175)</u>	<u>\$ (17,842)</u>

The above table excludes non-operating other income/expense, net, consisting of interest expense, interest income, and gains and losses from changes in the fair value of liability classified financial instruments such as liability classified warrants and convertible debt.

Note 16. Subsequent Events

At-the-Market Offering

From January 2, 2026, through March 13, 2026, the Company raised approximately \$0.1 million in gross proceeds (\$0.1 net of offering fees) from the sale of 18,880 shares of the Company’s common stock through its At-the-Market offering program. Since the initial shelf-registration in August 2024, the Company has, as of the date of this filing, raised approximately \$10.8 million in gross proceeds under the At-the-Market offering program, issuing approximately 10.7 million shares, for net proceeds of approximately \$10.4 million.

SeaStar Medical Holding Corporation
Notes to the Consolidated Financial Statements

Standby Equity Purchase Agreement

From January 2, 2026, through March 13, 2026, the Company raised approximately \$0.3 million in gross proceeds (\$0.3 million net of offering fees) from the sale of 130,184 shares of the Company's common stock through its standby equity purchase agreement facility. Since the initial registration in May 2025, the Company has, as of the date of this filing, raised approximately \$0.4 million in gross proceeds under the standby equity purchase agreement, issuing 138,184 shares, for net proceeds of approximately \$0.3 million.

Nasdaq Decision Letter

On January 20, 2026, the Company received a letter from Nasdaq confirming that the Company has regained compliance with the minimum bid price requirement of the Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Rule").

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

This Item 9A includes information concerning the controls and controls evaluation referred to in the certifications of our Chief Executive Officer and Chief Financial Officer required by Rule 13a-14 of the Exchange Act included in this Annual Report as Exhibits 31.1 and 31.2.

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

As required by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2025. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of December 31, 2025, at reasonable assurance levels, in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and (ii) is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Accordingly, we believe that the financial statements presented in this Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented herein.

Pursuant to Rule 13a-15(e), the term “disclosure controls and procedures” means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer’s management, including its Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management’s Annual Report on Internal Control Over Financial Reporting

Management is responsible for designing, implementing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. We have designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

We assessed the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the “Internal Control — Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission. This assessment was conducted utilizing our documentation of policies and procedures, risk control matrices, gap analysis, key process walk-throughs, and management’s knowledge of and interaction with our controls. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Internal control over financial reporting, no matter how well designed, has inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Further, because of changes in conditions, the effectiveness of internal control over financial reporting may vary over time.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the three months ended December 31, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to the definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2025.

We have adopted a Code of Business Conduct and Ethics that applies to all officers, directors, and employees in connection with their work for us.

We intend to satisfy any disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the Internet address and location specified above.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to the definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2025.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required under this item is incorporated herein by reference to the definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required under this item is incorporated herein by reference to the definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2025.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to the definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the Securities and Exchange Commission no later than 120 days after the close of the fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

- (1) For a list of the financial statements included herein, see Index to the consolidated financial statements on page 74 of this Annual Report, incorporated into this Item by reference.
- (2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.
- (3) Exhibits

Exhibit Index

Exhibit No.	Description
2.1†	Agreement and Plan of Merger, dated as of April 21, 2022, by and among LMF Acquisition Opportunities, Inc. (“LMAO”), LMF Merger Sub, Inc. and SeaStar Medical, Inc. (incorporated by reference to Exhibit 2.1 to Form 8-K filed by the registrant on April 26, 2022).
3.1	Third Amended and Restated Certificate of Incorporation of SeaStar Medical Holding Corporation, filed with the Secretary of State of Delaware on October 28, 2022 (incorporated by reference to Exhibit 3.1 to Form 8-K filed by the registrant on November 4, 2022).
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of SeaStar Medical Holding Corporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed September 20, 2023).
3.3	Second Certificate of Amendment of Third Amended and Restated Certificate of Incorporation of SeaStar Medical Holding Corporation (incorporated by reference to Exhibit 3.1 to Form 8-K filed by the registrant on June 7, 2024).
3.4	Third Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of SeaStar Medical Holding Corporation (incorporated by reference to Exhibit 3.4 to Form 10-K filed by the registrant on March 27, 2025).
3.5	Second Amended and Restated Bylaws of SeaStar Medical Holding Corporation (incorporated by reference to Exhibit 3.1 of Form 8-K filed by the registrant on April 18, 2024).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Form 8-K filed by the registrant on November 4, 2022).
4.2	Specimen Warrant Certificate (incorporated by reference to Exhibit 4.3 to Form 8-K filed by the registrant on November 3, 2022).
4.3	Description of Securities (incorporated by reference to Exhibit 4.5 of Form 10-K filed by the registrant on March 27, 2025).
4.4	Form of Series A Common Stock Purchase Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 of Form 8-K dated January 30, 2024).
4.5	Form of Series B Common Stock Purchase Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.3 of Form 8-K dated January 30, 2024).
4.6	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of Form 8-K filed by the registrant on July 11, 2024).
4.7	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.2 of Form 8-K filed by the registrant on July 11, 2024).
4.8	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of Form 8-K dated February 3, 2025).
4.9	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of Form 8-K filed by the registrant on February 3, 2025).
4.10	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 of Form 8-K filed by the registrant on February 3, 2025).
4.11	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of Form 10-Q filed by the registrant on August 13, 2025).
4.12	Form of Series A Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of Form 10-Q filed by the registrant on August 13, 2025).
4.13	Form of Series B Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.3 of Form 10-Q filed by the registrant on August 13, 2025).
4.14	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.4 of Form 10-Q filed by the registrant on August 13, 2025).
4.15	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of Form 8-K dated July 14, 2025).
4.16	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 of Form 8-K dated July 14, 2025).
4.17	Form of Placement Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.3 of Form 8-K dated July 14, 2025).
4.18	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 of Form 8-K dated August 1, 2025).
4.19	Form of Placement Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 of Form 8-K dated August 1, 2025).

10.1	Amended and Restated SeaStar Medical Holding Corporation 2022 Omnibus Incentive Plan (incorporated by reference to Exhibit 99.1 to Form S-8 filed by the registrant on August 8, 2025).
10.2	SeaStar Medical Holding Corporation 2022 Employee Stock Purchase Plan (incorporated by reference to Annex E to Form S-4 filed by the registrant on May 16, 2022).
10.3	Warrant Redemption Agreement, dated June 28, 2024, by and between SeaStar Medical Holding Corporation and an institutional investor (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on July 2, 2024).
10.4	Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on July 11, 2024).
10.5	At The Market Offering Agreement, dated August 20, 2024, by and between SeaStar Medical Holding Corporation, and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on August 21, 2024).
10.6	Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on February 3, 2025).
10.7	Purchase Agreement, dated April 25, 2025, by and between SeaStar Medical Holding Corporation, and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on April 25, 2025).
10.8	Registration Rights Agreement, dated April 25, 2025, by and between SeaStar Medical Holding Corporation, and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on April 25, 2025).
10.9	Form of Confidential Bonus Release Agreement (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on June 11, 2025).
10.10	Securities Purchase Agreement (incorporated by reference to Exhibit 10.13 of Form S-1/A filed by the registrant on June 20, 2025).
10.11	Engagement Agreement, dated May 17, 2024, by and between SeaStar Medical Holding Corporation and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.14 of Form S-1/A filed by the registrant on June 20, 2025).
10.12	Amendment to the Engagement Agreement, dated April 1, 2025, by and between SeaStar Medical Holding Corporation and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.15 of Form S-1/A filed by the registrant on June 20, 2025).
10.13	Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of Form 8-K filed by the registrant on July 14, 2025).
10.14	Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of Form -8-K filed by the registrant on August 1, 2025).
10.15	Consulting Agreement dated October 31, 2025, by and between the Company and Michael Messinger (incorporated by reference to Exhibit 10.1 of Form -8-K filed by the registrant on November 17, 2025).
10.16	Employment Agreement, dated May 18, 2022, by and between SeaStar Medical Holding Corporation and Kevin Chung (incorporated by reference to Exhibit 10.27 to Form S-4/A filed by the registrant on August 24, 2022).
10.17	Form of Amended and Restated Employment Agreement, by and between SeaStar Medical Holding Corporation and Eric Schlorff (incorporated by reference to Exhibit 10.32 to Form S-4/A filed by the registrant on August 24, 2022).
19.1	SeaStar Medical Holding Corporation Insider Trading Policy (incorporated by reference to Exhibit 19.1 to Form 10-K filed by the registrant on March 27, 2025).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Form 8-K filed by the registrant on November 4, 2022).
23.1**	Consent of Independent Registered Public Accounting Firm of SeaStar Medical Holding Corporation for fiscal year ended December 31, 2025.
24.1**	Power of Attorney (included on the signature page hereto).
31.1**	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1	SeaStar Medical Holding Corporation Compensation Recoupment Policy (incorporated by reference to Exhibit 97.1 of Form 10-K/A filed by the registrant on April 26, 2024).
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

+ Indicates management contract or compensatory plan or arrangement.

† Schedules and exhibits to this agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the SEC upon request.

** Filed herewith

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

SeaStar Medical Holding Corporation

Date: March 25, 2026

By: /s/ Eric Schlorff
Eric Schlorff
Chief Executive Officer
(Principal Executive Officer)

Date: March 25, 2026

By: /s/ Michael Messinger
Michael Messinger
Chief Financial Officer
(Principal Financial Officer)

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each of the undersigned constitutes and appoints Eric Schlorff his or her true and lawful attorney-in-fact and agent, with full power of substitution and revocation, for him or her and in his or her name, place and stead, in any and all capacities, to execute any or all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons in the capacities and on the dates indicated.

Name	Title	Date
<u>/s/ Eric Schlorff</u> Eric Schlorff	Chief Executive Officer and Director (Principal Executive Officer)	March 25, 2026
<u>/s/ Michael Messinger</u> Michael Messinger	Chief Financial Officer (Principal Financial Officer)	March 25, 2026
<u>/s/ Bradford K. Towne</u> Bradford K. Towne	Controller (Principal Accounting Officer)	March 25, 2026
<u>/s/ Jennifer A. Baird</u> Jennifer A. Baird	Chairperson of the Board of Directors	March 25, 2026
<u>/s/ John Neuman</u> John Neuman	Director	March 25, 2026
<u>/s/ Kenneth Van Heel</u> Kenneth Van Heel	Director	March 25, 2026
<u>/s/ Bernadette N. Vincent</u> Bernadette N. Vincent	Director	March 25, 2026

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 Nos. 333-276675, 333-275968, 333-275844, 333-281220, 333-280683, 333-286677 and Form S-8 Nos. 333-276978, 333-270070, 333-286671, and 333-289421 of SeaStar Medical Holding Corporation (the “Company”) of our report dated March 25, 2026, which includes an explanatory paragraph relating to the Company’s ability to continue as a going concern, relating to the consolidated financial statements as of and for the years ended December 31, 2025 and 2024, which appears in this Form 10-K.

/s/ WithumSmith+Brown, PC

East Brunswick, New Jersey

March 25, 2026

Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Eric Schlorff, certify that:

1. I have reviewed this annual report on Form 10-K of SeaStar Medical Holding Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2026

/s/ Eric Schlorff

Eric Schlorff

Chief Executive Officer

Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Michael Messinger, certify that:

1. I have reviewed this annual report on Form 10-K of SeaStar Medical Holding Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 25, 2026

/s/ Michael Messinger

Michael Messinger

Chief Financial Officer

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Eric Schlorff, Chief Executive Officer of SeaStar Medical Holding Corporation (the “Company”), certify that:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2025 as filed with the Securities and Exchange Commission (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 25, 2026

/s/ Eric Schlorff

Eric Schlorff
Chief Executive Officer

Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Michael Messinger, Chief Financial Officer of SeaStar Medical Holding Corporation (the “Company”), certify that:

1. the Annual Report on Form 10-K of the Company for the year ended December 31, 2025 as filed with the Securities and Exchange Commission (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 25, 2026

/s/ Michael Messinger

Michael Messinger
Chief Financial Officer